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Conference Room, Suite 700
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Contents

Federal Register

Vol. 77, No. 171

Tuesday, September 4, 2012

Agriculture Department
See Forest Service

Centers for Disease Control and Prevention
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53887–53888
Statements of Organization, Functions, and Delegations of Authority, 53888–53890

Centers for Medicare & Medicaid Services
RULES
Medicare and Medicaid Programs:
Electronic Health Record Incentive Program—Stage 2, 53968–54162
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53890–53891

Children and Families Administration
See Refugee Resettlement Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Child Care and Development Fund Plan for States/Territories for FFY 2014–2015, 53891–53892

Coast Guard
RULES
Safety Zones:
Liberty to Freedom Swims, Liberty Island, Upper Bay and Hudson River, NY, 53769–53772
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53898–53901
Imposition of Conditions of Entry:
Certain Vessels Arriving from the Republic of Yemen, 53901–53902

Commerce Department
See International Trade Administration
See Minority Business Development Agency
See National Oceanic and Atmospheric Administration

Commodity Futures Trading Commission
NOTICES
Orders:
Availability of Legal Entity Identifiers, 53870–53873

Consumer Product Safety Commission
PROPOSED RULES
Safety Standard for Magnet Sets, 53781–53801

Copyright Office, Library of Congress
PROPOSED RULES
Registration of Copyright:
Definition of Claimant, 53829

Defense Department
NOTICES
Defense Transportation Regulation, Part IV, 53873–53874

Education Department
PROPOSED RULES
Proposed Priorities, Requirements, Definitions, and Selection Criteria:
Supporting Effective Educator Development, 53819–53826

Employment and Training Administration
NOTICES
Affirmative Determinations Regarding Applications for Reconsideration:
Travelers Indemnity Company, Personal Insurance Remittance Center, Hartford, CT, 53912–53913
Amended Certifications Regarding Eligibility to Apply for Worker Adjustment Assistance:
Accellent, et al., Englewood, CO, 53913
Horton Automatics, Inc., et al., Corpus Christi, TX, 53914
River Bend Industries, LLC, et al., Fort Smith, AR, 53913–53914
Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance, 53914–53916
Investigations of Eligibility to Apply for Worker Adjustment Assistance, 53917

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Applications for Blanket Authorization to Export Previously Imported Liquefied Natural Gas:
Dow Chemical Co., 53874–53876
Proposed Subsequent Arrangements, 53876–53877

Environmental Protection Agency
RULES
Approvals and Promulgations of Air Quality Implementation Plans:
Washington; Determination of Clean Data for the 2006 24-Hour Fine Particulate Standard for the Tacoma, Pierce County Nonattainment Area, 53772–53773
Revisions to the California State Implementation Plan, South Coast Air Quality Management District, 53773–53775
PROPOSED RULES
Revisions to Stormwater Regulations:
NPDES Permit is not Required for Stormwater Discharges from Logging Roads; Clarification, 53834–53838

Equal Employment Opportunity Commission
PROPOSED RULES
Availability of Records, 53814–53819

Executive Office of the President
See Trade Representative, Office of United States

Federal Aviation Administration
NOTICES
Technical Standing Orders; Cancellations:
Airborne Automatic Dead Reckoning Computer Equipment Utilizing Aircraft Heading and Doppler Ground Speed and Drift Angle Data (for Air Carrier Aircraft), 53962

Airborne Doppler Radar Ground Speed and/or Drift Angle Measuring Equipment (For Air Carrier Aircraft), 53962

Federal Emergency Management Agency
RULES
Suspension of Community Eligibility, 53775–53776
NOTICES
Major Disaster Declarations:
Vermont; Amendment No. 1, 53902

Federal Energy Regulatory Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53877–53878
Applications:
L.S. Starrett Co., 53878–53880
Portland General Electric Co., 53880
Combined Filings, 53880–53883
Comment Deadline:
Algonquin Gas Transmission, LLC, 53883
Complaints:
Benjamin Riggs v. Rhode Island Public Utility Commission, 53883–53884
Compliance Filings:
Automatic Underfrequency Load Shedding and Load Shedding Plans Reliability Standards, 53884
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
High Mesa Energy, LLC, 53884
North Sky River Energy, LLC, 53884–53885
Meetings:
Jordan Cove Energy Project LP and Pacific Connector Gas Pipeline LP, 53885
Requests under Blanket Authorization:
CenterPoint Energy Gas Transmission Company, LLC, 53885–53886
Technical Conferences:
February 2011 Southwest Cold Weather Event Follow-up Technical Conference, 53886–53887

Federal Highway Administration
PROPOSED RULES
Procurement, Management, and Administration of Engineering and Design Related Services, 53802–53814

Federal Reserve System
NOTICES
Changes in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 53887
Acquisitions of Shares of a Savings and Loan Holding Company, 53887

Fish and Wildlife Service
PROPOSED RULES
Endangered and Threatened Wildlife and Plants:
12-Month Finding on a Petition to List the Mardon Skipper, 54332–54352
12-Month Finding on Petition to List Four Subspecies of Great Basin Butterflies as Endangered or Threatened Species, 54294–54329

Food and Drug Administration
PROPOSED RULES
Filing of Amendment to Food Additive Petition:
Nexira, 53801–53802
NOTICES
Determinations that Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness:
ALOXI (Palonosetron Hydrochloride) Capsules, 0.5 Milligram (Base), 53892–53893

Forest Service
NOTICES
East McCloud Plantations Thinning Projects:
Shasta–Trinity National Forest; California, 53839–53840
Meetings:
Amador County Resource Advisory Committee, 53841
Ashley Resource Advisory Committee, 53842
Delta–Bienville Resource Advisory Committee, 53841
Missoula County Resource Advisory Committee, 53840–53841
Sabine Resource Advisory Committee, 53842–53843
West Virginia Resource Advisory Committee, 53842

Health and Human Services Department
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Children and Families Administration
See Food and Drug Administration
See Refugee Resettlement Office
RULES
Health Information Technology:
Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition, etc., 54163–54292

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency
See Transportation Security Administration
NOTICES
Privacy Act; Systems of Records, 53893–53898

Housing and Urban Development Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
OneCPD Technical Assistance and Capacity Building Needs Assessment, 53903–53904
Buy American Exceptions under the American Recovery and Reinvestment Act of 2009, 53904–53905

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See National Park Service

International Trade Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Korea Free Trade Agreement, 53843–53844
Antidumping Duty Administrative Reviews; Results, Extensions, Amendments, etc.:
Ball Bearings and Parts Thereof from France and Italy, 53844–53845
Certain Frozen Warmwater Shrimp from the People's Republic of China, 53856–53862
Certain Steel Nails from the People's Republic of China, 53845–53856
Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation:
Advance Notification of Sunset Reviews, 53862–53863

Antidumping or Countervailing Duty Orders, Finding, or Suspended Investigations:
Opportunity to Request Administrative Review, 53863–53865
Export Trade Certificates of Review:
Colombia Poultry Export Quota, Inc., 53865–53867
Initiation of Five-Year (Sunset) Review, 53867–53868

International Trade Commission
NOTICES
Countervailing and Antidumping Duty Orders; Five-Year Reviews:
Certain Pasta from Italy and Turkey, 53909–53911

Justice Department
See Parole Commission

Labor Department
See Employment and Training Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
H–1B Technical Skills Training Grants and H–1B Jobs and Innovation Accelerator Challenge Grants, 53912

Land Management Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53905
Filing of Plats of Survey:
Montana, 53905–53906
South Dakota, 53906
Proposed Withdrawal and Opportunity for Public Meeting:
California, 53906–53907
Proposed Withdrawal Modification and Transfer of Administrative Jurisdiction:
Montana, 53907–53908

Library of Congress
See Copyright Office, Library of Congress

Maritime Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53962–53963
Requested Administrative Waiver of the Coastwise Trade Laws:
Vessel ZINGARA, 53963
Voluntary Intermodal Sealift Agreement, 53963–53965

Millennium Challenge Corporation
NOTICES
Meetings; Sunshine Act, 53917
Report on Countries That Are Candidates:
Millennium Challenge Account Eligibility in Fiscal Year 2013 and Countries That Would Be Candidates But For Legal Prohibitions, 53917–53919

Minority Business Development Agency
PROPOSED RULES
Petition for Inclusion of the Arab-American Community in the Groups Eligible for MBDA Services, 53780–53781

National Aeronautics and Space Administration
NOTICES
Meetings:
NASA Advisory Council; Science Committee; Planetary Science Subcommittee, 53919–53920
Public Nominations:
NASA Federal Advisory Committees, 53920–53921

National Archives and Records Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53921
Records Schedules:
Availability and Request for Comments, 53921–53923

National Oceanic and Atmospheric Administration
RULES
Snapper–Grouper Fishery of the South Atlantic:
Accountability Measures and Commercial Closures; Two Snapper–Grouper Species and Two Snapper–Grouper Species Complexes in the South Atlantic, 53776–53778
NOTICES
Meetings:
Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review, 53869–53870
New England Fishery Management Council, 53868–53869

National Park Service
PROPOSED RULES
Special Regulations:
Areas of the National Park System, Yellowstone National Park, 53826–53829
NOTICES
Environmental Impact Statements; Availability, etc.:
Winter Use Plan Yellowstone National Park, 53908–53909

National Science Foundation
NOTICES
Antarctic Conservation Act Permit Applications, 53923

Nuclear Regulatory Commission
RULES
Receipts-Based, Small Business Size Standard:
Confirmation of Effective Date, 53769
NOTICES
Facility Operating Licenses:
Applications and Amendments Involving No Significant Hazards Considerations, 53923–53935

Office of United States Trade Representative
See Trade Representative, Office of United States

Overseas Private Investment Corporation
NOTICES
Meetings; Sunshine Act, 53935

Parole Commission
NOTICES
Meetings; Sunshine Act, 53911–53912

Postal Service
PROPOSED RULES
Retirement of FASTforward Technology, 53830
Rules of Practice in Proceedings Relative to Administrative Offsets Initiated Against Former Employees of the Postal Service, 53830–53834
NOTICES
Meetings; Sunshine Act, 53936

Railroad Retirement Board
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53936

Refugee Resettlement Office
NOTICES
FY 2012 Refugee Targeted Assistance Formula Awards to State and Wilson/Fish Alternative Project Grantees, 53893

Securities and Exchange Commission
NOTICES
Applications:
Alvarez & Marsal, Inc. et al., 53936–53941
Emerging Global Advisors, LLC, et al., 53941–53948
Meetings; Sunshine Act, 53948
Self-Regulatory Organizations; Proposed Rule Changes:
Chicago Mercantile Exchange Inc., 53948–53950
EDGA Exchange, Inc., 53951–53952
EDGX Exchange, Inc, 53950–53951
NASDAQ Stock Market LLC, 53957–53958
NYSE Arca, Inc., 53955–53957
NYSE MKT LLC, 53952–53955

State Department
NOTICES
Culturally Significant Object Imported for Exhibition:
Determinations: Dancing Into Dreams, Maya Vases from the IK'Kingsdom, 53959
Culturally Significant Objects Imported for Exhibition:
Determinations: Pedimental Relief, 53959
Determinations: Roads of Arabia: Archaeology and the History of the Kingdom of Saudi Arabia, 53959

Trade Representative, Office of United States
NOTICES
WTO Dispute Settlement Proceeding Regarding Argentina – Measures Affecting the Importation of Goods, 53959–53961

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Maritime Administration
See Transportation Security Administration
PROPOSED RULES
Reports by Air Carriers on Incidents Involving Animals During Air Transport, 53779–53780
NOTICES
Meetings:
Advisory Committee for Aviation Consumer Protection, 53961

Transportation Security Administration
NOTICES
Meetings:
Aviation Security Advisory Committee, 53902–53903

U.S.–China Economic and Security Review Commission
NOTICES
Meetings:
To Prepare and Release 2012 Annual Report to Congress, 53965–53966

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 53968–54162
Health and Human Services Department, 54163–54292

Part III
Interior Department, Fish and Wildlife Service, 54294–54329

Part IV
Interior Department, Fish and Wildlife Service, 54332–54352

Reader Aids

Consult the Reader Aids section at the end of this page for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

10 CFR
2.....53769
171.....53769

14 CFR
Proposed Rules:
235.....53779

15 CFR
Proposed Rules:
1400.....53780

16 CFR
Proposed Rules:
1240.....53781

21 CFR
Proposed Rules:
172.....53801

23 CFR
Proposed Rules:
172.....53802

29 CFR
Proposed Rules:
1610.....53814

33 CFR
165.....53769

34 CFR
Proposed Rules:
Ch. I.....53819

36 CFR
Proposed Rules:
7.....53826

37 CFR
Proposed Rules:
202.....53829

39 CFR
Proposed Rules:
111.....53830
966.....53830

40 CFR
52 (2 documents) 53772, 53773
Proposed Rules:
122.....53834

42 CFR
412.....53968
413.....53968
495.....53968

44 CFR
64.....53775

45 CFR
170.....54163

50 CFR
622.....53776
Proposed Rules:
17 (2 documents) 54294, 54332

Rules and Regulations

Federal Register

Vol. 77, No. 171

Tuesday, September 4, 2012

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.

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2 and 171

[NRC–2012–0062]

RIN 3150–AJ14

Receipts-Based, Small Business Size Standard; Confirmation of Effective Date

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of August 22, 2012, for the direct final rule that appeared in the **Federal Register** of July 3, 2012 (77 FR 39385). This direct final rule amended the size standard that the NRC uses to qualify an NRC licensee as a ''small entity'' under the Regulatory Flexibility Act of 1980, as amended. The NRC is increasing its receipts-based, small business size standard from $6.5 million to $7 million to conform to the standard set by the Small Business Administration (SBA). This document confirms the effective date.

DATES: The effective date of August 22, 2012, is confirmed for this direct final rule.

ADDRESSES: Please refer to Docket ID NRC–2012–0062 when contacting the NRC about the availability of information for this direct final rule. You may access information and comment submittals related to this direct final rule, which the NRC possesses and are publicly available, by any of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0062.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Theresa Barczy, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: 301–492–3666, email: *theresa.barczy@nrc.gov.*

SUPPLEMENTARY INFORMATION: On July 3, 2012 (77 FR 39385), the NRC published in the **Federal Register** a direct final rule amending its regulations in parts 2 and 171 of Title 10 of the Code of Federal Regulations. The direct final rule amended the size standard that the NRC uses to qualify an NRC licensee as a ''small entity'' under the Regulatory Flexibility Act of 1980, as amended. The NRC is increasing its receipts-based, small business size standard from $6.5 million to $7 million to conform to the standard set by the SBA. This document confirms the effective date. In the direct final rule, the NRC stated that if any significant adverse comments were received, a notice of timely withdrawal of the direct final rule would be published in the **Federal Register**. A significant adverse comment is one where a commenter explains why the rule would be inappropriate, including challenges to its underlying premise or approach, or would be ineffective, or unacceptable without a change. The NRC did not receive any comments that warranted withdrawal of the direct final rule. Therefore, this rule was effective as scheduled.

Dated at Rockville, Maryland, this 28th day of August, 2012.

For the Nuclear Regulatory Commission.

Cindy K. Bladey,

Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 2012–21630 Filed 8–31–12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0717]

RIN 1625–AA00

Safety Zone; Liberty to Freedom Swims, Liberty Island, Upper Bay and Hudson River, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of Upper New York Bay, NY and the Lower Hudson River for the September 5, 2012 and September 15, 2012 Liberty to Freedom swim events. This temporary safety zone is necessary to protect the maritime public and event participants from the hazards associated with swim events. This rule is intended to restrict all vessels and persons from entering into, transiting through, mooring, or anchoring within the safety zone unless authorized by the Captain of the Port (COTP) New York or a designated representative.

DATES: This rule is effective from 9:30 a.m. on September 5, 2012 until 5 p.m. on September 15, 2012. This rule will be enforced from 9:30 a.m. until 11 a.m. on September 5, 2012 and from 3 p.m. until 5 p.m. on September 15, 2012.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2012–0717. To view documents mentioned in this preamble as being available in the docket, go to *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 rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West

Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LTJG Kristopher Kesting, Sector NY Waterways Management, U.S. Coast Guard; Telephone (718) 354–4154, E-Mail *Kristopher.R.Kesting@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking
COTP Captain of the Port

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b) (B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because sufficient information about the event was not received in time to publish a NPRM followed by a final rule before the effective date, thus making the publication of a NPRM impractical. The Coast Guard received the information about the events on July 14, 2012. Any delay encountered in this regulation's effective date by publishing a NPRM would be contrary to public interest, because immediate action is needed to provide for the safety of life on the navigable waters from the hazards of swimming in the Upper New York Bay and the Lower Hudson River, particularly in the vicinity of the shipping channel.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The event sponsor is unable and unwilling to postpone this event because the dates of these events were chosen based on optimal tide, current, and weather conditions needed to promote the safety of swim participants. In addition, any change to the date of the event would cause economic hardship on the marine event sponsor. The rule must become effective on the dates specified in order to provide for the safety of the swimmers and vessels operating in the area near this event. Delaying this rule would be impracticable and contrary to the public interest, and would expose swimmers and vessels to the hazards associated with the swim events.

For the same reason discussed above, under 5 U.S.C. 553(d)(3) the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

B. Basis and Purpose

The legal basis for this rule is 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

This temporary safety zone is necessary to ensure the safety of swimmers and vessels from hazards associated with the swim events.

C. Discussion of the Final Rule

This rule establishes a temporary safety zone on the navigable waters of the Upper New York Bay and the Lower Hudson River, in the vicinity of Liberty Island, Jersey City, Manhattan, and Governors Island. All persons and vessels shall comply with the instructions of the Captain of the Port (COTP) New York or the designated representative during the enforcement of the temporary safety zone. Entering into, transiting through, or anchoring within the temporary safety zone is prohibited unless authorized by the COTP New York, or the designated representative.

Based on the inherent hazards associated with open water swimming, the COTP New York has determined that swimmers in close proximity to water crafts pose a significant risk to the swimmers and vessels. The combination of a high traffic area, congested waterways, and limited visibility of active swimmers have the potential to result in serious injuries or fatalities. This temporary safety zone will restrict vessels from a portion of the Upper New York Bay and Lower Hudson River around the location of the swimmers during the event.

The Coast Guard has determined that this regulated area will not have a significant impact on vessel traffic due to its temporary nature and the fact that vessels will be allowed to transit the navigable waters around the location of the swimmers in the regulated area.

Advanced public notifications will also be made to local mariners through appropriate means, which will include, but are not limited to, the Local Notice to Mariners as well as Broadcast Notice to Mariners.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The Coast Guard's implementation of this temporary safety zone will be of short duration and is designed to minimize the impact to vessel traffic on the navigable waters. This temporary safety zone will only be enforced for approximately 2 hours. Due to the location, vessels will be able to transit around the zone in a safe manner.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

(1) This rule will affect the following entities, some of which may be small entities: the owners and operators of vessels intending to transit or anchor in a portion of the navigable waters in the vicinity of the marine events during the effective periods.

(2) This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons: this rule will be in effect for 2 hours; vessel traffic could pass safely around the safety zone, and the Coast Guard will notify mariners before activating the zone by appropriate means including but not

limited to Local Notice to Mariners and Broadcast Notice to Mariners.

3. 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. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

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). 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.

4. Collection of Information

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

5. Federalism

A rule has implications for federalism under Executive Order 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 determined that this rule does not have implications for federalism.

6. Protest Activities

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

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

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

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 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.

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

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

14. Environment

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

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREA

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C.Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–0717 to read as follows:

§ 165.T01–0717 Safety Zone; Liberty to Freedom Swim, Liberty Island, Upper Bay and Hudson River, NY.

(a) *Regulated Area.* All navigable waters of the Upper New York Bay and lower Hudson River, NY, bound by the following points: position 40°41′16.4″ N, 074°02′57.3″ W, then northeast to position 40°41′57.0″ N, 074°02′07.3″ W, then north to position 40°42′25.9″ N, 074°02′04.6″ W, then northeast to position 40°42′51.2″ N, 074°01′03.2″ W, then south to position 40°42′16.5″ N, 074°01′07.1″ W, then southwest to position 40°41′03.6″ N, 074°02′34.6″ W, then back to the point of origin.

(b) *Effective Date.* This rule is effective from 9:30 a.m. on September 5, 2012 until 5:00 p.m. on September 15, 2012. This rule will be enforced from 9:30 a.m. until 11:00 a.m. on September 5, 2012 and from 3:00 p.m. until 5:00 p.m. on September 15, 2012.

(c) *Definitions.* The following definitions apply to this section:

(1) *Designated Representative.* A ''designated representative'' is any Coast

Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port Sector New York (COTP), to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) *Official Patrol Vessels.* Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP.

(3) *Spectators.* All persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(d) *Regulations.* (1) The general regulations contained in 33 CFR 165.23, as well as the following regulations, apply.

(2) No vessels, except for event coordinators and support vessels, will be allowed to transit the safety zone without the permission of the COTP. Vessels not associated with the event that are permitted to enter the regulated areas shall maintain a separation of at least 100 yards from the participants.

(3) All persons and vessels shall comply with the instructions of the COTP or the designated representative. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. Failure to comply with a lawful direction may result in expulsion from the regulated area, citation for failure to comply, or both.

(4) Vessel operators desiring to enter or operate within the regulated area shall contact the COTP or the designated representative via VHF channel 16 or 718–354–4353 (Sector New York command center) to obtain permission to do so.

(5) Spectators or other vessels shall not anchor, block, loiter, or impede the transit of event participants or official patrol vessels in the regulated areas during the effective dates and times, unless authorized by COTP or the designated representative.

(6) The COTP or the designated representative may delay or terminate any marine event in this subpart at any time it is deemed necessary to ensure the safety of life or property.

Dated: August 20, 2012.

G.A. Loebl,

Captain, U.S. Coast Guard, Captain of the Port New York.

[FR Doc. 2012–21717 Filed 8–31–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2012–0380; FRL– 9723–4]

Approval and Promulgation of Air Quality Implementation Plans; Washington; Determination of Clean Data for the 2006 24-Hour Fine Particulate Standard for the Tacoma, Pierce County Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is making a final determination that the Tacoma, Pierce County nonattainment area (hereafter referred to as ''Tacoma, Pierce County'' or ''the area'') has clean data for the 2006 24-hour fine particulate matter ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS). This determination is based upon complete, quality-assured, quality-controlled, and certified ambient air monitoring data showing that the area has monitored attainment of the 2006 $PM_{2.5}$ NAAQS based on the 2009–2011 data available in EPA's Air Quality System (AQS) database. EPA's determination relieves the area from the requirements to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning State Implementation Plans (SIPs) related to attainment of the standard for so long as the area continues to meet the 24-hour 2006 $PM_{2.5}$ NAAQS.

DATES: *Effective Date:* This final rule is effective on October 4, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R10–OAR–2012–0380. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy for public inspection during normal business hours at EPA Region 10, Office of Air, Waste and Toxics, 1200 Sixth Avenue, Seattle WA, 98101.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt at telephone number: (206) 553–0256, email address: *hunt.jeff@epa.gov,* or the above EPA, Region 10 address.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. What action is EPA taking?
II. What is the effect of this action?
III. Statutory and Executive Order Reviews

I. What action is EPA taking?

EPA is making a final determination that the Tacoma, Pierce County nonattainment area has clean data for the 2006 24-hour $PM_{2.5}$ NAAQS. This determination is based upon complete, quality-assured, quality-controlled, and certified ambient air monitoring data showing that the area has monitored attainment of the 2006 $PM_{2.5}$ NAAQS based on 2009–2011 monitoring data.

On July 5, 2012 (77 FR 39657), EPA proposed a determination of clean data for the Tacoma, Pierce County nonattainment area. A discussion of the rationale behind this determination and the effect of the determination were included in the notice of proposed rulemaking. EPA received no comments on this notice of proposed rulemaking.

II. What is the effect of this action?

Under the provisions of EPA's $PM_{2.5}$ implementation rule (*See* 40 CFR 51.1004(c)), the requirements for the Tacoma, Pierce County nonattainment area to submit an attainment demonstration and associated reasonably available control measures (including reasonably available control technology), a reasonable further progress plan, contingency measures, and any other planning SIPs related to attainment of the 2006 $PM_{2.5}$ NAAQS are suspended for so long as the area continues to meet the 24-hour 2006 $PM_{2.5}$ NAAQS. If EPA subsequently determines that the area violates the 24-hour 2006 $PM_{2.5}$ NAAQS, the basis for the suspension of the specific requirements, set forth at 40 CFR 51.1004(c), would no longer exist and the area would thereafter have to address the pertinent requirements.

This action does not constitute a redesignation of the area to attainment for the 24-hour 2006 $PM_{2.5}$ NAAQS under section 107(d)(3) of the Clean Air Act (CAA). Further, this action does not involve approving a maintenance plan for the area as required under section 175A of the CAA, nor does it find that the area has met all other requirements for redesignation. Even after this determination of attainment by EPA, the designation status of the area is nonattainment for the 24-hour 2006 $PM_{2.5}$ NAAQS until such time as EPA

determines that the area meets the CAA requirements for redesignation to attainment and takes action to redesignate the area.

III. Statutory and Executive Order Reviews

A. General Requirements

This action makes a determination of attainment based on air quality, and will result in the suspension of certain Federal requirements, and will 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 Order 12866 (58 FR 51735, October 4, 1993);
- 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 CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rulemaking that the Tacoma, Pierce County $PM_{2.5}$ nonattainment area has clean data for the 2006 24-hour $PM_{2.5}$ standard does not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 5, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

This clean data determination for the 24-hour 2006 $PM_{2.5}$ NAAQS for the Tacoma, Pierce County nonattainment area 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, Particulate matter, Reporting and recordkeeping requirements.

Dated: August 20, 2012.

Dennis J. McLerran,

Regional Administrator, Region 10.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart WW—Washington

■ 2. In § 52.2475, paragraph (e)(4) is added to read as follows:

§ 52.2475 Approval of plans.

* * * * *

(e) * * *

(4) Tacoma

(i) *Determination of Clean Data.* EPA has determined, as of *September 4, 2012,* that based on 2009 to 2011 ambient air quality data the Tacoma, Pierce County nonattainment area has attained the 24-hour 2006 $PM_{2.5}$ NAAQS. This determination, in accordance with 40 CFR 51.1004(c), suspends the requirements for the area to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIPs related to attainment of the standard for as long as the area continues to meet the 24-hour 2006 $PM_{2.5}$ NAAQS.

(ii) [Reserved]

* * * * *

[FR Doc. 2012–21560 Filed 8–31–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0236; FRL–9711–2]

Revisions to the California State Implementation Plan, South Coast Air Quality Management District (SCAQMD)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval of a revision to the SCAQMD portion of the California State Implementation Plan (SIP). This action was published on June 1, 2012 and concerns particulate matter (PM) emissions from cement manufacturing facilities. We are approving a local rule that regulates this emission source under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: This rule will be effective on October 4, 2012.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2012–0236 for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps, multi-volume reports), and some may not be available in either location (*e.g.,* confidential business information (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: Robert Marinaro, EPA Region IX, (415) 972–3019, *marinaro.robert@epa.gov.*

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

Table of Contents

I. Proposed Action
II. Public Comments and EPA Responses
III. EPA Action
IV. Statutory and Executive Order Reviews

I. Proposed Action

On June 1, 2012 (77 FR 32483), EPA proposed to approve the following rule into the California SIP.

Local agency	Rule #	Rule title	Amended	Submitted
SCAQMD	1156	Further Reduction of Particulate Emissions from Cement Manufacturing Facilities.	3/6/09	4/29/09.

We proposed to approve this rule because we determined that it complied with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

EPA's proposed action provided a 30-day public comment period. During this period we received one comment from Jim Malmberg. The comments and our responses are summarized below.

Comment: ''Burdening businesses in Southern California with additional government regulations when unemployment in the area is near 12 percent is absolutely ridiculous. The fact that you are trying to regulate emissions from cement plants in the area is doubly offensive as the construction industry has been disproportionally hurt by the economic downturn. The only thing that this rule is likely to accomplish is an increased price for concrete and a corresponding increase in unemployment. I am unaware of anyone ever having dropped dead from living too close to a cement manufacturer.''

Response: EPA's approval of this rule does not impose new costs or controls on industry; it is merely making local controls federally enforceable.

III. EPA Action

This comment does not change EPA's assessment that the submitted rule complies with relevant CAA requirements. Therefore, as authorized in section 110(k)(3) of the Act, EPA is fully approving this rule into the California SIP.

IV. Statutory and Executive Order Reviews

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

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

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 5, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: July 23, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

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

PART 52 [AMENDED]

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(362) (i)(B)(*2*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(362) * * *

(i) * * *

(B) * * *

(*2*) Rule 1156, ''Further Reductions of Particulate Emissions from Cement Manufacturing Facilities,'' amended on March 6, 2009.

* * * * *

[FR Doc. 2012–21563 Filed 8–31–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2012–0003; Internal Agency Docket No. FEMA–8243]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *http://www.fema.gov/fema/csb.shtm.*

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register.**

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and Location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain federal assistance no longer available in SFHAs
Region VII				
Missouri: Callaway County, Unincorporated Areas.	290049	September 30, 1983, Emerg; January 3, 1985, Reg; Sept. 5, 2012, Susp..	September 5, 2012.	September 5, 2012.
Region X				
Washington: Battle Ground, City of, Clark County.	530025	June 2, 1975, Emerg; April 15, 1981, Reg; Sept. 5, 2012, Susp..	September 5, 2012.	September 5, 2012.
Clark County, Unincorporated Areas	530024	September 6, 1974, Emerg; August 2, 1982, Reg; September 5, 2012, Susp..	.....do*	Do.
La Center, City of, Clark County	530248	December 3, 1986, Emerg; December 3, 1986, Reg; September 5, 2012, Susp..	.....do	Do.
Ridgefield, City of, Clark County	530298	January 21, 1976, Emerg; May 19, 1981, Reg; September 5, 2012, Susp..	.....do	Do.
Vancouver, City of, Clark County	530027	June 2, 1972, Emerg; August 17, 1981, Reg; September 5, 2012, Susp..	.....do	Do.
Washougal, City of, Clark County	530028	July 25, 1974, Emerg; March 2, 1981, Reg; September 5, 2012, Susp..	.....do	Do.
Yacolt, Town of, Clark County	530269	December 14, 1995, Emerg; N/A, Reg; September 5, 2012, Susp..	.....do	Do.

*do = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: August 23, 2012.

David L. Miller,

Associate Administrator, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2012–21701 Filed 8–31–12; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 100812345–2142–03]

RIN 0648–XC132

Snapper-Grouper Fishery of the South Atlantic; Accountability Measures and Commercial Closures for Two Snapper-Grouper Species and Two Snapper-Grouper Species Complexes in the South Atlantic

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures (AMs) for the commercial sector of two snapper-grouper species and two snapper-grouper species complexes in the South Atlantic for the 2012 fishing year through this temporary rule. NMFS has determined that the respective annual catch limit (ACLs) for the deep-water complex (including yellowedge grouper, blueline tilefish, silk snapper, misty grouper, queen snapper, sand tilefish, black snapper, and blackfin snapper), as well as the porgy complex (including jolthead porgy, knobbed porgy, whitebone porgy, scup, and saucereye porgy) will have been reached by September 8, 2012. NMFS has determined that the respective ACLs for yellowtail snapper and gray triggerfish will have been reached by September 11, 2012. Therefore, NMFS closes the commercial sector for these two snapper-grouper species and two snapper-grouper species complexes in the exclusive economic zone (EEZ) of the South Atlantic. This closure is necessary to protect the snapper-grouper resource.

DATES: The closure for the deep-water complex as well as the porgy complex (including jolthead porgy, knobbed porgy, whitebone porgy, scup, and saucereye porgy) is effective 12:01 a.m., local time, September 8, 2012, until 12:01 a.m., local time, January 1, 2013. The closure for yellowtail snapper and gray triggerfish is effective 12:01 a.m., local time, September 11, 2012, until 12:01 a.m., local time, January 1, 2013.

FOR FURTHER INFORMATION CONTACT: Catherine Hayslip, telephone: 727–824–5305, or email: *Catherine.Hayslip@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic, which includes yellowtail snapper, gray triggerfish, the deep-water complex, and the porgy complex, is managed under the Fishery Management Plan (FMP) for Snapper-Grouper Fishery of the South Atlantic Region (Snapper-Grouper FMP). The Snapper-Grouper FMP was prepared by the South Atlantic Fishery Management Council and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Background

The 2006 reauthorization of the Magnuson-Stevens Act implemented new requirements that established ACLs and AMs to end overfishing and prevent overfishing from occurring. AMs are management controls to prevent ACLs from being exceeded, and to correct or mitigate overages of the ACL if they occur.

The Comprehensive ACL Amendment to the Snapper-Grouper FMP, the Golden Crab Fishery of the South Atlantic Region FMP, the Dolphin and Wahoo Fishery off the Atlantic States

FMP, and the Pelagic Sargassum Habitat of the South Atlantic Region FMP published March 16, 2010 (77 FR 15916). In part, the final rule for the Comprehensive ACL Amendment specified ACLs and AMs for species in the Snapper-Grouper FMP that are not undergoing overfishing, including the two snapper-grouper species and two snapper-grouper species complexes affected by this temporary rule. Implementation of ACLs and AMs for these two snapper-grouper species and two snapper-grouper species complexes is intended to prevent overfishing from occurring in the future, while maintaining catch levels consistent with achieving optimum yield for the resources.

Pursuant to the AMs established in the FMP and codified at 50 CFR 622.49(b)(8)(i)(A), 622.49(b)(14)(i)(A), 622.49(b)(17)(i)(A), and 622.49(b)(23)(i)(A), NMFS closes the commercial sector for these two snapper-grouper species and two snapper-grouper species complexes in the exclusive economic zone (EEZ) of the South Atlantic.

Deep-Water Complex

The AM at 50 CFR 622.49(b)(8)(i) requires NMFS to close the commercial sector for the deep-water complex (including yellowedge grouper, blueline tilefish, silk snapper, misty grouper, queen snapper, sand tilefish, black snapper, and blackfin snapper) for the remainder of the fishing year when the ACL is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. The commercial ACL for the deep-water complex, implemented through the Comprehensive ACL Amendment, is 343,869 lb (155,976 kg), round weight. Based on the best scientific information available, NMFS has determined that the commercial ACL of 343,869 lb (155,976 kg), round weight, for the deep-water complex will be reached on or before September 8, 2012. Accordingly, NMFS is implementing an AM to close the commercial sector for the deep-water complex in the South Atlantic EEZ at 12:01 a.m., local time, on September 8, 2012.

Porgy Complex

The AM at 50 CFR 622.49(b)(23)(i) requires NMFS to close the commercial sector for the porgy complex (jolthead porgy, knobbed porgy, whitebone porgy, scup, and saucereye porgy), for the remainder of the fishing year when the ACL is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. The commercial ACL for the porgy complex, implemented through the Comprehensive ACL Amendment, is 35,129 lb (15,934 kg), round weight. Based on the best scientific information available, NMFS has determined that the commercial ACL of 35,129 lb (15,934 kg), round weight, for the porgy complex will be reached on or before September 8, 2012. Accordingly, NMFS is implementing an AM to close the commercial sector for the jolthead porgy, knobbed porgy, whitebone porgy, scup, and saucereye porgy complex in the South Atlantic EEZ at 12:01 a.m., local time, on September 8, 2012.

Yellowtail Snapper

The AM at 50 CFR 622.49(b)(14)(i) requires NMFS to close the commercial sector for yellowtail snapper for the remainder of the fishing year when the ACL is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. The commercial ACL for yellowtail snapper, implemented through the Comprehensive ACL Amendment, is 1,142,589 lb (518,270 kg), round weight. Based on the best scientific information available, NMFS has determined that the commercial ACL of 1,142,589 lb (518,270 kg), round weight, for yellowtail snapper will be reached on or before September 11, 2012. Accordingly, NMFS is implementing an AM to close the commercial sector for yellowtail snapper in the South Atlantic EEZ at 12:01 a.m., local time, on September 11, 2012.

Gray Triggerfish

The AM at 50 CFR 622.49(b)(17)(i) requires NMFS to close the commercial sector for gray triggerfish for the remainder of the fishing year when the ACL is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. The commercial ACL for gray triggerfish, implemented through the Comprehensive ACL Amendment, is 305,262 lb (138,465 kg), round weight. Based on the best scientific information available, NMFS has determined that the commercial ACL of 305,262 lb (138,465 kg), round weight, for gray triggerfish will be reached on or before September 11, 2012. Accordingly, NMFS is implementing an AM to close the commercial sector for gray triggerfish in the South Atlantic EEZ at 12:01 a.m., local time, September 11, 2012.

Closure Provisions That Apply to All of These Two Snapper-grouper Species and Two Snapper-grouper Species Complexes

During the closure, all sale or purchase of these two snapper-grouper species and two snapper-grouper species complexes is prohibited and harvest or possession of these two snapper-grouper species and two snapper-grouper species complexes in or from the South Atlantic EEZ is limited to the bag and possession limit, as specified at 50 CFR 622.39(d)(1) and (d)(2). This bag and possession limit applies in the South Atlantic on board a vessel for which a valid Federal charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, without regard to where such species were harvested, *i.e.,* in state or Federal waters. The commercial sector for these two snapper-grouper species and two snapper-grouper species complexes will reopen on January 1, 2013, the beginning of the 2013 commercial fishing season.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of these two snapper-grouper species and two snapper-grouper species complexes, which are components of the South Atlantic snapper-grouper fishery, and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.49(b)(8)(i)(A), 622.49(b)(14)(i)(A), 622.49(b)(17)(i)(A), and 622.49(b)(23)(i)(A) 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.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive the requirements to provide prior notice and opportunity for public comment on this temporary rule. Such procedures are unnecessary and contrary to the public interest because the AMs established by the Comprehensive ACL Amendment and located at 50 CFR 622.49(b)(8)(i)(A), 622.49(b)(14)(i)(A), 622.49(b)(17)(i)(A), and 622.49(b)(23)(i)(A) have already been subject to notice and comment and authorize the Assistant Administrator for Fisheries, NOAA, (AA) to file a notification with the Office of the Federal Register to close the commercial sector for these two snapper-grouper species and two snapper-grouper

species complexes for the remainder of the fishing year, if commercial landings for these two snapper-grouper species and two snapper-grouper species complexes, as estimated by the SRD, reach or are projected to reach their respective commercial sector ACL. All that remains is to notify the public of the commercial closures for these two snapper-grouper species and two snapper-grouper species complexes for the remainder of the 2012 fishing year. Additionally, there is a need to immediately implement the closure for these two snapper-grouper species and two snapper-grouper species complexes for the 2012 fishing year, to prevent further commercial harvest and prevent the ACL from being exceeded, which will protect the snapper-grouper resources in the South Atlantic. Therefore, providing prior notice and opportunity for public comment on this action would be contrary to the public interest because many of those affected by the closure need as much time as possible to adjust business plans to account for the reduced commercial fishing season.

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: August 29, 2012.

Lindsay Fullenkamp,

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

[FR Doc. 2012–21676 Filed 8–29–12; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 77, No. 171
Tuesday, September 4, 2012

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 235

[Docket No. DOT–OST–2010–0211]

RIN 2105–AE07

Reports by Air Carriers on Incidents Involving Animals During Air Transport

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Extension of comment period on proposed rule.

SUMMARY: This action extends the comment period of an NPRM on the reporting of incidents involving animals during air transport that was published in the **Federal Register** on June 29, 2012. See 77 FR 38747. The Department of Transportation is extending the period for interested persons to submit comments on this rulemaking from August 28, 2012, to September 27, 2012. This extension is a result of a request to extend the comment period for the proposal.

DATES: Comments must be received by September 27, 2012. Comments received after this date will be considered to the extent practicable.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2010–0211 by any of the following methods:

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

Instructions: You must include the agency name and docket number DOT–OST–2010–0211 or Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comment. All comments will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, a business, a labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://DocketsInfo.dot.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Vinh Q. Nguyen, Trial Attorney, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202–366–9342 (phone), 202–366–7152 (fax), *vinh.nguyen@dot.gov.* You may also contact Blane A. Workie, Deputy Assistant General Counsel, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202–366–9342 (phone), 202–366–7152 (fax), *blane.workie@dot.gov.*

SUPPLEMENTARY INFORMATION: On June 29, 2012, the Department published a Notice of Proposed Rulemaking (NPRM) concerning the requirement for air carriers to report to the Department incidents involving the loss, injury, or death of an animal during air transport. The NPRM proposed to: (1) Expand the reporting requirement to U.S. carriers that operate scheduled service with at least one aircraft with a design capacity of more than 60 seats; (2) expand the definition of ''animal'' to include all cats and dogs transported by the carriers, regardless of whether the cat or dog is transported as a pet by its owner or as part of a commercial shipment (e.g., shipped by a breeder); and (3) require all covered carriers to provide in their December reports for each year the total number of animals that were lost, injured, or died during air transport for the calendar year. We also sought comment on requiring carriers to report the total number of animals transported in the calendar year in the December reports. Comments on the matters proposed were to be received 60 days after publication of the NPRM, or by August 28, 2012.

Request for Comment Period Extension

We received a joint request for an extension of time in the comment period for this rulemaking from Airlines for America (A4A), the Regional Airline Association (RAA), the Air Carrier Association of America, Inc. (ACAA), and their respective members (the petitioners). According to the request, the extension of time is needed so interested parties have sufficient time to review and comment on the preliminary regulatory analysis (PRA). The petitioners state that as of July 20, 2012, the docket associated with this rulemaking did not yet include the Department's PRA, which provides the cost and benefit analysis underpinning the proposal. The petitioners state that comment development cannot progress until the PRA is available. The PRA was posted in the docket on July 24, 2012.

Under the circumstances, we concur with the request for an extension of the comment period. We have decided to grant an extension of 30 days, or until September 27, 2012, for the public to comment on the NPRM. In doing so, we have balanced the stated need for additional time for comments with the need to proceed expeditiously with this important rulemaking. We take note of the fact that with the additional 30 days we are granting here, interested parties will have more than two months to comment on the PRA, which we believe is adequate time for analysis and coordination regarding the proposals. Accordingly, the Department finds that good cause exists to extend the time for comments on the proposed rule from August 28, 2012, to September 27, 2012. We do not anticipate any further extension of the comment period for this rulemaking. Comments received after September 27, 2012, will be considered to the extent practicable.

Request for Clarification

In addition to requesting that the comment period be extended, the petitioners posed a number of questions

to the Department concerning the proposed requirement that carriers report the total number of animals transported during a calendar year with that year's December reports, the cost to carriers of amending the definition of ''animal'' for reporting purposes, and the number of carriers affected by the reporting requirement.

Issues Concerning the Proposed Requirement That Carriers Report the Total Number of Animals Transported in the Calendar Year in the December Reports

The petitioners state that there are conflicting statements between the NPRM summary and the NPRM Regulatory Analyses and Notices (RAN) section with respect to the proposed requirement that carriers report the total number of animals transported in the calendar year in the December reports. They state that while the RAN section indicates that carriers would be required to report only during the months where the carriers experience a reportable animal incident, the preamble asks whether carriers should be required to file reports in months when no incident takes place. The petitioners seek clarification on this issue and request that the RAN section of the preamble be clarified if the proposal is that carrier be required to file negative reports.

As stated in the RAN section, in addition to proposing that covered carriers report the total number of animals transported in the calendar year in their December reports, the Department proposed that covered carriers only submit a report during the months when the carriers have a reportable animal incident. However, we also sought comment on whether to require carriers to file reports even if the carriers did not have any incidents involving the loss, injury, or death of an animal during a particular month. This is not inconsistent. The NPRM is not proposing that carriers file a negative report but is soliciting comment on this point so we can determine whether the final rule should include a general requirement that covered carriers must submit reports each month even if the carriers do not have any reportable incidents during a particular month or perhaps a requirement that carriers must file a December report regardless of whether any incidents occurred in that month to cover the total number of animals transported that year.

Issues Concerning the Cost to Covered Carriers of Amending the Definition of Animal

The petitioners state that for the 15 carriers that are currently required to report incidents involving the loss, injury, or death of an animal during air transport, the RAN is incorrect in stating that there would be no additional costs associated with amending the definition of ''animal'' for reporting purposes to include all cats and dogs transported by the carrier regardless of whether the cat or dog is transported as a pet by its owner or as part of a commercial shipment. They state that the 15 carriers already subject to the reporting requirement would likely incur additional costs, and the Department should correct the RAN.

The statement in the RAN that there would be no additional costs to the 15 carriers that already collect information on incidents involving loss, injury, or death of an animal refers to costs associated with actually filing monthly reports. The Department acknowledges that there would be costs associated with collecting more information to report, i.e., not only on incidents involving pets but also incidents involving dogs and cats that are shipped commercially. In the NPRM, the Department states that it believes the cost of the proposed expanded definition of an animal covered by the reporting rule would impact airlines but the cost would still be minimal. We encourage comments and data about expected costs resulting from the expansion of the definition of ''animal.''

Issues Concerning the Scope of the Reporting Requirement

The petitioners state that although the RAN states that the scope of the carriers covered by the animal incident reporting requirements would expand under the NPRM proposal from 15 to 36 carriers, the NPRM does not list the carriers so there is no way to verify if the list is accurate. They point out that presumably the PRA lists the potentially impacted carriers and that informed comment cannot progress until the PRA and that information is available.

The PRA does in fact list the carriers that would be affected by the NPRM and, as noted above, the PRA was posted in the docket on July 24, 2012. The public is invited to comment on the accuracy of that list.

Issued this 28th day of August, 2012, in Washington, DC under authority delegated in 14 CFR part 1.

Robert S. Rivkin,

General Counsel.

[FR Doc. 2012–21615 Filed 8–31–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Minority Business Development Agency

15 CFR Part 1400

[Docket No. 120517080–2402–04]

Petition for Inclusion of the Arab-American Community in the Groups Eligible for MBDA Services

AGENCY: Minority Business Development Agency, Commerce.

ACTION: Notice of proposed rulemaking and request for comments; amendment.

SUMMARY: The Minority Business Development Administration publishes this notice to extend the date on which it plans to make its decision on a petition from the American-Arab Anti-Discrimination Committee requesting formal designation from August 30, 2012 to November 30, 2012.

FOR FURTHER INFORMATION CONTACT: For further information about this Notice, contact Josephine Arnold, Minority Business Development Agency, 1401 Constitution Avenue NW., Room 5053, Washington, DC 20230, (202) 482–2332.

SUPPLEMENTARY INFORMATION: On May 30, 2012, the Minority Business Development Agency (MBDA) published a notice of proposed rulemaking and request for comments regarding a petition received on January 11, 2012 from the American-Arab Anti-Discrimination Committee (ADC) requesting formal designation of Arab-Americans as a minority group that is socially or economically disadvantaged pursuant to 15 CFR Part 1400. The Notice included a thirty-day comment period that ended on June 29, 2012, but also stated that MBDA will make a decision on the petition no later than June 27, 2012. On June 12, 2012, MBDA published a notice in the **Federal Register** extending the date for making its decision to July 30, 2012. On August 3, 2012, MBDA published a second amendment to extend the deadline for the decision until August 30, 2012, to allow MBDA to complete its independent review and analysis of the issues raised in the petition and comments received to the petition. The Agency has determined that further analysis of the information collected during its independent review is necessary to ensure a reasoned and sound decision. Therefore, MBDA is extending, for an additional ninety (90) day period, its consideration of the issues addressed in the petition and the information presented by MBDA's independent review. The Agency will

make its decision on the petition on or before November 30, 2012. This extension will not prejudice the petitioner.

Minority Business Development Agency.

David Hinson,

National Director.

[FR Doc. 2012–21704 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–21–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1240

Safety Standard for Magnet Sets

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Based on available data, the U.S. Consumer Product Safety Commission (the Commission, the CPSC, or we) has determined preliminarily that there may be an unreasonable risk of injury associated with children ingesting high-powered magnets that are part of magnet sets. These magnet sets are aggregations of separable, permanent, magnetic objects intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. In contrast to ingesting other small parts, when a child ingests a magnet, the magnetic properties of the object can cause serious, life-threatening injuries. When children ingest two or more of the magnets, the magnetic forces pull the magnets together, and the magnets pinch or trap the intestinal walls or other digestive tissue between them, resulting in acute and long-term health consequences. Although magnet sets have only been available since 2008, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments between January 1, 2009 and December 31, 2011.

To address the unreasonable risks of serious injury associated with these magnet sets, the Commission is issuing this notice of proposed rulemaking (NPR), which would prohibit such magnet sets. Under the proposal, if a magnet set contains a magnet that fits within the CPSC's small parts cylinder, magnets from that set would be required to have a flux index of 50 or less, or they would be prohibited. The flux index would be determined by the method described in ASTM F963–11, Standard Consumer Safety Specification for Toy Safety.

The Commission solicits written comments concerning the risks of injury associated with these magnet sets, the regulatory alternatives discussed in this NPR, other possible ways to address these risks, and the economic impacts of the various regulatory alternatives. This proposed rule is issued under the authority of the Consumer Product Safety Act (CPSA).

DATES: Written comments in response to this document must be received by the Commission no later than November 19, 2012.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2012–0050, by any of the following methods:

Submit electronic comments in the following way:

Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (email), except through *www.regulations.gov.*

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

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

FOR FURTHER INFORMATION CONTACT: Jonathan D. Midgett, Ph.D., Project Manager, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814–4408; telephone: (301) 504–7692, or email: *jmidgett@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The Commission is proposing a safety standard that would prohibit magnet sets that have been involved in serious injuries. The Commission believes that this proposed rule is necessary to address an unreasonable risk of injury and death associated with these magnet sets.

1. History With Magnetic Toys

In the mid-2000s, construction toys for children featuring small, powerful magnets were introduced into the toy market. Several children's magnetic construction toys were recalled because the magnets detached from the plastic housing of the toy. (Release #07–164). We received reports of incidents in which children and infants had swallowed the small magnets that had detached from such toys. In some incidents, children swallowed intact magnetic components that were small parts.[1] These incidents revealed that if a child swallows more than one small, powerful magnet or one such magnet and a ferromagnetic object, the objects can attract each other across tissue inside the stomach and intestines and cause perforations and/or blockage, which, if not treated immediately, can be fatal. We are aware of one death and numerous cases requiring intestinal surgery following ingestion of multiple small, powerful magnets from these toys.

To address the hazard in toys, the CPSC worked with ASTM to develop voluntary standard requirements for toys containing magnets. These requirements became part of ASTM F963, *Consumer Safety Specification for Toy Safety,* which is now a mandatory CPSC standard. ASTM F963–11 defines a ''hazardous magnet'' and a ''hazardous magnetic component'' (*i.e.,* a toy piece that contains an embedded hazardous magnet) as one that has a flux index greater than 50 and that is a small object. ASTM F963 applies to toys intended for children under 14 years of age. The flux index of a magnet is an empirical value developed by ASTM as a way to estimate the attraction force of a magnet. The ASTM working group established a flux index of 50 as a cutoff for what it considered to be a ''safe'' magnet, based on measurements of toys on the market. Most of the measured magnets were cylindrical in shape, and some had been involved in known incidents. When the ASTM graphed their measurements, they showed a good correlation (fairly linear relationship) between calculated flux index and measured attraction force for

[1] The requirements of 16 CFR part 1501 are intended to minimize the hazards from choking, ingestion, or inhalation to children under 36 months of age created by small objects. The requirements state, in part, that no toy (including removable, liberated components, or fragments of toys) shall be small enough without being compressed to fit entirely within a cylinder of the specified dimensions.

a majority of the magnets. Based on this graph, ASTM considered the flux index a reliable way to gauge a magnet's relative attraction force. Since the magnets from toys involved in incidents had flux index measurements greater than 70, the ASTM working group chose a flux index of 50 as a cutoff because it was significantly below the values for the incident magnets.

2. Introduction of Magnetic Sets

In 2008, a new type of magnet product came onto the market. The basic product was an aggregated mass of 216 BB-size powerful magnets, generally marketed as adult desk toys for general amusement. These magnet sets were introduced in 2008, but 2009 was the first year with significant sales to U.S. consumers. The products are described more fully in section B of this preamble.

In February 2010, CPSC staff received its first incident report involving this product. No injury resulted from this incident. Shortly after receiving this report, CPSC staff collected and evaluated samples of magnet sets.

In December 2010, we received our first consumer incident report involving the surgical removal of magnets that were part of a magnet set. Information about incidents involving magnet sets is discussed in section C of this preamble.

3. Prior Compliance Actions Concerning Magnet Sets

The CPSC has been warning consumers about the hazards of magnet ingestion since 2006, because of the injuries that have occurred to children from hazardous magnets that were part of construction toys intended for children. Several recalls have been issued for toys containing magnets.

In December 2009, we received a consumer complaint that the magnet sets intended for adults posed hazards similar to magnets in toys. As a follow-up to that complaint, during that month, a sample was collected by staff and age graded by the Directorate for Engineering Sciences, Division of Human Factors to be, in developmental terms appropriate for children ages 9 years old and up.

In February 2010, the CPSC received its first consumer incident report involving a child and a set of magnets intended for adults. A 9-year-old boy swallowed 7 spherical magnets while mimicking body piercings. He was not injured because the magnets passed through his system as a single mass. The magnets had been purchased for a 13-year-old.

Samples of the product were detained and collected at the Customs and Border Protection site in February 2010. At the time of collection, the product was labeled for use by children 13+ years of age. Because of the age grade on the product and the manufacturer's intent, it was subject to the requirements of the toy standard. The Office of Compliance and Field Operations (Compliance) issued a Notice of Noncompliance to the firm in March 2010. At the time, there was very little incident data associated with this product. The firm agreed to a corrective action that included, in part, new warnings to keep the product away from children, a change in the appropriate age for use of the product, and requests to retailers to list the product as appropriate only for consumers over 14 years of age. The firm also removed inventories labeled ''13+.'' The firm also agreed to ask retailers who market products primarily, though not exclusively, to children to execute a Responsible Sellers Agreement prohibiting marketing and sales to children; stop the sale of these magnets to retailers that market products exclusively to children; and providing a Responsible Sellers Agreement to general use stores for their information.

In December 2010, we received the first report of the surgical removal of magnets from a child who had ingested multiple magnets that came from a magnet set intended for adults. During 2011, Compliance activity included evaluation of the marketing and labeling of the product category, collecting product marketed to children under 13 and evaluating compliance with ASTM F963. In addition, where products did not have labeling or marketing information, the agency encouraged those firms to develop marketing and labeling to ensure that they were not marketed to children. More firms were issued Notices of Noncompliance for marketing to children younger than 14 years.

In response to continuing injuries associated with the products and children of various ages, we published a public service announcement (PSA) in November 2011, concerning the hazard in cooperation with two manufacturers. Reported incidents involving children continued to increase unabated from 8 cases in 2010, 17 cases in 2011, and 25 cases in 2012 (as of July 8, 2012). Twenty two incidents were reported before the PSA; 28 more followed during the eight months after it. A high percentage of the injuries resulted in surgeries or other invasive procedures. Of the 50 reports known to staff, 22 required surgery, and 10 required either invasive procedures such as endoscopies or colonoscopies. In 2011, and into spring 2012, staff continued to identify additional firms offering this product on the Internet with labeling and marketing violations.

Given the continued injuries to children, Compliance began negotiation of corrective action plans with 11 of 13 magnet set importers that voluntarily agreed to cease the importation, distribution, and continued sale of their magnet sets. Two of the importers did not agree to stop sale and are the subject of administrative actions recently initiated by the Commission. As those complaints allege, among other things, CPSC staff experts do not believe warnings will ever be effective in protecting children from this hidden hazard.

B. The Product

1. Description of the Product

The magnet sets covered by this proposed rule typically are comprised of numerous identical, spherical, or cube-shaped magnets, approximately 3 to 6 millimeters in size, with the majority made from NdFeB (Neodymium-Iron-Boron or NIB). These magnets exhibit strong attractive qualities. The magnetized neodymium-iron-boron cores are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding.

Often referred to as ''magnet balls'' or ''rare earth magnets,'' the products currently are marketed as: adult desk toys, the ''puzzles of the future,'' stress relievers, science kits, and educational tools for ''brain development.'' As shown in product instructions and in videos on related Web sites, these products can be used and reused to make various two- and three-dimensional forms, jewelry, and toys, such as a spinning top.

The products are sold in sets of varying size, from as few as 27 magnets to more than 1,000. Most of the magnets have been sold in sets of either 125 balls or sets of 216 to 224 balls, although some firms have sold just a few balls as extras. Based on product information provided by marketers, the most common magnet size is approximately 5 mm in diameter, although balls as small as about 3 mm have been sold, as have sets of larger magnet balls (perhaps 15 mm to 25 mm in diameter). In addition to magnetic ball sets, desk sets of small magnetic cubes have also been sold, although they have comprised a relatively small share of the market. The leading marketer of such magnet sets recently added small magnetic rods—intended to be used with balls to make

geometric shapes—to its desk toy product line.

The most common color of these magnets is a glossy, highly reflective silver, with the spheres often described as similar in appearance to BBs or ball bearings. Some firms now include sets in a wide range of colors, or combinations of colors, ranging from bright pink, green, and blue, to darker shades, such as purple and black. Most, with the exception of the smaller sets, are sold with a container, such as a square plastic cube, a metal tin, and/or a soft pouch. Most brands are sold in nondescript containers, such as metal tins or black fabric boxes. The largest seller uses colorful, transparent packaging that simulates the cube floating within.

The age labeling of hazardous magnet sets varies; currently, most products carry an age label and are marked ''14+.'' Some sets have no specific age recommendation on the package, even though retail Web sites may identify them as intended for ages ''13+'' or ''14+.'' The small parts warning [2] is sometimes included on the packaging (*i.e.,* ''choking hazard, not for children under 3''), as are warnings to keep the product away from all children.

The proposed rule would define magnet sets as: ''any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture, mental stimulation, or stress relief.''

2. Use of the Product

Although firms that sell magnet sets state that they intend them as desk toys for adults, these sets are found in offices and homes and in locations within the home beyond desk tops, such as on refrigerators. Magnet sets have some appeal for virtually all age groups. They tend to capture attention because they are shiny and reflect light. They are smooth, which gives them tactile appeal, and they make soft snapping sounds as they are manipulated. They have the properties of a novelty, which arouses curiosity; incongruity, which tends to surprise and amuse; and complexity, which tends to challenge and maintain interest. Their strong magnetic properties cause them to move in unexpected ways, with pieces snapping together suddenly, and moving apart—occasionally quite quickly. These properties or characteristics of magnets are likely to seem magical to younger children and may evoke a degree of awe and amusement among older children and teens. These features are the foundation of the product's appeal as a challenging puzzle or as a manipulative or jewelry. They may also be used as a stress ball and as a way to hold things in place.

Children from toddlers through teens have been exposed to these products in the home setting and elsewhere. Ingestion incidents have been reported to involve children 5 years of age and younger and follow similar scenarios as other ingestion incidents among this age group. Mouthing and ingestion of non-food items is a normal part of the exploratory behavior of preschool children. Caregivers, in a few cases, said they had intended to keep the sets away from the victims, but did not realize they had failed to do so, until after the child became ill and the magnets had already caused internal injuries. In other incidents, the child reportedly had never mouthed or ingested objects previously, and as a result, they were permitted by the caregiver to play with the magnets. As might be expected, in a number of cases, the magnets were not in their original containers, and caregivers were unaware that some were missing from the set and in the child's possession. Several importers sell sets of spares, small numbers of balls to replace those lost or missing from a larger set.

These products would also be appealing to children of early-to-middle elementary school age, who might be capable of controlling the magnetic forces exhibited by the pieces while constructing various forms depicted in the product instructions and on the related Web sites. Simple three-dimensional puzzles begin to interest children as they approach 8 and 9 years of age; and 9 through 12 year olds are interested in highly complex puzzles. Children in the 9 through 12 year age group have the reading skills to follow directions for three-dimensional puzzles, and they have the fine motor skills required to handle small, abstract, or interlocking pieces. Nine-year-olds can complete puzzles with 100 to 500 pieces; and 10 through 12 year olds enjoy the challenge of puzzles with 500 to 2,000 pieces. Children in this age group also can engage in activities that require the type of meticulous work and attention that would be needed to create the complex patterns and structures found in the paper and video instructions related to the magnet sets. Additionally, magnets typically are included in elementary school (ages 6 through 12) science curricula, the age at which children are taught the basic concepts of magnetism.

For all of these reasons, magnet sets are sometimes purchased for children under the age of 14, despite the warnings or labeling. This is consistent with reviews on retail Web sites, which indicate that these products are being purchased for children. Approximately one-third of 53 adults reviewing one manufacturer's product on Amazon.com reported purchasing them for children 8 through 11 years of age.

Thus, it is foreseeable that some portion of these products will be purchased for elementary school children and teens. Given the relatively low cost for some sets, children in these age groups also may purchase the magnet sets themselves. The incident reports reflect behaviors that are beyond the intended use of the product, but that are foreseeable for the groups using them. The mouthing of objects, common among younger children, develops into less obvious and more socially acceptable oral habits, which may continue through childhood and adolescence and into adulthood (*e.g.,* mouthing or chewing a fingertip, fingernail, knuckle, pen, pencil, or other object, especially while concentrating or worrying). This tendency toward mouthing behavior involving magnets could account for some reported ingestions, where incident details are lacking.

Where details are provided, the incident reports describe scenarios that are consistent with the behaviors of children in this age range. Although exploratory play is generally associated with very young children, people of all ages use their senses to explore unfamiliar phenomena. More discussion of the hazard scenarios involving these products is provided in section C.2 of this preamble.

3. The Market

Based on information reviewed on product sales, including reports by firms to the Office of Compliance and Field Operations, the number of such magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million. This reflects a combination of retail sales directly to consumers (through company Web sites and other Internet retail sites) and sales to retailers who market the products. A review of retail prices reported by importers and observed on Internet sites suggests prices typically ranging from about $20 to $45, with an average price of about $25.

The small powerful magnets most likely to be affected by this proposed rule are made from alloys of

[2] See 16 CFR § 1500.19(b)(1).

neodymium, iron, and boron. They are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding. Based on available information, all of the small magnets used in magnet sets, as well as most of the finished and packaged products that would be subject to CPSC regulation, are produced by manufacturers located in China.

All of the firms that have marketed the products are believed to import them packaged and labeled for sale to U.S. consumers. Several Chinese manufacturers have the facilities and production capacity to meet the orders of U.S. importers, and there are no major barriers to market entry for firms wishing to source products from China for sale in the United States. Firms often have sales arrangements with Internet retailers who hold stock for them and process orders.

We have identified about 25 U.S. firms and individuals who have recently imported magnetic sets for sale in the United States. The combined sales of the top seven firms have probably accounted for the great majority (perhaps more than 98%) of units sold. One firm is believed to have held a dominant position in the market for magnetic desk sets since it entered the market in 2009. That firm, and a few of the larger firms (including a firm based in Canada with a branch office in the United States), have marketed the products through accounts with retailers, in addition to selling directly to consumers on the Internet, using their own Web sites or other Internet shopping sites. In addition to products offered for sale by U.S. importers, consumers also have the ability to purchase magnetic sets directly from sources in Hong Kong or China; many that market products through ''stores'' on a leading Internet shopping site.

C. Risk of Injury

The risk addressed in this proceeding concerns damage to intestinal tissue caused by the ingestion of more than one magnet from a magnet set, magnets that are attracted to each other in the digestive system, damaging the intestinal tissue trapped between the magnets. In rare cases, there can be interaction between magnets in the airways and digestive tract (esophagus). Serious injury and death are likely consequences when children ingest strong magnets.

1. Incident Data

NEISS data. CPSC staff reviewed data from the National Electronic Surveillance System (NEISS) database of magnet-related ingestion cases treated in emergency departments from January 1, 2009 to December 31, 2011.[3] To derive estimates, CPSC staff considered all cases reported through NEISS from January 1, 2009 to December 31, 2011, which mentioned ''magnet'' in the narrative field of NEISS reports. This review produced an estimated 6,100 magnet-related ingestions for that period of time (note that this includes incidents involving all types of magnets, not just magnet sets). This excludes cases with descriptions such as ''kitchen magnet'' or ''plastic-covered magnet.'' Staff further analyzed cases that possibly involved magnets that were from magnet sets. This review yielded a count of 72 magnet ingestion cases during this time period, which staff determined (based on a review of narratives in the NEISS reports) to involve or possibly involve magnets from magnet sets. Based on the magnet ingestion cases treated in NEISS hospital emergency departments, staff determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in U.S. emergency departments during this time period. NEISS cases are coded from medical records so brand name is rarely available, but descriptions of the products from the NEISS narrative suggests that the magnets involved in these cases are magnets from magnet sets. For more information about the process for developing the estimates of incidents, see the memorandum from the Directorate for Epidemiology at Tab A of staff's briefing package *http://www.cpsc.gov/library/foia/foia12/brief/magnetstd.pdf*. It is possible that some number of the estimated 4,400 magnet ingestion-related injuries not classified as high-powered magnets could be attributable to the ingestion of magnets from high powered magnet sets. However, the information provided in the NEISS reports did not provide sufficient detail to place them into that category.

Staff reviewed the NEISS data to obtain more information about incidents involving magnet sets. With regard to age, the largest portion of these incidents involved children 4 through 12 years of age. Of the estimated 1,700 ingestion incidents related to magnet sets, 1,200 of the victims are in the 4- through 12-year-old age group (70.6 percent). It is quite possible that some portion of the estimated 4,400 ''magnets, type unknown/other type'' category of incidents also involved magnet sets and children in the 4- through 12-year-old age group. Of the estimated 1,700 ingestions, most (approximately 1,600) were treated and released from the hospital.

Databases other than NEISS. In addition to reviewing NEISS data, staff also reviewed incidents reported through other CPSC databases, such as the Injury or Potential Injury Incident database (IPII) and the In-depth Investigation database (INDP). These databases provided more detailed descriptions, and thus, included more information about the products involved and the incident scenarios. In reviewing the initial set of incidents from these databases, staff considered all reported incidents from January 1, 2009 through June 30, 2012, that involved a magnet and an ingestion or injury was reported. Excluded from this review were magnets in children's toys, as well as magnets that were determined to be a different type other than small, strong magnets from sets of magnets. Staff focused on one hazard pattern: ingestion of magnets. Other reported hazard patterns, such as allergic reactions, ear injuries, and a hand injury were excluded.

From review of INDP and IPII databases, we are aware of 50 reported incidents occurring from January 1, 2009 through June 30, 2012 involving the ingestion of magnets by children between the ages of 1 and 15. Of those 50 incidents, 38 involved the ingestion of high-powered, ball-shaped magnets contained in products that meet the definition above of ''magnet set''; and 5 of those 50 incidents possibly involved ingestion of this type of magnet. We discuss these 43 incidents (the 38 incidents, plus the 5 possible incidents) in more detail below.[4]

In 35 of the 43 incidents, two or more magnets were ingested. Hospitalization was required in order to treat 29 of the 43 incidents, with surgery necessary to

[3] The Commission collects information on hospital emergency room-treated injuries through the NEISS database. This data can be used to provide national estimates of product-related injuries treated in U.S. hospital emergency departments. Incidents reported to the Commission represent a minimum count of injuries. To account for incidents that are not reported to the Commission, the staff calculates an estimated number of such injuries.

[4] Six of the remaining seven incidents (out of the 50 incidents) involved ingestion of magnets that were part of, or designed to be, part of jewelry, including beads, faux tongue rings, and earrings. One incident involved the ingestion of a magnetic rock. The rock magnet and magnets in jewelry would not meet the proposed definition of ''magnet set'' and would not be covered by this proposed rulemaking.

remove the magnets in 20 of the 29 hospitalizations. In 9 of the 29 hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents that likely involved magnets from hazardous magnet sets, the magnets were ingested by children younger than 4 years old or between the ages of 4 and 12 years.

In 20 of the 43 incidents, the victims reportedly put the magnets in their mouths because they thought the magnets were edible; they wished to emulate jewelry piercings; or they simply mouthed the magnets while playing with them. In 23 of those 43 incidents, there is insufficient information to determine how the magnets were being used at the time of the ingestion.

In 30 of the 43 incidents, the reports indicate the source of the magnets ingested. In 10 of the incidents, the magnets were owned by a relative and were obtained, presumably by the victim, without the relative's knowledge. In 5 incidents, the magnets were given to the child by an adult; and in 12 incidents, the magnets were obtained from a friend or classmate. In three instances, the magnets were purchased by the victim. The number of ingestion incidents involving magnets from magnet sets has increased over time, from 7 in 2010, to 16 in 2011, and 20, as of June 30, 2012.

2. Hazard Scenarios

The incident reports describe scenarios that are consistent with behaviors of children in the age range described in the incidents. In the incidents reported among the 8- through 12-year-old age group, one child described wanting to feel the force of the magnets through his tongue; one was trying to see if the magnets would stick to her braces; and another wanted to see if the magnets would stick together through her teeth. Another common scenario accounted for half of the reported ingestion incidents among 8 to 15 year olds. Children used at least two and as many as seven magnets to simulate piercings of their tongue, lips, or cheeks. On the tongue or lip, children sometimes used more than two magnets to form the appearance of a ring. This is a type of role-play behavior, particularly for the younger children in the group, and the magnets serve as highly realistic props.

In this section, we summarize some of the incident reports to demonstrate a few of the hazard scenarios that have been reported in incidents involving ingestion of magnets from magnet sets.

In one incident, a 10-year-old girl simulating a tongue piercing, accidentally swallowed two magnetic balls. That same day, her mother took her to the local emergency room, and she was admitted for 5 days; during that time, the movement of the magnets was monitored by 10 x-rays, 3 CT scans, and an endoscopy. Ultimately, the magnets were manipulated from their eventual position in the colon into the appendix via laparoscopic surgery and removed by an appendectomy.

In another incident, a 13-year-old girl accidentally swallowed five small, spherical, high-powered magnets when they suddenly snapped together while she was mimicking a lip piercing. Although her abdominal pains began and worsened over the next 2 days, she did not tell her mother of the ingestion until 3 days later. She was then taken to hospital, where abdominal x-rays confirmed ingestion of five magnetic balls. Medical staff initially tried unsuccessfully to remove the magnets using an oral bowel cleansing solution and then a colonoscopy procedure. Eventually she underwent surgery, and the magnets—located in three different places in her small intestine—were removed during a surgical procedure that involved resection of damaged bowel tissue and removal of her appendix. The victim's complicated recovery resulted in hospitalization for 14 days, and the surgery left a 4-inch abdominal scar.

In another incident, an 18-month-old boy sustained life-threatening intestinal injuries and will have lasting adverse health effects after ingesting three small, spherical magnets. The boy exhibited symptoms of diarrhea and vomiting and was clutching at his right side. When his mother took him to the local hospital, he was diagnosed with an ear infection. When his symptoms did not resolve a few days later, she took him to a second hospital where, reportedly, he was diagnosed with bronchitis, given some medication, and released. One or 2 days later, his mother noticed that his stomach was distended and took him to a third hospital. Abdominal x-rays revealed three small balls, requiring immediate surgical intervention to remove the foreign objects. The procedure required resection of 6 inches of the child's small intestine and resection of 3 inches of his large intestine. The victim remained in intensive care for 1.5 weeks before being released. He continued to have diarrhea and other intestinal problems (at least 2 months post-surgery when the IDI was completed).

In another incident, a 3-year-old girl swallowed eight small spherical magnets from a magnet set, which she found on a refrigerator door. An x-ray revealed two joined magnets that appeared to be located in the victim's esophagus, plus another six magnets that appeared to be joined together in the victim's stomach. A second x-ray image, taken the next day at a different hospital, showed that the magnets had not moved. A third x-ray at a Children's Hospital showed no movement of the magnet pair (described as 3mm beads) in the esophageal area, and some movement of the group in the abdomen. Pre-intervention, the treating physicians correctly recognized that she might have aspirated a magnet into her airways that was interacting through tissues with a magnet located in the esophagus. The girl underwent three coordinated procedures: (1) A bronchoscopy that removed one ''magnetic bead'' from her right bronchus; (2) an esophagogastro-duodenoscopy (endoscopy) that removed one magnetic bead from the mid-esophagus, and five magnetic beads from the stomach; and (3) a diagnostic laparoscopy, followed by laparoscopic-assisted removal of the remaining magnet, plus laparoscopic repair of a gastric perforation and a small bowel perforation.

In another incident, a 23-month-old male ingested eight small spherical magnets from a product described as a ''magnetic puzzle.'' He started vomiting overnight and worsened the next day. He was taken to an urgent care facility, where a bilateral ear infection initially was suspected. A few hours later, as the child's condition worsened and he lost consciousness intermittently, an abdominal x-ray indicated six small balls that the mother recognized immediately, and informed the staff, were magnets from the puzzle. He was transferred to a Children's Hospital where an x-ray revealed some slight movement of the magnets. According to the mother, the doctors thought the magnets would pass naturally. An x-ray taken the following day showed the magnets to be located between the small and large intestine; therefore, surgery was undertaken to remove them. During surgery, two balls were found in the small intestine and six balls were found outside of the bowel in the abdominal cavity. These were removed and a small intestine perforation repaired. Staff does not have access to the full medical records, but according to the parents, extremely serious complications ensued after the first surgery. The child underwent several sequential surgeries over the next 10 days to repair leaks (unclear if this involved missed perforations/failure of repairs/new

perforations) and treat a blood clot, ischemic necrotic bowel, and serious infection stemming from the initial magnet injury. Ultimately, after what appears to be at least five or six operations, the child was stabilized but was still retained in an intensive care unit for more than a month, having lost all but 10 to 15 centimeters of small intestine (*HS staff notes the small intestine is about 600 to 700 centimeters long)*. He is being fed intravenously and has a colostomy bag to remove waste products. He will require a bowel transplant and his long-term prognosis is poor.

As these scenarios demonstrate (and further discussed in the next section), parents and caregivers may not realize that the child has ingested magnets. Thus, diagnosis and treatment is delayed, and the severity of the resulting injuries increases.

3. Details Concerning Injuries

As indicated in the previous section describing some of the incident scenarios, diagnosis of injury from magnet ingestion is complicated by multiple factors, and the resulting injuries can be very serious. Medical professionals may not be aware of the dangers posed by ingestion of high-powered magnets and the corresponding need for immediate evaluation and monitoring. Standard diagnostic tools, such as x-rays, may not demonstrate fully that the ingested item is a magnet and they may not allow medical professionals to identify the number of magnets ingested. Moreover, magnets may appear in an x-ray to be other nonmagnetic items that children commonly ingest, such as beads, which typically are monitored without surgical intervention and are allowed to pass through the child's gastrointestinal tract. Furthermore, treatment for injuries resulting from the ingestion of these magnets often is delayed, much to the serious detriment of the patient because the symptoms associated with damage to intestinal tissue resulting from the ingestion of these magnets frequently resemble the symptoms associated with less serious conditions, such as the stomach flu.

Accurate and timely diagnoses also are complicated by the fact that children and teens may not attribute their gastrointestinal symptoms to prior ingestion of magnets, and they may be unable or unwilling to communicate to their parents, caregivers, or medical personnel that they have ingested magnets. Accordingly, the delay of surgical intervention due to the patient's presentation with non-specific symptoms and/or medical personnel's lack of awareness of the dangers posed by multiple magnet ingestion can exacerbate life-threatening internal injuries and has resulted in the need for a bowel transplant.

In medical terms, the magnet injuries are pressure necrosis injuries. The unique mechanism of injury involving harmful tissue compression by strong magnets has become established in recent years. Ingested magnets residing in relatively close proximity to one other are mutually attracted through intestinal walls. The magnets interact rapidly and forcefully. The magnetic attraction can occur over distances of about 10 to 20 mm for a pair of magnets, to distances much greater than that, as the number of magnets involved increases. The attraction forces operating between just one pair of magnets (or a magnet and another ferromagnetic object) is strong enough to withstand any normal muscular contractions of the gastrointestinal tissues (GI) (peristaltic or mixing motions), as well as the intermittent turbulent flow of the considerable volumes of gastrointestinal fluid in the small intestine, or the passage of semisolid contents in the large intestine. The magnets remain coupled, exerting strong bilateral compression forces on the trapped GI tissues, sufficient to block their blood and nutrient supply. The extreme pressure exerted on the trapped tissues ultimately is directly responsible for the progressive tissue injury, which starts with local inflammation and ulceration, progressing to tissue death, then perforation, or fistula formation.

Fistulas (abnormal connections or passageways between two organs or vessels that normally do not connect) cause serious, debilitating symptoms, but generally are not as acutely urgent as perforations. Perforations present a serious risk of leakage of gut contents into the abdominal cavity which, within hours, can escalate quickly from an area of local infection, to peritonitis (an inflammation of the peritoneum, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs), then life-threatening systemic infection (sepsis).

In some rare cases, ingested magnets have caused loops of the bowels to become twisted; this obstructs passage of gut contents and deprives the twisted gut segment of blood. It is considered an extremely urgent situation, requiring immediate surgical intervention to prevent the trapped segment from becoming necrotic, and/or from rupturing and causing contamination of the abdominal cavity. Magnets have also trapped and perforated mesenteric tissues, presenting the possibility that larger blood vessels in the gut mesentery could be damaged, which could cause an intra-abdominal hemorrhage.

Once attracted magnetically to each other through intestinal walls, the magnets involved in GI injuries are unlikely to disengage spontaneously or to move position until they are removed by clinicians. A pair of magnets might be uncoupled by stronger attraction forces exerted by a larger number of magnets in a separate GI location (which then could cause further injury, perhaps unrecognized, in a different GI location). If magnets fall through perforations into the peritoneal cavity, they are expected to require surgical intervention and to have a relatively high associated morbidity.

Complications after these abdominal surgeries include bleeding, infection, and ileus (temporary paralysis of gut motility). Adhesions (where bands of intra-abdominal scar tissue form that can interfere with gut movement and can cause obstruction) may occur as a short-term or long-term (years) complication, frequently resulting in bowel obstructions requiring additional surgeries, and thus, creating a cycle. In females, there also can be future fertility concerns related to abdominal scar tissue and adhesions. In cases where long segments of injured bowel have to be removed, digestive function of victims can be impaired permanently, resulting in malabsorption, diarrhea, cramping, total parental nutritional feeding (and consequent frequent bouts of sepsis), need for a bowel transplant, and even death.

D. Statutory Authority

This proceeding is conducted pursuant to the Consumer Product Safety Act (CPSA). Magnet sets are ''consumer products'' that can be regulated by the Commission under the authority of the CPSA. *See* 15 U.S.C. 2052(a).

The Commission is authorized, under section 7 of the CPSA, to promulgate a mandatory consumer product safety standard that sets forth certain performance requirements for a consumer product or that sets forth certain requirements that a product be marked or accompanied by clear and adequate warnings or instructions. 15 U.S.C. 2056. A performance, warning, or instruction standard must be reasonably necessary to prevent or reduce an unreasonable risk or injury. In addition, if the Commission finds that no feasible consumer product standard under section 7 would adequately protect consumers from an unreasonable risk or injury associated with hazardous

magnet sets, the Commission may promulgate a rule under section 8 of the CPSA declaring hazardous magnet sets to be banned products. 15 U.S.C. 2057.

Section 9 of the CPSA specifies the procedure the Commission must follow to issue a consumer product safety standard under section 7. In accordance with section 9, the Commission may commence rulemaking by issuing an NPR including the proposed rule and a preliminary regulatory analysis in accordance with section 9(c) of the CPSA and requesting comments with respect to the risk of injury identified by the Commission, the regulatory alternatives being considered, and other possible alternatives for addressing the risk. *Id.* 2058(c). Next, the Commission will consider the comments received in response to the proposed rule and decide whether to issue a final rule and a final regulatory analysis. *Id.* 2058(c)–(f).

According to section 9(f)(1) of the CPSA, before promulgating a consumer product safety rule, the Commission must consider, and make appropriate findings to be included in the rule, concerning the following issues: (1) The degree and nature of the risk of injury that the rule is designed to eliminate or reduce; (2) the approximate number of consumer products subject to the rule; (3) the need of the public for the products subject to the rule and the probable effect the rule will have on utility, cost, or availability of such products; and (4) means to achieve the objective of the rule while minimizing adverse effects on competition, manufacturing, and commercial practices. *Id.* 2058(f)(1).

According to section 9(f)(3) of the CPSA, to issue a final rule, the Commission must find that the rule is ''reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product'' and that issuing the rule is in the public interest. *Id.* 2058(f)(3)(A)&(B). In addition, if a voluntary standard addressing the risk of injury has been adopted and implemented, the Commission must find that: (1) the voluntary standard is not likely to eliminate or adequately reduce the risk of injury, or that (2) substantial compliance with the voluntary standard is unlikely. *Id.* 2058(f)(3(D). The Commission also must find that expected benefits of the rule bear a reasonable relationship to its costs and that the rule imposes the least burdensome requirements that would adequately reduce the risk of injury. *Id.* 2058(f)(3)(E)&(F).

The Commission seeks input on whether it should be regulating under section 7 and 9 of the CPSA or seeking a ban under section 8 of the CPSA or under similar provisions of the Federal Hazardous Substances Act.

E. Relevant Existing Standards

Currently, there is no voluntary standard applicable to magnet sets. The Consumer Product Safety Improvement Act of 2008 (CPSIA) mandated ASTM F963–11, *Standard Consumer Safety Specification for Toy* Safety, as a consumer product safety standard (Section 106 of the CPSIA). Whether the toy standard is applicable to magnet sets is not the subject of this rulemaking.

F. Description of the Proposed Rule

The Commission is proposing a rule that would prohibit certain high-powered magnet sets. As described in previous sections of this preamble, we are aware of serious injuries resulting from children ingesting such magnets. Magnets that do not have the prohibited characteristics and magnets that are not parts of magnet sets would still be allowed.

1. Scope, Purpose, and Effective Date—§ 1240.1

This section of the proposed rule would state that the proposed requirements in 16 CFR part 1240 are intended to reduce or eliminate an unreasonable risk of injury to children who ingest magnets that are part of hazardous magnet sets. The standard would apply to all magnet sets, as defined in § 1240.2, that are manufactured or imported on or after the date 180 days after publication of a final rule.

2. Definitions—§ 1240.2

This section of the proposed rule would define the term ''magnet set'' to mean ''any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief.'' This definition would not include other magnetic products that do not meet the definition, such as toys intended for children and jewelry. Magnets that are part of a toy intended for children are already covered by the requirements in ASTM F963–11, *Standard Consumer Safety Specification for Toy Safety,* which is a mandatory CPSC standard. The Commission seeks comment on the scope of the products proposed to be covered by this proposed rule and, in particular, whether risks are presented by magnets in science kits or craft and hobby kits no matter how they are age graded and labeled.

The Commission also seeks comment on whether the definition of ''magnet set'' should include single, i.e., individual, magnets in order to ensure that the regulation prohibits the sale of individual magnets for use as aggregated manipulative or construction desk toys. This is because the hazard posed by magnets attracting in the body can occur when magnets are purchased individually or as a set.

3. Requirements—§ 1240.3

This section would set forth the requirements for magnet sets. If a magnet set contains a magnet that fits within the small parts cylinder that CPSC uses for testing toys, magnets from that set would be required to have a flux index of 50 or less. The Commission recognizes the possible hazard that could be posed by magnets that are purchased individually and subsequently aggregated. Therefore, the proposed language in § 1240.3(a) applies to magnet sets that contain a single magnet that fits completely within the small-parts cylinder described in 16 CFR 1501.4.

The Commission seeks comment regarding whether the proposed language in § 1240.3(a) applies to magnet sets that contain one magnet, or more than one magnet, that fits completely within the small-parts cylinder described in 16 CFR 1501.4.

The small parts cylinder referenced in the proposed rule is specified in 16 CFR part 1501—Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts. If an object fits completely within the small parts cylinder, this indicates that the object is small enough to be ingested. If a magnet that is part of a magnet set is too large to fit within the small parts cylinder, it would not be prohibited, regardless of the magnet's flux index. Thus, it might be possible for manufacturers to make magnet sets that contain strong magnets so long as the magnets are sufficiently large, although the large size could reduce their utility.

Small magnets (*i.e.,* those that fit within the small parts cylinder) that are part of a magnet set must have a flux index of 50 or less. This limit is based on the level that is specified in ASTM F963–11, *Standard Consumer Safety Specification for Toy Safety,* which is a mandatory CPSC standard. As discussed in section A.1 of this preamble, the flux index of a magnet is an empirical value

developed by ASTM as a way to estimate the attraction force of a magnet.

The flux index limit of 50 was developed by ASTM, with CPSC staff's participation, to address injuries resulting from strong magnets that separated from toys. The limit was based on an analysis of magnets that were involved in incidents. The Commission seeks input on the limit particularly as to whether there may be health risks should a large number of magnets be ingested even if such magnets are at or below the flux limit of 50.

4. Test Procedure for Determining Flux Index—§ 1240.4

This section of the proposed rule would describe how to determine the flux index of magnets that are part of a magnet set. If the magnet set contains more than one shape or size of magnet, at least one of each shape and size would be selected for testing. The flux index of the selected magnets would be measured in accordance with the procedure set forth in section 8.24.1 through 8.24.3 of ASTM F963–11, *Standard Consumer Safety Specification for Toy Safety*. The flux index of the magnet is calculated by multiplying the square of the magnet's surface flux density (in KGauss) by its maximum cross-sectional area (in mm^2). The ASTM standard uses a gauss meter and probe that measures the surface flux density at 0.015 inches (0.38 mm) above the magnet's surface. The area is measured at the largest cross-section of the magnet that is perpendicular to the axis of its magnetic poles.

We are proposing to use the methodology specified in ASTM F963–11 to measure the flux index of magnets that are part of a magnet set. The test method was developed to address hazards posed by magnets that are part of a toy. Such magnets are likely to be individual magnets that separate from a toy. Magnet sets may contain hundreds of magnets. Thus, such magnets are more likely to be aggregated than magnets separated from toys. When magnets are aggregated, their magnetic strength may increase. Children exposed to magnets from these magnet sets may ingest more magnets than they would if a magnet separates from a toy. Thus, it may be desirable to develop a method for testing the strength of aggregated magnets. We are interested in receiving comments that would address this issue.

5. Findings—§ 1240.5

In accordance with the requirements of the CPSA, we are proposing to make the findings stated in section 9 of the CPSA. The proposed findings are discussed in section N of this preamble.

G. Alternatives

The Commission has considered alternatives to reduce the risk of injuries related to the ingestion of magnets contained in magnet sets. However, as discussed below, the Commission does not believe that any of these would adequately reduce the risk of injury.

1. Voluntary Recalls

Although several of the companies that manufacture or import magnet sets have voluntarily agreed to recall (and in some cases, stop selling) these products, and several retailers have agreed to stop sale, the Commission has been unsuccessful in negotiating voluntary recalls and stop sales with several companies that control a significant portion of the magnet set market, including the company that sells more than 70 percent of the magnet sets purchased in the United States. It is extremely unlikely that all manufacturers/importers will voluntarily agree to stop selling and recall their magnet sets. Moreover, recalls would not prevent new entrants into the market in the future.

2. Voluntary Standard

Currently, there is no applicable voluntary standard in effect. A group of magnet set importers and distributors have requested that ASTM International develop a voluntary standard for the labeling and marketing of these products. Specifically, these companies have requested the formation of a voluntary standard to: (1) Provide for appropriate warnings and labels on packages of these magnets sets; and (2) establish guidelines for restricting the sale of these magnet sets to children, by not selling to stores that sell children's products exclusively and not selling the magnet sets in proximity to children's products. However, despite companies' marketing and labeling to attempt to limit children's exposure to magnets, ingestion incidents involving children continue to occur and the labeling does not change the attractiveness of the product to children or the intrinsic play value of the magnet sets. From the date that the firm with the largest share of the market undertook certain labeling enhancements and marketing restrictions through June of 2012, the Commission has learned of 47 additional incidents involving ingestion of magnets from hazardous magnet sets, 26 involving ingestion of the company's hazardous magnets. As discussed more fully in the next section of this preamble, we do not believe that warnings would adequately reduce the injuries associated with this product.

3. Warnings

It is unlikely that additional or different warnings on the packages of magnet sets would significantly reduce the ingestion-related injuries caused by high-powered magnets. Safety and warnings literature consistently identifies warnings as a less effective hazard-control measure than designing out the hazard or guarding the consumer from a hazard. Warnings do not prevent consumer exposure to the hazard, but rely on persuading consumers to alter their behavior in some way to avoid the hazard. With this product, warnings are particularly unlikely to adequately reduce or eliminate the ingestion of these magnets.

Warnings are especially unlikely to be effective among children because children may lack the cognitive ability to appraise a hazard or appreciate the consequences of their own actions and may not understand how to avoid hazards effectively. In addition, warning design guidelines and literature commonly recommend that the text of warnings intended for the general public be written at no higher than the 6th grade reading level, which is equivalent to a child about 11 years old. A warning that met this guideline presumably would not be understood by many children younger than 11.

Older children, more advanced cognitively, are able to appreciate better the hazards described in a warning. However, these children value peer acceptance more than parental guidelines, and social influences and peer pressure can drive adolescent behavior more strongly than their own independent thought processes. Furthermore, adolescents are at a developmental stage in which they test limits and bend rules. Therefore, warnings about keeping the product away from children could have the unintended effect of making the product more appealing to some children. Older children might view such warnings as attempts to restrict personal freedom or self-expression, which could result in responses that are contrary to the warning's recommendations. For example, warnings about not using the product in the specific ways that might place them at risk, such as mimicking piercings, might have the unintended effect of encouraging this behavior among these children. Repeated use of the product in this way, without ingesting the magnets, most likely will convince these children that the hazard is not especially likely or is not relevant to them.

The ingestion warnings that currently accompany these products appear to be aimed at adults, primarily parents and other caregivers. Staff generally found the content of these warnings to be lacking in the following ways. The warnings often refer to children swallowing the magnets, without describing the incident scenarios that might lead to ingestion among older children and adolescents, whom caregivers may not believe are likely to put magnets into their mouths. Some warnings refer to the potential for swallowed magnets to stick to intestines, without referring to other magnets or ferromagnetic objects. Other warnings refer to magnets sticking together or attaching to other metallic objects inside the body, but they fail to explain that the magnets can attract through the walls of the intestines and forcefully compress these tissues. Without detailed information such as this, consumers may not understand how swallowing magnets differs from swallowing other small parts, or how magnets sticking together could pose a hazard rather than simply pass through the child's system. In sum, without a clear, explicit, and accurate description of the nature of the hazard and its consequences, consumers may have difficulty developing an accurate mental model of the hazard scenario and might find the warning implausible. In such situations, consumers are unlikely to comply with the action recommended in the warning.

Even if warnings could communicate the ingestion hazard, its consequences, and appropriate hazard-avoidance measures in a way that would be understood by most parents and other caregivers, the resulting warnings may not be effective at substantially reducing the incidence of magnet ingestions if consumers do not concur with what the warning states. Avoiding the ingestion hazard requires consumers to keep the product away from all children, or at least children in the incident age group, which is 15 years old and younger. Caregivers who read and understand the warnings may attempt to keep this product out of the hands of young children, but are not likely to be so diligent about heeding the warning with older children and adolescents. Unless caregivers are convinced that their child is likely to mimic lip, nose, or similar piercings or to perform other activities that might lead them to place magnets into their mouth or nose, caregivers may doubt that the warnings are relevant to their child, despite the warnings' assertions to the contrary.

Even if caregivers believe the warnings, several factors may prevent compliance. Some children, especially those who are older, may have peers who already own and use magnets from magnet sets. Some personally may have used the product before. Knowing this, caregivers might feel significant social pressure from the child, other family members and friends, to purchase the product for their children, or allow their children to use the product, especially if magnet sets are very popular among the child's peers. Caregivers who own the product and attempt to heed the warnings might find it quite difficult to prevent their child's access to the magnets and still keep the product reasonably accessible for their own use.

Moreover, securing the product from a child after every use requires time and effort, and warnings research has shown that even small increases in time and effort can prevent compliance with warnings. If the caregiver cannot secure the product properly—without dismantling the shapes and forms created during use—and the caregiver has created especially challenging or interesting designs with the magnets, the caregiver might feel compelled to keep the forms intact and, as a result, fail to secure the product properly. In addition, the difficulty of attempting to identify an appropriate location to store the magnet sets may dissuade consumers from doing so, particularly for a product often marketed to be for ''stress relief.'' Attempts to secure the product also may fail because the caregiver underestimates the abilities of their child and places the product in locations that seem secure but are still accessible to the child. Teens may have cognitive and motor skills similar to an adult's, making it extremely challenging to keep the magnet sets out of their hands. Furthermore, if caregivers know that their children have friends who own and use magnet sets, caregivers are likely to conclude that securing their magnet set will not prevent exposure to other identical or similar products. This may lead caregivers to reject the warning message.

Based on these concerns about the likely effectiveness of warnings for magnet sets, we do not believe that warning labels would adequately reduce the risk of injury presented by these products. We are interested in receiving comments on the warnings issues.

4. Packaging Restrictions

Theoretically, magnet sets could be sold with special storage containers to reduce the likelihood that children would access the magnets. Possible storage might include: a container that would clearly indicate when a magnet is missing from the set, or a package that is child resistant. Aside from the evident challenges in developing such containers, their effectiveness at reducing ingestions is doubtful. Such approaches would depend on consumers securing the packaging after each use. As discussed above, consumers may be reluctant to place the product back in its packaging after they have created designs with the magnets.

5. Restrictions on Sales of Magnet Sets

Another possible alternative to address the hazard of children ingesting magnets from magnet sets might be to limit the places where magnet sets are sold, keeping them away from toy stores, children's sections of stores, and other such locations. It is not clear that the Commission would have the regulatory authority to impose such sales restrictions by rule. In any event, such restrictions are unlikely to reduce ingestions significantly. As discussed in section B.2 of this preamble, children access these magnets from sources other than stores. The magnet sets may be available in the home after a caregiver has purchased them. Such sales restrictions are unlikely to deter teens. Moreover, restrictions on in-store sale of magnet sets would not affect Internet sales.

6. No Action

Another option is for the Commission to take no regulatory action to address the risk of injury posed by magnet sets. It is possible that, over time, increased awareness of the hazard could result in some reduction in ingestions. The magnitude of any such reduction in incidents is uncertain, but would likely be smaller than if the Commission issues the proposed rule.

H. Preliminary Regulatory Analysis

The Commission is proposing to issue a rule under sections 7 and 9 of the CPSA. The CPSA requires that the Commission prepare a preliminary regulatory analysis and that it be published with the text of the proposed rule. 15 U.S.C. 2058(c). The following discussion is extracted from staff's memo, ''Preliminary Regulatory Analysis of a Proposed Rule that Would Prohibit Certain Small Powerful Magnet Sets.''

1. Introduction

The Commission has preliminarily determined to issue a rule prohibiting magnet sets that have been involved in incidents resulting in serious injuries to children who have ingested magnets that are part of these magnet sets. Some of these incidents have required surgery to remove individual magnets ingested

by children. Reported incidents of magnet ingestion involved young children who put the magnets in their mouth and adolescents and teens who paired magnets to mimic tongue or lip piercings. This behavior has led to the powerful magnets being swallowed, resulting sometimes in severe medical consequences, including significant damage to the gastrointestinal tract.

The proposed rule would prohibit magnet sets that do not meet the requirements of the proposed rule. Thus, for magnet sets that contain more than one magnet, if any of the magnets would fit within the small parts cylinder, the magnet set would be prohibited, unless the small magnets meet the specified flux index limit. This performance standard for magnet sets would effectively ban current designs of magnetic desk sets of the type that have become popular in recent years.

2. Description of the Product and Market

Magnetic desk sets that would be affected by the scope of the proposed rule are comprised of small powerful magnetic balls, cubes, and/or cylinders that can be arranged in many different geometric shapes. These magnet sets were introduced in 2008, but the first year with significant sales to U.S. consumers was 2009.[5] Most have been sold in sets of either 125 balls or sets of 216 to 224 balls, although some firms have sold just a few balls as extras, and others have sold large sets of more than 1,000 magnetic balls. Based on product information provided by marketers, the most common magnet size is approximately 5 mm in diameter; although balls as small as about 3 mm have been sold, as have sets of larger magnet balls (perhaps 15 mm to 25 mm in diameter).[6] In addition to magnetic ball sets, desk sets of small magnetic cubes have also been sold, although they have comprised a relatively small share of the market. The leading marketer of such magnet sets has recently added small magnetic rods—intended to be used with balls to make geometric shapes—to its desk toy product line.

Based on information reviewed on product sales, including reports by firms to the Office of Compliance and Field Operations, the number of such magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million. This value range reflects a combination of retail sales directly to consumers (through company Web sites and other Internet retail sites) and sales to retailers who market the products. A review of retail prices reported by importers and observed on Internet sites suggest prices typically ranging from about $20 to $45, with an average price of about $25.

The small powerful magnets most likely to be affected by this proposed rule are made from alloys of neodymium, iron, and boron. The magnetized neodymium-iron-boron cores are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding. Nearly 100 percent of neodymium and other rare earth metals now are mined in China, which also reportedly holds a nearly worldwide monopoly on the production of neodymium-iron-boron magnets. Based on available information, all of the small magnets used in magnet sets, as well as most of the finished and packaged products that would be subject to CPSC regulation, are produced by manufacturers located in China.[7]

As noted above, none of the magnetic sets within the scope of the proposed rule are produced domestically. All of the firms that have marketed the products are believed to import them packaged and labeled for sale to U.S. consumers. Several Chinese manufacturers have the facilities and production capacity to meet the orders of U.S. importers; and there are no major barriers to market entry for firms wishing to source products from China for sale in the United States. For example, some of the firms with smaller sales volumes reported to Compliance staff that they mainly marketed products (sourced from manufacturers in China) through sales arrangements with a leading Internet retailer, which held stock for them and processed orders. A review of the product listings of the Internet retailer found that several other firms have similar business models. Other U.S. firms and individuals sell magnetic sets they have imported from China through ''stores'' they maintain on another major Internet shopping site.

To date, the Directorate for Economic Analysis has identified about 25 U.S. firms and individuals who have recently imported magnetic desk sets for sale in the United States. The combined sales of the top seven firms have probably accounted for the great majority (perhaps over 98%) of units sold. Due to resource constraints, the compliance division targeted 13 firms for corrective action. Eleven agreed to stop sale pending negotiations for a corrective action plan, two are now the subject of administrative cases recently initiated by the Commission. One firm is believed to have held a dominant position in the market for magnetic desk sets since it entered the market in 2009. That firm, and a few of the larger firms (including a firm based in Canada with a branch office in the United States), have marketed the products through accounts with retailers, in addition to selling directly to consumers on the Internet, using their own Web sites or other Internet shopping sites. In addition to products offered for sale by U.S. importers, consumers also have the ability to purchase magnetic sets directly from sources in Hong Kong or China, many of which market products through ''stores'' on a leading Internet shopping site.[8]

3. Evaluation of the Proposed Rule

Societal Costs and the Potential Benefits of a Rule Prohibiting Certain Magnetic Desk Sets

Estimated Societal Costs of Injuries

The purpose of the proposed rule is to prevent serious intestinal injuries that can result when children ingest two or more of the magnets in the subject magnet sets (or one magnet and another ferromagnetic object) (Inkster, 2012). The draft proposed rule would prohibit magnet sets that do not meet specified performance requirements. Therefore, benefits of the proposed rule would be the resulting reduction in injuries. Based on a review of magnet ingestion incidents reported through CPSC databases that include the Injury or Potential Injury Incident database (IPII) and the In-depth Investigation database (INDP), CPSC staff is aware of 38 confirmed incidents involving ingestion of one or more powerful magnets from a subject magnetic desk set since the product was introduced in 2008 (Garland, 2012). An additional five incidents possibly involved magnets from such magnet sets. No fatalities involving the products are known to the CPSC.

Our analysis of the potential benefits of the proposed rule focuses on injuries

[5] However, small neodymium-iron-boron magnets previously have been, and continue to be, marketed by firms, such as magnet suppliers and distributors of educational products.

[6] One firm's larger magnet balls are reportedly made with cores of strontium ferrite ($SrO{\cdot}6Fe_2O_3$), rather than neodymium-iron-boron.

[7] One importer reported that some of the magnet sets it sells and ships to U.S. consumers are made from bulk magnets received from its supplier in China that it repackages in its U.S. office.

[8] More than 40 such stores shipping magnetic desk toys directly from Hong Kong or China were identified in a brief review of product offerings on the Internet site.

reported through the National Electronic Injury Surveillance System (NEISS), a probability sample of U.S. hospital emergency departments that can be used to provide national estimates of product-related injuries initially treated in U.S. hospital emergency departments. Based on a review of incident narratives coded from emergency department medical records for magnet ingestion cases obtained from NEISS hospitals, the Directorate for Epidemiology staff has identified 72 magnet ingestions from 2009 through 2011, which were determined to involve, or possibly involve, the magnets of interest. Although manufacturer or brand name information is rarely available in the medical records extracted for NEISS, three of the 72 NEISS-reported cases (4.2%) did mention a brand name of magnet sets that are the magnets of interest; 69 cases (95.8%) were determined to have possibly involved the magnets of interest because the case narratives included terms such as ''high powered,'' ''magnetic ball,'' ''magnetic marble,'' ''BB size magnet,'' or ''magnetic beads'' (Garland, 2012).

Based on the 72 NEISS-reported magnet cases, there were an estimated 1,716 injuries treated in U.S. hospital emergency departments during the 2009 through 2011 study period. Roughly 6 percent were hospitalized injuries, as opposed to being treated and released. The benefits of the proposed rule can be estimated as the reduction in the societal costs associated with the injuries that would be prevented by the proposed rule. The Directorate for Economic Analysis bases estimates of the societal costs of emergency department-treated magnet injuries on the CPSC's Injury Cost Model (ICM) (Miller et al., 2000). The ICM is fully integrated with NEISS, and it estimates the societal costs of injuries reported through NEISS. Additionally, based on empirical relationships between the number of medically attended injuries treated in emergency departments and the number of injuries treated in other settings, the ICM also estimates the number and societal costs of medically attended injuries treated outside of emergency departments, such as in doctors' offices and clinics. The estimates of societal costs provided by the ICM depend upon (and vary by) the injury diagnosis, the body part affected, the injury disposition (*i.e.,* treated in a doctor's office, treated and released from a hospital emergency department, or hospitalized), and the age and sex of the victim.

Table 1 provides *annual* estimates of the injuries and the societal costs associated with ''high-powered and/or ball-shaped magnet ingestions'' that *involve,* or *possibly involve,* the magnets that are the subject of the proposed rule. As shown in the table, the 2009 through 2011 NEISS estimates suggest an estimated *annual* average of about 572 emergency department-treated injuries, including 537 injuries that were treated and released and 35 injuries that were hospitalized. About 70 percent of these emergency department-treated ingestions involved children ages 4 through 12 years. Just over half of the magnet cases from the emergency departments of the hospitals that comprise the NEISS sample appear to have involved the ingestion of more than one magnet.[9] Additionally, based on estimates from the ICM, there were another 870 injuries treated annually outside of hospital emergency departments.

After including the injuries treated outside of hospital emergency departments, there was an annual average of about 1,442 medically attended injuries involving ingestions of magnets that were defined as at least ''possibly of interest.'' These injuries resulted in annual societal costs of about $24.8 million (in 2011 dollars) during the 2009–2011 time period. The average estimated societal costs per injury were about $13,000 for injuries treated outside of emergency departments and hospitals (such as in a doctor's office or clinics), about $17,000 for those that were treated and released from emergency departments, and about $112,000 for those that were admitted to hospitals for treatment. Medical costs and work losses (including work losses of caregivers) accounted for about 25 percent of these injury cost estimates, and the less tangible costs of injury associated with pain and suffering accounted for about 75 percent of the estimated injury costs (Miller et al., 2000).

TABLE 1—ESTIMATED AVERAGE ANNUAL MEDICALLY ATTENDED INJURIES AND ASSOCIATED SOCIETAL COSTS FOR HIGH-POWERED AND/OR BALL-SHAPED MAGNET INGESTIONS THAT WERE DETERMINED TO INVOLVE OR POSSIBLY INVOLVE THE MAGNETS OF INTEREST, 2009–2011

Injury disposition	Estimated No.	Estimated societal costs ($ millions) *
Treated and Released from Hospital Emergency Department (NEISS)	537	$9.1
Admitted to Hospital Through the Emergency Department (NEISS)	† 35	3.9
Medically Treated Outside of Hospital Emergency Department (ICM)	870	11.7
Total Medically Attended Injuries	1,442	24.8

* In 2011 dollars.

† According to the Directorate for Epidemiology, the estimated number of hospital-admitted emergency department-treated injuries is a not a reliable estimate because of the small number of cases upon which the estimate was based.

It should be noted that there is uncertainty concerning these estimates. Some of the cases described as ''possibly'' involving the magnet injuries that were included in Table 1 may not have involved the magnets that are the subject of the NPR. As noted above, about 95.8 percent of the cases upon which the table was based were described as only possibly involving the magnets of interest because NEISS narratives are not required to list manufacturer or brand name. Hence, it is possible that Table 1 overstates the societal costs associated with the magnets that would be included in the proposed rule.

[9] In contrast to the available evidence on the number of magnets ingested from the NEISS estimates, 37 of 40 non-NEISS incidents reported to the CPSC involved the ingestion of more than one magnet (see Garland, Table 10). The difference may be related to the number of cases upon which the NEISS estimate was based, which may have been too small to provide reliable estimates. Alternatively, it is possible that the non-NEISS injury reports to the CPSC tended to involve the more serious cases with multiple magnets.

On the other hand, in addition to the magnet cases upon which the table was based, there were also 175 NEISS cases (representing about 1,440 emergency department-treated injuries annually) in which the magnet type was unknown. These cases included those in which the case narrative mentioned that a magnet was involved, but presented insufficient information to classify the magnet type. Consequently, to the extent that the unknown magnet types involved those that would be covered by the proposed rule, the Table 1 results would tend to understate the societal costs associated with the magnets subject to the proposed rule.

Estimated Benefits of the Proposed Rule

As noted above, the benefits of a proposed magnet rule would be the reduction in the societal costs of the injuries that would be prevented. In general, because the proposed rule would effectively ban certain types of magnet sets, all ingestion injuries that would have involved magnets that, in the absence of the proposed rule, would have been sold after the effective date of the proposed rule, will be prevented. However, if children, adolescents, and teens cannot play with or use the prohibited magnets, they could play with or use substitute products that may also result in injury. Hence, the overall benefits of the proposed rule should be measured as the *net reduction* in injuries, and the concomitant reduction in societal costs, that would result.

These issues make it difficult to estimate with much certainty the prospective benefits of a proposed rule. However, if we assume that the injuries presented in Table 1 provide a generally accurate estimate of the annual injuries that would be prevented by the proposed rule, and that the risk associated with the use of substitute products is small, the expected benefits might amount to roughly $25 million annually.

Potential Costs of a Rule Prohibiting Certain Magnetic Desk Sets

The profits of firms represent a measure of the benefits to businesses that result from the production and sale of products. Similarly, the use value or ''utility'' that consumers receive from products represent the benefits of product use by the consuming public. Consequently, the costs of a proposed rule that effectively bans certain magnetic sets would consist of: (1) the lost profits of firms that would be barred from producing and selling the product in the future, and (2) the lost use value experienced by consumers who would no longer be able to purchase the prohibited magnets at any price.

Market Wide Profits

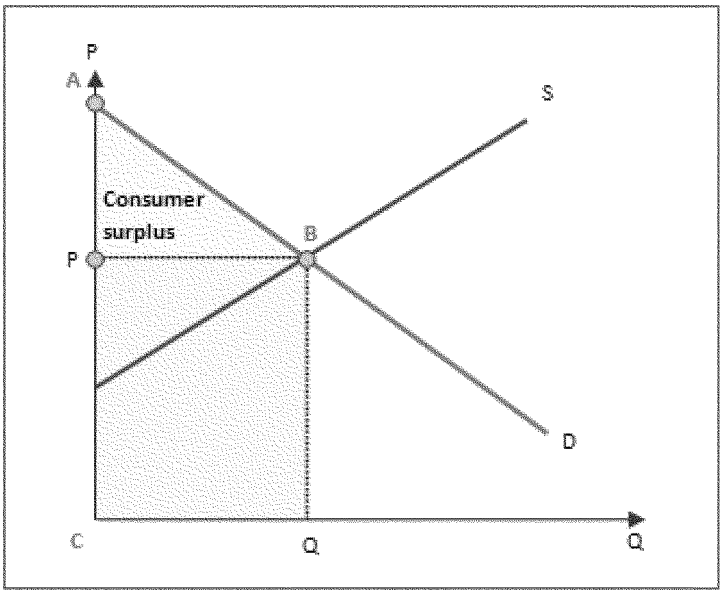
First consider ''profits,'' which would be defined as the total revenue (TR) received by firms resulting from the sale of the subject magnets, less the total costs (TC) needed to produce, distribute, and market them. We do not have firsthand knowledge of the profits of firms marketing the magnetic desk sets, but we do have information that may help us provide an upper limit.

Based on the available information described earlier, sales of the magnetic desk sets may have averaged roughly 1 million annually during the 2009–2011 study period, with an average retail price of about $25 per set. Thus, total industry revenues may have averaged about $25 million annually (*i.e.,* 1 million sets × $25 per set). Additional information provided by firms to the Office of Compliance and Field Operations suggests that the average import cost of the magnets to U.S. importers may have amounted to about $10 per set, or an annual average of about $10 million (*i.e.,* 1 million sets × $10 import cost per set). Thus, total revenues, less import costs, might have averaged about $15 million annually (*i.e.,* $25 million − $10 million). While the share of profits from this $15 million in net revenues is unknown, it seems unlikely that profits would amount to more than about half, or about $7.5 million annually. Thus, the costs of a proposed rule in terms of reduced profits might amount to as much as $7.5 million on an annual basis.[10]

Lost Utility to Consumers

We cannot estimate in any precise way the use value that consumers receive from these products, but we can describe it conceptually. In general, use value includes the amount of: (1) Consumer expenditures for the product, plus (2) what is called ''consumer surplus.'' In the case of the magnetic desk sets, given sales of about 1 million sets annually, and an average retail price of about $25 per set, consumer expenditures would amount to about $25 million annually. This $25 million represents the minimum value that consumers would expect to get from these products. It is represented by the area of the rectangle CPBQ in the standard supply and demand graph below, where P equals $25, and Q equals 1 million units.

[10] While most of these potential profits would accrue to importers, who also sell the magnetic desk toys directly to consumers, some portion would accrue to other retailers.



The consumer surplus is given by the area of the triangle PAB under the graph's demand function, and represents the difference between the market clearing price and the maximum amount consumers would have been willing to pay for the product. This consumer surplus will vary for individual consumers, but it represents a benefit to consumers over and above what they had to pay. For example, while tickets to a concert or football game might sell for $100 each, some consumers who buy them for $100 would have been willing to pay $150 per ticket. In other words, they paid $100 and received benefits that they value at $150. Hence, each of these consumers would receive a *consumer surplus* of $50.[11]

In general, the use value for the magnetic desk sets obtained by consumers is represented by the area of the trapezoid CABQ. However, the prospective *loss* in use value associated with the proposed rule prohibiting certain magnetic desk sets would amount to, at most, the area of the triangle representing the consumer surplus. This is because consumers would no longer be able to obtain utility from the prohibited product, but they would, nevertheless, still have the $25 million (represented by the rectangle CPBQ) that they would have spent on magnetic sets in the absence of a ban. While they can no longer purchase magnetic desk sets, which would have been their first choice, they can use this money to buy other products providing use value.

We have no information regarding aggregate consumer surplus, and hence, the amount of utility that would be lost from a ban of magnetic sets. While the magnetic desk sets clearly provide ''utility'' to purchasers, they are not necessities. Consequently, the demand for magnetic desk sets is probably *not* price inelastic, a factor that would tend to reduce estimates of utility losses.[12] Additionally, if the magnetic sets are ''faddish,'' they may not be the type of product that will be used intensively by consumers over long periods of time. However, if, for example, consumers who purchased the magnetic sets at an average price of $25 would have been willing to spend, on average, $35 per set, the lost utility from the desk sets might amount to about $10 million on an annual basis (*i.e.,* $[\$35 - \$25] \times 1$ million units annually).

Finally, it should be noted that the loss in consumer surplus just described represents the maximum loss of consumer utility from the proposed rule; the actual loss is likely to be lower. This is because consumers are likely to gain some amount of consumer surplus from products that are purchased in the place of magnetic desk sets. If, for example, there were close substitutes for magnetic desk sets (*i.e.,* desk sets that are almost as satisfying and similarly priced), the overall loss in consumer surplus (and hence, the costs of the proposed rule) would probably tend to be small. On the other hand, if there are no close substitutes, the costs of the proposed rule would tend to be higher. Nevertheless, the proposed rule will result in some level of lost utility. By purchasing magnetic desk sets rather than other products, consumers are revealing that they have a preference for the magnetic desk sets that are likely to provide more utility than a substitute purchase.

Sensitivity of Results to Product Life Assumptions

Implicit in this analysis has been the assumption that the expected useful life of the magnetic desk sets is about 1 year. Because this product has only been in widespread consumer use since 2009, this assumption is made without extensive knowledge about the actual use of the magnetic sets by consumers. Magnetic desk sets are relatively durable products, purchased at an average price of about $25. However, many consumers may find them to be novelties that soon lose much of their appeal. Thus, even if some of the products remain in homes or offices longer than a year, the risk of ingestion by children may be much higher in the first month or two after they are purchased. On the other hand, the magnets may be put away in a place accessible by children at some later date. Although it is somewhat speculative, it seems reasonable to assume that the effective useful product life of magnetic desk sets is, on average, no more than about a year.

[11] If the above graph represents the market for tickets, the demand curve (AD) describes the quantity of tickets demanded at each price (*i.e.,* the quantity of tickets consumers are willing and able to purchase at each price). In this example, the $150 the consumer would have been willing to pay for the ticket is represented on the demand curve at a point to the left of point B. The consumer surplus is given by the relevant point on the demand curve (*i.e.,* where price = $150), minus the market clearing price of $100.

[12] To say that the demand for a product is ''price inelastic'' means that the quantity demanded tends to be insensitive to changes in the price of the product. Gasoline is an example of a product with an inelastic demand, meaning consumers are not likely to reduce substantially their purchase of gasoline (at least in the short run) even if the price increases substantially.

However, it should also be noted that the results of our analysis are not particularly sensitive to this product life assumption. For example, had we assumed that the average product life was about 2 years, rather than 1 year, estimates of the number of sets in use at any given time would approximately double, reducing the estimated *annual* risk of injury, per magnetic desk set in use (and hence, reduce estimated societal costs per set) by about half. However, this reduced estimate of annual societal costs would itself be offset by the fact that the sets remain in use for 2 years, rather than 1 year. Thus, annual benefits would be halved, but benefits would be accrued over a 2-year period rather than 1 year. Consequently, even if we had doubled the assumed product life, the relationship between benefits and costs would have remained about the same.

Alternatives to the Proposed Rule

There are several possible alternatives that the Commission might consider instead of a proposed rule prohibiting certain magnetic desk sets.

Alternative Performance Requirements

As an alternative to the proposed rule, the Commission could consider promulgating an alternative set of requirements that could reduce the risk of injury from magnetic desk sets. Performance requirements might allow a different flux index for the magnets sold as manipulative desk sets; different specifications regarding shapes and sizes of magnets within the scope of the standard; or some other criteria that have not yet been developed (but not as stringent as in the proposed rule). The advantage of such an approach is that it could reduce the potentially unreasonable risk of injury associated with magnetic desk sets and at the same time allow adults to continue to use the product. One practical question, however, is whether such a standard would eliminate or substantially affect the physical qualities of the products that make them enjoyable for adults. Additionally, the expected injury reduction would depend upon the parameters of the performance requirements that are established.

Safer Packaging

A possible alternative might be for magnetic desk sets to be sold with special storage containers that are fitted to the product so that consumers would be able to determine whether any of the magnets were missing from the sets. Such an approach might prevent injuries resulting from a small number of magnets being separated from a set without the owner knowing. In reality, though, many consumers may not use such containers because it could require time to form the magnets into a shape (*e.g.,* a cube) to make them fit in the containers; or they might want to keep the magnets out of their container in a shape or structure that took time and effort to construct.

Alternatively (or in combination), the magnets could be sold in child-resistant packaging. Such an approach has the potential to reduce ingestion injuries, but it may result in several practical problems. Child-resistant packaging would not prevent teens and adolescents (and even some younger children) from opening the packaging. Additionally, the child-resistant packaging would have to be secured after each use. According to the Division of Human Factors, it is unlikely that adults would accept child-resistant packaging for a product like the magnetic desk sets because of the level of inconvenience it would involve (Sedney & Smith, 2012). Also, for the reasons described above, consumers may leave magnets outside of their container.

Warnings

The Commission could require strong warnings on labels and on product instructions designed to prevent the use of the magnetic desk sets by children. The Division of Human Factors, Directorate for Engineering Sciences (HF) memorandum contains an extensive discussion concerning warnings and their potential effectiveness (Sedney & Smith, 2012). Based on HF staff's examination, the ingestion warnings that currently accompany magnetic desk sets are generally aimed at adults, but appear to be deficient in terms of their content. For example, some warn against children swallowing the magnets without describing the incident scenarios. Some warnings refer to the propensity for swallowed magnets to stick to intestines without referring to the presence of other magnets or metal objects. Others warnings did refer to magnets sticking together or attaching to other metallic objects inside the body, but without explaining that the magnets can attract through the walls of the intestines and forcefully compress these tissues, resulting in serious injuries. According to CPSC staff, without detailed information in the warnings, consumers may not really understand how swallowing magnets differs from swallowing other small parts or how magnets sticking together could pose a hazard.

CPSC staff believes that it may be possible to develop warnings that could adequately communicate the ingestion hazard, the consequences of ingestion, and how to avoid the hazard. To the extent that the subject magnets present a ''hidden'' hazard about which consumers are unaware, explicit and adequate warnings could reduce ingestions and allow adults to continue to enjoy the use of the product. However, the effectiveness of such warnings is unknown, and CPSC staff doubts that even well-written warnings would substantially reduce the incidence of magnet ingestions. Some caregivers who read and understand the message may attempt to keep the magnets out of the hands of young children, but staff doubts many caregivers would attempt to keep the product away from older children and adolescents. Additionally, staff is doubtful that children old enough to understand the warnings would abide by them.

Restrictions on the Sale of Magnetic Desk Sets

Another option for the Commission to consider might be to prohibit sales of magnetic desk sets in toy stores, children's sections of general purpose stores, and near cash registers of stores that sell any children's products. Sales limitations or requirements for strong warnings might also be required on Web sites advertising the sale of magnets on the Internet.

The details for developing a set of sales limitations and requirements would need to be worked out, but the idea would be to make sure that magnetic desk sets, to the extent possible, are not sold at locations where children are likely to be present. Sales requirements might also be combined with strong and explicit warnings could be developed although the staff has expressed serious concern as to whether such warnings can ever overcome the attractiveness of the magnets and their intrinsic play value.

Such sales limitations, in combination with adequate and explicit warnings, may increase consumer awareness of the hazard, and possibly reduce the number of ingestions. Some parents would still allow their children (especially older children and adolescents) to play with the magnetic desk sets despite the warnings. Also, some young children will get into the packaging, even if parents try to restrict the use of the desk sets. Nevertheless, combining sales limitations with explicit warnings might educate parents about the hidden nature of the hazard, while at the same time allow adults to continue to use a

product that they apparently enjoy. We are interested in receiving comments that would address this issue.

Address Through Corrective Actions Rather Than Regulatory Action

Alternatively, the Commission could continue to address the hazard by means of Corrective Action Plans. While staff believes this approach may be deficient, such a strategy might be combined with other actions described above to achieve some reductions in the hazard.

Summary

Based on reports to the CPSC, ingestions of small magnets contained in magnetic desk sets have caused multiple, high severity injuries that require surgery to remove the magnets and repair internal damage. However, because of the lack of definitive information on the number of injuries involving magnetic desk sets that would be prevented by a proposed rule, there is uncertainty concerning the benefits that would result. If we assume that the NEISS cases identified by the Directorate for Epidemiology staff as involving high-powered and/or ball-shaped magnet ingestions actually involved the magnets that would be prohibited, then the estimated benefits of the rule might amount to about $25 million annually.

The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, are also uncertain. However, based on annual estimates available for the 2009 – 2011 study period, these costs could amount to about $7.5 million in lost profits and some unknown quantity of lost utility.

There are alternative regulatory actions that the Commission could consider that might allow the magnetic desk sets to continue to be marketed. For example, the Commission, by regulation, could issue alternative performance requirements or require warnings that explicitly describe the hazard and how to avoid it. Other options might be to develop requirements for the packaging of the magnetic desk sets (*e.g.,* develop requirements for child-resistant packaging); and/or place limitations on how and where the magnetic desk sets can be sold. These alternative actions—which might be considered alone, or in combination—would have varying levels of effectiveness.

I. Paperwork Reduction Act

The proposed rule would not require manufacturers (including importers) to perform testing or require manufacturers or retailers to keep records. For this reason, the proposed rule does not contain ''collection of information requirements'' as that term is used in the Paperwork Reduction Act, 44 U.S.C. 3501–3520. Therefore, the proposed rule need not be submitted to the Office of Management and Budget (OMB) in accordance with 44 U.S.C. 3507(d) and implementing regulations codified at 5 CFR 1320.11.

J. Initial Regulatory Flexibility Analysis

1. Introduction

The Regulatory Flexibility Act (RFA) generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. Section 603 of the RFA calls for agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. The initial regulatory flexibility analysis is to contain:

(1) A description of the reasons why the action is being considered;

(2) A succinct statement of the objectives of, and legal basis for, the proposed rule;

(3) A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(4) A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the types of professional skills necessary for the preparation of the report or record; and

(5) An identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

Accordingly, staff prepared an initial regulatory flexibility analysis, which is summarized below.

2. Description of the Proposed Rule and Reasons for Considering It

As discussed previously, the proposed rule would prohibit magnet sets that do not meet the specified requirements described in section F of this preamble. Some of the incidents that have come to the attention of the Commission involving ingestions of magnets from desk sets have resulted in severe medical consequences, including significant damage to the stomach or intestines. Based on a review of emergency department-treated magnet ingestions obtained through the NEISS, the Directorate for Epidemiology staff has identified 72 magnet ingestions from 2009 through 2011, which were determined to involve, or possibly involve, the magnets of interest. Based on these injuries, staff estimates that there has been an *annual* average of about 572 emergency department-treated injuries involving the products, including 537 injuries that were treated and released and 35 injuries that were hospitalized.[13] Additionally, based on estimates from the CPSC's Injury Cost Model (ICM), which is integrated with NEISS, there were 870 other injuries treated annually outside of hospital emergency departments, such as in doctors' offices and clinics. The estimated total of 1,442 medically attended injuries involving magnet ingestions, which were defined as at least ''possibly of interest,'' resulted in average annual societal costs of nearly $25 million during 2009 through 2011, based on estimates provided by the ICM.

3. Products Within the Scope of the Proposed Rule

This proposed rule would cover magnet sets that are comprised of sets of small powerful magnetic balls, cubes, and/or cylinders that can be arranged in many different geometric shapes. The products have been described as desk toys, games, puzzles, and stress relievers. The small powerful magnets most likely to be affected by the proposed rule are made from alloys of neodymium, iron, and boron. We are interested in receiving comments that would address this issue both as to the type of products that should be covered and the composition of the magnets. More information concerning the product and the market is provided in section B of the preamble.

4. Small Businesses Subject to the Proposed Rule and Possible Economic Impacts

The proposed rule would impact U.S. importers and retailers of manipulative desk sets that are comprised of small powerful magnets of the size and magnetic force proscribed by the proposed rule. None of the magnetic desk sets within the scope of the proposed rule are produced domestically. All of the firms that have marketed the products are believed to import them from manufacturers in China, packaged and labeled for sale to U.S. consumers. The Directorate for Economic Analysis has indentified about 25 firms and individuals in the United States who have recently

[13] Average annual estimates are from the Injury Cost Model evaluation of 72 emergency department-treated injuries during 2009–2011 determined to have involved, or possibly having involved, magnets of interest (Garland, 2012).

imported the product for sale to consumers. All of the importers are small businesses under U.S. Small Business Administration (SBA) size standards (SBA, 2012).[14]

Based on information on product sales reviewed by the Directorate for Economic Analysis staff, including reports by firms to the Office of Compliance and Field Operations (Compliance), the number of manipulative magnetic desk sets that have been sold by U.S. importers since the products were introduced in 2008 may total about 2.7 million sets, with a value to the firms of roughly $50 million. This value range reflects a combination of retail sales directly to consumers (through company Web sites and other Internet retail sites) and sales to retailers who market the products.

Although there are about 25 U.S. importers of magnet sets that would fall within the scope of the rule, the economic impact of the rule will be most severe for the seven firms that account for the great majority (perhaps over 98%) of units sold. Perhaps five of these larger importers derive most or all of their revenues from the sale of magnetic desk toys falling within the scope of the rule, or related products, such as books and surfaces upon which magnetic designs are constructed. These firms would be severely affected by the proposed rule, which would effectively ban the magnet sets that they have been importing and selling. Consequently, they may go out of business. Two of the other leading importers of magnetic desk sets apparently have fairly broad product offerings, which could lessen the severity of the economic impact of a rule. Nevertheless, the impacts of the proposed rule could be considered significant for these small importers.

Nearly all of the perhaps 18 other recent U.S. importers of magnetic desk sets have sold relatively few of the products. These importers sourced the products from manufacturers in China and have marketed the magnet sets through online ''stores'' maintained on Internet retail sites. Many of these importers are individuals who may also market a variety of other products through the same Internet outlets. For individuals and firms with these business models, the discontinuance of certain magnetic desk sets as a source of revenue as a result of the rule is less likely to cause significant economic hardship, unlike the firms or individuals who derive most, or all, of their revenue from sales of magnetic desk sets and related products.

Although a large share of magnetic desk sets are sold directly to consumers by the importers using their own Internet Web sites or other Internet shopping sites, a rule prohibiting these products would also affect retailers of the products, whether selling them online or physically in stores. However, these retailers are not likely to derive significant proportions of total revenues from sales of affected desk sets, and the impacts on individual firms should be minimal.

5. Objectives of, and Legal Basis for, the Proposed Rule

The purpose of the proposed rule is to reduce the risk of injury from ingestion of one or more small, powerful magnets that comprise the subject consumer products. As noted above, the estimated total of 1,442 medically attended injuries involving magnet ingestions that were defined as at least ''possibly of interest'' resulted in annual societal costs of about $25 million during the 2009 to 2011 time period. These incident numbers may change over the course of the rulemaking because the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) has provided the Commission with some additional incident data and is currently surveying their members regarding any additional incident data they may have to share with the Commission. After receiving this data the Commission may conduct its own survey to collect additional data similar to the exposure surveys the Commission has conducted in the ATV rulemaking. However, it is expected that the proposed rule would substantially reduce the future incidence and cost to society of ingestions of the subject magnetic desk sets. As discussed in section D of this preamble, the rule is being proposed under the authority of the CPSA.

6. Other Federal Rules

We are not aware of any federal rules that may duplicate, overlap, or conflict with the proposed rule.

7. Alternatives to the Proposed Rule

There are possible alternatives to the proposed rule that would reduce the impact of a rule on small businesses. These alternatives would include the following:

a. Adoption of a Performance Standard With Different Provisions

As an alternative to the proposed rule, the Commission could consider promulgating a different set of performance requirements to reduce the risk of injury from magnetic desk sets. Performance requirements might require a different flux index for the magnets sold as manipulative desk sets, different specifications regarding shapes and sizes of magnets within the scope of the standard, or some other criteria that have not been developed yet. The advantage of such an approach is that, theoretically, it could reduce the potentially unreasonable risk of injury associated with magnetic desk sets, and at the same time, allow adults to continue to use the product. One practical question, however, is whether such a standard would eliminate or substantially reduce the physical qualities of the products that make them enjoyable for adults.

b. Safer Packaging Options

In theory, magnetic desk sets could be sold with special storage containers that are fitted to the product so that consumers would be able to determine whether any of the magnets were missing from the sets. Such a requirement might prevent injuries that result from a small number of magnets becoming separated from a set without the owner knowing. In reality, though, many consumers might be unlikely to use such containers because using a container could require consumers to take time to form the magnets into a shape (e.g., a cube) in order for the magnets to fit back into the container, or consumers might wish to keep the magnets in a formation that took time and effort to construct.

Alternatively, the magnets could be sold in child-resistant packaging. Such an approach has the potential to reduce ingestion injuries, but it may suffer from several practical problems. Child-resistant packaging would not prevent teens and adolescents (and even some younger children) from opening the packaging. Additionally, the packaging would have to be secured after each use. According to the Division of Human Factors, it is unlikely that adults would accept child-resistant packaging for a product such as the magnetic desk set because of the level of inconvenience it would involve.

It is not clear that the Commission would have the authority to require either of these approaches through regulation.

c. Warnings/Labeling Requirements

The Commission could require labeling on affected magnetic desk sets to warn consumers in lieu of a rule that prohibits the products. Following its evaluation of this alternative, the

[14] The SBA size standard for ''Other Miscellaneous Nondurable Goods Merchant Wholesalers'' (which includes importers) is 100 employees and the size standard for ''Non-store Retailers—Electronic Shopping'' is $30 million in average annual receipts (SBA, 2012).

Division of Human Factors, Directorate for Engineering Sciences, concluded: ''it may be possible to develop warnings that could inform parents and other caregivers better about the ingestion hazard, its consequences, and appropriate hazard-avoidance measures. Nevertheless, the resulting warnings may not be effective at motivating caregivers to comply, and therefore, they may not reduce substantially the incidence of magnet ingestions.''

d. Restrictions on the Sale of Magnetic Desk Sets

Another option might be to prohibit sales of magnetic desk sets in toy stores, children's sections of general purpose stores, and near cash registers of stores that sell any children's products. Advertising and sales limitations or requirements for strong warnings might also be required at Web sites advertising the sale of magnets on the Internet.

The details for developing a set of sales limitations and requirements would need to be worked out (and the legal authority to impose such restrictions by regulation is uncertain), but the idea would be to make sure that magnetic desk sets, to the extent possible, are not sold at locations where children are likely to be present. Sales requirements might also be combined with strong and explicit warnings of the sort that CPSC staff has suggested could be developed.

Such sales limitations, in combination with adequate and explicit warnings, may increase consumer awareness of the hazard, and possibly reduce ingestions. Some parents would still allow their children (especially older children and adolescents) to play with the magnetic desk sets despite the warnings. Also, some young children will get into the packaging even if parents try to restrict the use of the products. Nevertheless, combining sales limitations with explicit warnings might educate parents about the hidden nature of the hazard, while at the same time allow adults to continue to use a product that apparently they enjoy.

e. Address Through Corrective Actions Rather Than Regulatory Action

Alternatively, the Commission could continue to address the hazard by means of Corrective Action Plans. While we believe this approach may be deficient, such a strategy might be combined with other actions described above to achieve some reductions in the hazard.

f. Taking No Action

The Commission could take no regulatory action to reduce the risk of ingestion injuries associated with magnetic desk sets. Under this alternative, future societal losses would be determined by the numbers of products in use, other factors that affect the likelihood that young children, adolescents, and teens will ingest the magnets, and the awareness and response of the medical community to the hazards presented by ingested magnets. Theoretically, over time, increased awareness of the hazards by caregivers could make it more likely that the magnets will be kept away from young children and older children, and school personnel could be made more aware of the hidden dangers of using strong magnets to mimic tongue or lip piercings. Also, the medical community seems to be taking steps to become better educated about the risks of ingested magnets, which should lead to monitoring of patients' medical status more quickly, which would reduce the adverse medical consequences of magnet ingestions.

8. Summary

The results of this initial regulatory flexibility analysis suggest that the proposed rule would likely have a significant adverse impact on seven of the small importers of magnetic desk sets, and perhaps five of these firms that derive most or all of their revenue from the sale of magnetic desk sets might go out of business. Some possible alternatives to a rule prohibiting the products have been identified. All of these alternatives would reduce the expected impact of the rule on small businesses. However, these alternatives might not achieve the same level of benefits as the proposed rule.

K. Environmental Considerations

Usually, CPSC rules establishing performance requirements are considered to ''have little or no potential for affecting the human environment,'' and environmental assessments are not usually prepared for these rules (see 16 CFR 1021.5(c)(1)). This proposed rule falls within the categorical exemption.

L. Executive Order 12988 (Preemption)

As required by Executive Order 12988 (February 5, 1996), the CPSC states the preemptive effect of the proposed rule as follows:

The regulation for hazardous magnet sets is proposed under authority of the CPSA. 15 U.S.C. 2051–2089). Section 26 of the CPSA provides that ''whenever a consumer product safety standard under this Act is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as the performance, composition, contents, design, finish, construction, packaging or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal Standard''. 15 U.S.C. 2075(a). Upon application to the Commission, a state or local standard may be excepted from this preemptive effect if the state or local standard: (1) provides a higher degree of protection from the risk of injury or illness than the CPSA standard, and (2) does not unduly burden interstate commerce. In addition, the federal government, or a state or local government, may establish and continue in effect a non-identical requirement that provides a higher degree of protection than the CPSA requirement for the hazardous substance for the federal, state or local government's use. 15 U.S.C. 2075(b).

Thus, with the exceptions noted above, the magnet set requirements proposed in today's **Federal Register** would preempt non-identical state or local requirements for magnet sets designed to protect against the same risk of injury.

M. Effective Date

The Commission proposes that this rule would become effective 180 days from publication of a final rule in the **Federal Register** and would apply to all magnet sets manufactured or imported on or after that date. The CPSA requires that consumer product safety rules take effect not later than 180 days from their promulgation unless the Commission finds there is good cause for a later date. 15 U.S.C. 2058(g)(1).

N. Proposed Findings

The CPSA requires the Commission to make certain findings when issuing a consumer product safety standard. Specifically, the CPSA requires that the Commission consider and make findings about the degree and nature of the risk of injury; the number of consumer products subject to the rule; the need of the public for the rule and the probable effect on utility, cost, and availability of the product; and other means to achieve the objective of the rule, while minimizing the impact on competition, manufacturing, and commercial practices. The CPSA also requires that the rule must be reasonably necessary to eliminate or reduce an unreasonable risk of injury

associated with the product and issuing the rule must be in the public interest. 15 U.S.C. 2058(f)(3).

In addition, the Commission must find that: (1) If an applicable voluntary standard has been adopted and implemented, that compliance with the voluntary standard is not likely to adequately reduce the risk of injury, or compliance with the voluntary standard is not likely to be substantial; (2) that benefits expected from the regulation bear a reasonable relationship to its costs; and (3) that the regulation imposes the least burdensome requirement that would prevent or adequately reduce the risk of injury. *Id.* These findings are discussed below.

*Degree and nature of the risk of injur*y. Based on a review of NEISS data, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. From review of INDP and IPII databases, we are aware of 50 reported incidents occurring from January 1, 2009 through June 30, 2012, involving the ingestion of magnets by children between the ages of 1 and 15. Of those 50 incidents, 38 involved the ingestion of high-powered, ball-shaped magnets that were contained in products that meet the above definition of ''magnet set,'' and 5 of those 50 incidents possibly involved ingestion of this type of magnet. Hospitalization was required in order to treat 29 of the 43 incidents, with surgery necessary to remove the magnets in 20 of the 29 hospitalizations. In 10 of the 29 hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents that likely involved magnets from hazardous magnet sets, the magnets were ingested by children younger than 4 years old, or between the ages of 4 and 12.

Once ingested, these strong magnets begin to interact in the gastrointestinal tract, which can lead to tissue death, perforations, and/or fistulas, and possibly intestinal twisting and obstruction. If left untreated, these injuries can lead to infection of the peritoneal cavity and other life-threatening conditions. The number of magnets swallowed increases the risk of attraction and injury, but as few as two magnets can cause serious internal damage in a very short period of time. The fact that many medical professionals do not appreciate the health consequences of magnet ingestion increases the severity of the risk because a doctor who is unfamiliar with these strong magnets may send a child home and expect the magnets to pass naturally. There are also health consequences to the treatment and surgery for removal of ingested magnets. There may be a risk of gastrointestinal bleeding; leakage of holes that were repaired; rupturing of resectioned bowels; temporary paralysis of the bowels; use of a colostomy bag; IV feeding initially, or for some longer time period; and compromise of nutrition and digestive function. Long-term health consequences can be severe as well: loss of intestinal tissue; compromised nutrition absorption; adhesions and scarring of intestines; need for a bowel transplant; and possible impediments to fertility with girls. Even those children who pass the magnets naturally and do not require surgery still need close observation by doctors and may undergo sequential x-rays, thus, exposing children to repeated dosages of radiation.

Number of consumer products subject to the rule. The market has increased substantially since magnet sets were first introduced. We estimate that the number of such magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million.

The need of the public for magnet sets and the effects of the rule on their utility, cost, and availability. We cannot estimate, in any precise way, the use value that consumers receive from these products. In general, this would be the amount of money that consumers expend on the product, plus the consumer surplus (*i.e.,* the difference between the market price and the maximum amount consumers would have been willing to pay for the product). Although the proposed rule would prohibit the magnet sets currently on the market, it is conceivable that a similar product that meets the requirements of the proposed rule could be developed that would serve a similar purpose of the magnet sets that the proposed rule would prohibit.

Other means to achieve the objective of the rule, while minimizing the impact on competition and manufacturing. Various alternatives to the proposed rule are discussed in previous sections of this preamble. We do not believe that options other than the proposed rule prohibiting certain magnet sets would sufficiently reduce the number and severity of injuries resulting from the ingestion of magnets from these magnet sets. As discussed above, the circumstances associated with this product limit the likely effectiveness of warning labels. Despite existing warning labels and market restrictions, ingestion incidents have continued to occur. Parents and caregivers may not appreciate the hazard associated with magnet sets, and as a result, they will continue to allow children access to the product. Children may not appreciate the hazard and will continue to mouth the items, swallow them, or, in the case of young adolescents and teens, mimic body piercings. Once the magnets are removed from their carrying case, the magnets bear no warnings to guard against ingestion or aspiration; the small size of the individual magnets precludes the addition of such a warning. Because individual magnets are shared easily among children, many end users of the product are likely to have had no exposure to any warning.

Unreasonable risk. As noted previously, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. Injuries resulting from such ingestions of magnets can be severe and life-threatening. The risk posed by these magnets may not be appreciated by caregivers and children, as they may assume, mistakenly, that the consequences of ingesting magnets would be similar to ingesting any other small object. However, once ingested, these strong magnets are mutually attracted to each other and exert compression forces on the trapped gastrointestinal tissue.

We estimate that the societal costs of resulting injuries could amount to $25 million annually. This would be the expected benefits that could result from the proposed rule. The costs of the proposed rule would consist of the lost profits to firms that produce and sell magnet sets, plus the lost use value that consumers would experience when the product is no longer available. We estimate these costs to be about $7.5 million in lost profits and some unknown quantity of lost utility. Considering the injuries associated with magnet sets—and the resulting societal costs, balanced against the likely impact that the proposed rule would have on firms producing and selling the product, and on consumers who would lose the utility of the product— we preliminarily conclude that magnet sets pose an unreasonable risk of injury and that the proposed rule is reasonably necessary to reduce that risk.

Public interest. This proposed rule is in the public interest because it would reduce magnet-related deaths and injuries in the future. A rule prohibiting certain magnet sets from the chain of commerce will mean that children will have less access to this product, thereby

reducing the number of incidents of children swallowing the magnets and the resulting cost to society of treating these injuries. The Commission seeks comment on this issue and also whether similar actions regarding lawn darts and dive sticks have had the effect of reducing injuries by reducing the access to the product.

Voluntary standards. Currently, there is no voluntary standard for magnetic sets. A group of magnet set importers and distributors have requested the formation of a voluntary standard by ASTM International for the labeling and marketing of these products. The companies have requested the formation of a voluntary standard to: (1) Provide for appropriate warnings and labeling on packages of these magnet sets, and (2) establish guidelines for restricting the sale of these magnet sets to, or for the use of children, such as: not selling to stores that sell children's products exclusively, and not selling the magnets in proximity to children's products. Such a voluntary standard would have many of the same limitations as would a labeling standard.

Relationship of benefits to costs. Based on reports to the CPSC, ingestions of small magnets contained in magnet sets have caused multiple, high severity injuries that require surgery to remove the magnets and repair internal damage. Although there is some uncertainty concerning the benefits that would result from the proposed rule, we estimate that benefits of the rule might amount to about $25 million annually.

The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, also are uncertain. However, based on annual estimates available for the 2009–2011 study period, these costs could amount to about $7.5 million in lost profits and some unknown quantity of lost utility.

Least burdensome requirement. We have considered several alternatives to the proposed rule prohibiting certain magnet sets. We conclude that none of these alternatives would adequately reduce the risk of injury. Alternative performance requirements might allow a different flux index for magnets contained in magnetic sets. Theoretically, this might allow some current products to continue to be produced. However, it is unclear that a different flux index would permit products that have the desired physical qualities to make them sufficiently enjoyable to adults while adequately reducing the characteristics that make these strong magnets hazardous to children. Some type of special storage containers or other packaging requirements might be possible. However, it is unlikely that consumers would use such containers, particularly if they wish to keep the magnets out of the container and maintain whatever shape they have constructed with the magnets. We have considered the possibility of requiring rigorous warnings on the products or in the instructions for the products. However, magnet sets currently on the market provide warnings concerning the potential hazard to children. It is unlikely that even strengthened warnings would substantially reduce the incidence of magnet ingestions. This is particularly true for incidents involving older children and adolescents. Moreover, children who are old enough to understand the warnings may still not abide by them. Some type of sales restriction, limiting the location where magnet sets could be sold, might be possible. However, even with restrictions on sales, ingestions are still likely to occur as children encounter these magnets in the home, at school, or other locations when adults have bought them and they are available to children. The Commission could continue to address the hazard from magnet sets through corrective actions, *i.e.,* recalls of the product. However, such action would do nothing to prevent additional companies from continuing to enter the market and import magnet sets into the country. The Commission has the option of taking no regulatory action. Although it is possible that, with increased awareness of the hazard over time, some reduction in ingestions could occur, the magnitude of any such reduction in incidents is uncertain and would likely be smaller than if the Commission issues the proposed rule.

O. Request for Comments

We request comments on all aspects of this proposed rule. We ask for comments concerning the risks of injury associated with these magnet sets; the regulatory alternatives discussed; other possible ways to address these risks; and the economic impacts of the various regulatory alternatives. We specifically seek comments concerning the following issues:

- The proposed definition of ''magnet sets'' that would be covered by the rulemaking and other issues related to scope of the proposal
- The appropriateness of the proposed flux index limit of 50 or less
- The adequacy of the proposed test procedure for determining the flux index, particularly whether it would be sufficient to account for the strength of aggregated magnets
- Alternatives to the small parts cylinder that limits the size of the magnets at issue
- The likelihood that a magnet set could function as entertainment for adults and meet the proposed requirements
- All alternatives to the proposed regulatory action
- Issues related to warnings for these products
- The options of conducting the rulemaking under section 8 of the CPSA or under provisions of the FHSA
- Whether the definition of magnet set should include magnets sold individually with the possibility that they could be aggregated into a set of two or more magnets by consumers, and if so, whether such individually sold magnets are already covered by the definition of magnet set contained in the proposed rule at 16 CFR 1240.2(b), or whether the definition should be amended with additional language such as ''whether sold individually or as part of a set.''
- Proposed § 1240.3(a) would apply to magnet sets that contain a magnet that fits completely within the small-parts cylinder described in 16 CFR 1501.4. Should it instead apply to sets with at least two magnets that fit completely within the small parts cylinder?

P. Conclusion

For the reasons stated in this preamble, the Commission preliminarily concludes that magnet sets that do not meet the specified proposed requirements present an unreasonable risk of injury.

List of Subjects in 16 CFR Part 1240

Consumer protection, Imports, Infants and children, Labeling, Law enforcement.

For the reasons stated in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

1. Add part 1240 to read as follows:

PART 1240—SAFETY STANDARD FOR MAGNET SETS

Sec.
1240.1 Scope, purpose, and effective date.
1240.2 Definitions.
1240.3 Requirements.
1240.4 Test procedure for determining flux index.
1240.5 Findings.

Authority: 15 U.S.C. 2056 and 2058.

§ 1240.1 Scope, purpose, and effective date.

This part 1240, a consumer product safety standard, prescribes requirements

for magnet sets, as defined in § 1240.2. These requirements are intended to reduce or eliminate an unreasonable risk of injury to children who ingest magnets that are part of hazardous magnet sets. This standard applies to all magnet sets, as defined in § 1240.2, that are manufactured or imported on or after [180 days after publication of a final rule].

§ 1240.2 Definitions.

(a) The definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) apply to this part 1240.

(b) *Magnet set* means any aggregation of separable, permanent, magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief.

§ 1240.3 Requirements.

(a) *Small parts.* Magnet sets containing a magnet that fits completely within the cylinder described in 16 CFR 1501.4, must meet the requirement in paragraph (b) of this section.

(b) *Flux index.* When tested in accordance with the method described in § 1240.4, small magnets, as determined in paragraph (a) of this section, must have a flux index of 50 or less.

§ 1240.4 Test procedure for determining flux index.

(a) Select at least one magnet of each shape and size that the magnet set contains.

(b) Measure the flux index of the selected magnets in accordance with the procedure in sections 8.24.1 through 8.24.3 of ASTM F963–11, *Standard Consumer Safety Specification for Toy Safety,* approved December 1, 2011. The Director of the **Federal Register** approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, PO Box 0700, West Conshohocken, PA 19428; telephone 610–832–9585; *www.astm.org.* You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or 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.*

§ 1240.5 Findings.

(a) *The degree and nature of the risk of injury.* Based on a review of NEISS data, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. From review of INDP and IPII databases, we are aware of 50 reported incidents occurring from January 1, 2009 through June 30, 2012, involving the ingestion of magnets by children between the ages of 1 and 15 years. Of those 50 incidents, 38 involved the ingestion of high-powered, ball-shaped magnets that were contained in products that meet the above definition of ''magnet set,'' and five of those 50 incidents possibly involved ingestion of this type of magnet. Hospitalization was required in order to treat 29 of the 43 incidents, with surgery necessary to remove the magnets in 20 of the 29 hospitalizations. In 9 of the 29 hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents that likely involved magnets from hazardous magnet sets, the magnets were ingested by children who were less than 4 years old or between the ages of 4 and 12 years old.

Once ingested, these strong magnets begin to interact in the gastrointestinal tract, which can lead to tissue death, perforations, and/or fistulas, and possibly bowel twisting and obstruction. If left untreated, these injuries can lead to infection of the peritoneal cavity and other life-threatening conditions. The number of magnets swallowed increases the risk of attraction and injury; however, as few as two magnets can cause serious internal damage in a very short period of time. The fact that many medical professionals do not appreciate the health consequences of magnet ingestion increases the severity of the risk because a doctor who is unfamiliar with these strong magnets may send a child home and expect the magnets to pass naturally. There are also health consequences associated with treatment and surgery for removal of ingested magnets. There may be a risk of gastrointestinal bleeding; leakage of holes that were repaired; rupturing of resectioned bowels; temporary paralysis of the bowels; use of a colostomy bag; IV feeding, initially, or for some longer time period; and compromise of nutrition and digestive function. Long-term health consequences can be severe as well: loss of intestinal tissue; compromised nutrition absorption; adhesions and scarring of intestines; need for a bowel transplant; and possible impediments to fertility with girls. Even those children who pass the magnets naturally and do not require surgery still need close observation by doctors and may undergo sequential x-rays, thus exposing children to repeated dosages of radiation.

Number of consumer products subject to the rule. The market has increased substantially since magnet sets were first introduced. We estimate that the number of such magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million.

The need of the public for magnet sets and the effects of the rule on their utility, cost and availability. We cannot estimate in any precise way the use value that consumers receive from these products. In general, this would be the amount of money that consumers expend on the product, plus the consumer surplus (*i.e.,* the difference between the market price and the maximum amount of money that consumers would have been willing to pay for the product). Although the proposed rule would prohibit the magnet sets currently on the market, it is conceivable that a similar product that meets the requirements of the proposed rule could be developed that would serve a similar purpose as the magnet sets that the proposed rule would prohibit.

Other means to achieve the objective of the rule, while minimizing the impact on competition and manufacturing. Various alternatives to the proposed rule are discussed in previous sections of this preamble. We do not believe that options other than the proposed rule prohibiting certain magnet sets would sufficiently reduce the number and severity of injuries resulting from the ingestion of magnets from these magnet sets. As discussed above, the circumstances associated with this product limit the likely effectiveness of warning labels. Despite existing warning labels and market restrictions, ingestion incidents have continued to occur. Parents and caregivers may not appreciate the hazards associated with magnet sets, and as a result, they will continue to allow children access to the product. Children may not appreciate the hazards, and they will continue to mouth the items, swallow them, or, in the case of young adolescents and teens, mimic body piercings. Once the magnets are removed from their carrying case, the magnets bear no warnings to guard against ingestion or aspiration; and the small size of the individual magnets precludes the addition of such

a warning. Because individual magnets are easily shared among children, many end users of the product are likely to have had no exposure to any warning.

Unreasonable risk. As noted previously, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. Injuries resulting from such ingestions of magnets can be severe and life-threatening. The risk posed by these magnets may not be appreciated by caregivers and children, as they may assume, mistakenly, that the consequences of ingesting magnets would be similar to ingesting any other small object. However, once ingested, these strong magnets are mutually attracted to each other and exert compression forces on the trapped gastrointestinal tissue.

We estimate that the societal costs of resulting injuries could amount to $25 million annually. This would be the expected benefits that could result from the proposed rule. The costs of the proposed rule would consist of the lost profits of firms that produce and sell magnet sets, plus the lost use value that consumers would experience when the product is no longer available. We estimate these costs to be about $7.5 million in lost profits and some unknown quantity of lost utility. Considering the injuries associated with magnet sets and the resulting societal costs, balanced against the likely impact that the proposed rule would have on firms producing and selling the product, and the impact on consumers who would lose the utility of the product, we conclude, preliminarily, that magnet sets pose an unreasonable risk of injury. Additionally, we conclude that the proposed rule is reasonably necessary to reduce that risk.

Public interest. This proposed rule is in the public interest because it may reduce magnet-related deaths and injuries in the future. A rule prohibiting certain magnet sets from the chain of commerce will mean that children will have less access to this product, thereby reducing the number of incidents of children swallowing the magnets and the resulting cost to society of treating these injuries.

Voluntary standards. Currently, there is no voluntary standard for magnetic sets. A group of magnet set importers and distributors have requested the formation of a voluntary standard by ASTM International for the labeling and marketing of these products. The companies have requested the formation of a voluntary standard to: (1) Provide for appropriate warnings and labeling on packages of these magnet sets, and (2) establish guidelines for restricting the sale of these magnet sets to, or for the use of children, such as by not selling to stores that sell children's products exclusively, and by not selling magnet sets in proximity to children's products. Such a voluntary standard would have many of the same limitations as a labeling standard.

Relationship of benefits to costs. Based on reports to the CPSC, ingestions of small magnets contained in magnet sets have caused multiple, high severity injuries that require surgery to remove the magnets and repair internal damage. Although there is some uncertainty concerning the benefits that would result from the proposed rule, we estimate that benefits of the rule might amount to about $25 million annually. The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, are also uncertain. However, based on annual estimates available for the 2009–2011 study period, these costs could amount to about $7.5 million in lost profits and some unknown quantity of lost utility. We believe that there would be a reasonable relationship between the anticipated benefits and costs of the proposed rule.

Least burdensome requirement. We have considered several alternatives to the proposed rule prohibiting certain magnet sets. We conclude that none of these alternatives would adequately reduce the risk of injury. Alternative performance requirements might allow a different flux index for magnets contained in magnetic sets. Theoretically, this might allow some current products to continue to be produced. However, it is unclear whether a different flux index would permit products that have the desired physical qualities to make them enjoyable to adults would reduce adequately the characteristics that make these strong magnets hazardous to children. Some type of special storage containers or other packaging requirements might be possible. However, it is unlikely that consumers would use such containers, particularly if they wish to keep the magnets out of the container and maintain whatever shape they have constructed with the magnets. We have considered the possibility of requiring rigorous warnings on the products or in the instructions for the products. However, magnet sets currently on the market provide warnings concerning the potential hazard to children. It is unlikely that even strengthened warnings would substantially reduce the incidence of magnet ingestions. This is particularly true for incidents involving older children and adolescents. Moreover, children who are old enough to understand the warnings still may not abide by them. Some type of sales restriction limiting the location where magnet sets could be sold might be possible. However, even with restrictions on sales, ingestions are still likely to occur as children encounter these magnets in the home, at school, or in other locations when adults have bought them and they are available to children. Finally, the Commission could continue to address the hazard from magnet sets through corrective actions, *i.e.,* recalls of the product. However, such action would do nothing to prevent additional companies from continuing to enter the market and import magnet sets into the country. The Commission has the option of taking no regulatory action. Although it is possible that, with increased awareness of the hazard over time, some reduction in ingestions could occur, the magnitude of any such reduction in incidents is uncertain and would likely be smaller than if the Commission issues the proposed rule.

Dated: August 28, 2012.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2012–21608 Filed 8–31–12; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2011–F–0765]

Nexira; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Nexira proposing that the food additive regulations be amended to provide for the expanded safe use of acacia gum (gum arabic) in foods.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by October 4, 2012.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–

305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1309.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** on December 20, 2011 (76 FR 78866), FDA announced that a food additive petition (FAP 1A4784) had been filed by Nexira, c/o Keller and Heckman LLP, 1001 G St. NW., Suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 172.780 *Acacia (gum arabic)* (21 CFR 172.780) to provide for the expanded safe use of acacia gum (gum arabic) in food.

Under 21 CFR 171.1(c)(H), either a claim of categorical exclusion under 21 CFR 25.30 or § 25.32 (21 CFR 25.32) or an environmental assessment under 21 CFR 25.40 is required to be submitted in a food additive petition. A claim of categorical exclusion under § 25.32(k) was submitted with the petition, which applies to substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food. The Agency reviewed the claim of categorical exclusion submitted by the petitioner and stated in the original filing notice its determination that, under § 25.32(k), the proposed action was of a type that does not individually or cumulatively have a significant effect on the human environment, and therefore, neither an environmental assessment nor an environmental impact statement is required.

However, upon further review of the petition, the Agency has decided that the food additive may act to replace macronutrients in food and, therefore, the categorical exclusion in § 25.32(k) is not applicable for the proposed action. The Agency informed the petitioner of this decision, who subsequently submitted an environmental assessment.

The potential environmental impact of this petition is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **DATES** and **ADDRESSES**) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the Agency finds that an environmental impact statement is not required, and this petition results in a regulation, the notice of availability of the Agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: August 28, 2012.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2012–21639 Filed 8–31–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 172

[FHWA Docket No. FHWA–2012–0043]

RIN 2125–AF44

Procurement, Management, and Administration of Engineering and Design Related Services

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA proposes to update the regulations governing the procurement, management, and administration of engineering and design related services directly related to a highway construction project and reimbursed with Federal-aid highway program (FAHP) funding. The intent is to make the regulations consistent with prior changes in legislation and other applicable regulations. These revisions also address certain findings and recommendations for the oversight of consultant services contained in national review and audit reports.

DATES: Comments must be received on or before November 5, 2012. Late comments will be considered to the extent practicable.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, or submit electronically at *http://www.regulations.gov* or fax comments to (202) 493–2251. All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Page 19477–78), or you may visit *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Jon Obenberger, Preconstruction Team Leader, FHWA Office of Program Administration, (202) 366–2221, or via email at *jon.obenberger@dot.gov*, or Mr. Steven Rochlis, Attorney Advisor, FHWA Office of the Chief Counsel, (202) 366–1395, or via email at *steve.rochlis@dot.gov.* Office hours for the FHWA are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at: *http://www.regulations.gov.* The Web site is available 24 hours each day, 366 days this year. Please follow the instructions. Electronic submission and retrieval help and guidelines are available under the help section of the Web site.

An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: *http://www.archives.gov/federal-register/*, or the Government Printing Office's Web page at: *http://www.gpo.gov/fdsys.*

Background

The FHWA proposes to modify existing regulations for the administration of engineering and design related service contracts to ensure consistency and compliance with prior changes in authorizing

legislation codified in 23 U.S.C. 112(b)(2) and changes in other applicable Federal regulations. Proposed revisions will also address certain findings contained in a 2008 U.S. Government Accountability Office (GAO) review report (*http://www.gao.gov/products/GAO-08-198*) regarding increased reliance on consulting firms by State transportation agencies (STAs) and a 2009 DOT Office of Inspector General (OIG) audit report (*http://www.oig.dot.gov/library-item/4710*) regarding oversight of engineering consulting firms' indirect costs claimed on Federal-aid grants. This rulemaking does not otherwise impose any new burdens on States, local public agencies, or other grantees and subgrantees.

The primary authority for the procurement, management, and administration of engineering and design related services directly related to a highway construction project and reimbursed with FAHP funding is codified in 23 U.S.C. 112(b)(2). On November 30, 2005, the Transportation, Treasury, Housing and Urban Development, the Judiciary, the District of Columbia, and Independent Agencies Appropriations Act, 2006 (Pub. L. 109–115, 119 Stat. 2396, HR 3058), commonly referred to as the ''2006 Appropriations Act,'' was signed into law. Section 174 of this Act amended 23 U.S.C. 112(b)(2) by removing the provisions that permitted States to use ''alternative'' or ''equivalent'' State qualifications-based selection procedures and other procedures for acceptance and application of consultant indirect cost rates that were enacted into State law prior to June 9, 1998.

Effective on the date of enactment of the ''2006 Appropriations Act,'' States and local public agencies could no longer use alternative or equivalent procedures. States and local public agencies are required to procure engineering and design related services in accordance with the qualifications-based selection procedures prescribed in the Brooks Act (40 U.S.C. 1101 et seq.) and to accept and apply consultant indirect cost rates established by a cognizant Federal or State agency in accordance with the Federal Acquisition Regulation (FAR) cost principles (48 CFR part 31). To comply with the amendments to 23 U.S.C. 112(b)(2), this proposed rulemaking will remove all references to alternative or equivalent procedures.

In addition, the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council published a final rule in the **Federal Register** of August 30, 2010 (75 FR 53129), and effective on October 1, 2010, raising the Federal simplified acquisition threshold established in 48 CFR 2.101 of the FAR from $100,000 to $150,000 to account for inflation using the Consumer Price Index as required in statute. The FHWA proposes to revise the small purchase procedures section to reflect this increase in the Federal threshold.

The proposed revisions will also address certain findings and recommendations contained in the aforementioned GAO review and OIG audit reports, clarify existing requirements to enhance consistency and compliance with Federal laws and regulations, and address evolutions in industry practices regarding the procurement, management, and administration of consultant services.

Specific proposed revisions are described in the section-by-section analysis below.

Section-by-Section Discussion of the Proposals

The FHWA proposes to revise 23 CFR part 172—Administration of Engineering and Design Related Service Contracts as follows:

Title—Administration of Engineering and Design Related Services Contracts

The title of this part would be changed to Procurement, Management, and Administration of Engineering and Design Related Services to reflect the range of requirements and Federal interests associated with the procurement, management, and administration of engineering and design related services addressed within this part.

Section 172.1—Purpose and Applicability

Section 172.1 would be amended to clarify the applicability of the requirements of this part for the procurement, management, and administration of engineering and design related services and the requirements of the common grant rule (49 CFR part 18) for procurement of these and other consultant services reimbursed with FAHP funding.

Section 172.3—Definitions

Section 172.3 would be amended to clarify the definitions of ''audit'' and ''cognizant agency'' to provide consistency with the FAR cost principles (48 CFR part 31) and with industry guidance established in the American Association of State Highway and Transportation Officials (AASHTO) Uniform Audit and Accounting Guide, 2010 Edition (*http://audit.transportation.org/Documents/2010_Uniform_Audit_and_Accounting_Guide.pdf*). The definition of ''competitive negotiation'' would be amended to remove references to State alternative or equivalent procedures prohibited by sec. 174 of the ''2006 Appropriations Act.'' The definitions of ''contracting agencies'' and ''one-year applicable accounting period'' would be amended to provide consistency with other terminology of this part. The definition of ''engineering and design related services'' would be amended to also include professional services of an architectural or engineering nature as defined by State law, consistent with the Brooks Act and common grant rule requirements. Definitions would be added for the terms ''contract,'' ''contract modification,'' ''Federal cost principles,'' ''fixed fee,'' ''scope of work,'' and ''State transportation agency (STA)'' to clarify the meaning of each within the context of the regulation. A definition would also be added for ''management role'' to clarify the types of services and roles performed by consultants that require FHWA or direct grantee approval.

Section 172.5—Methods of Procurement

This section would be redesignated as sec. 172.7 and revised. The title would be changed to Procurement Methods and Procedures, to reflect the proposed content which would address not only methods of procurement, but also the procurement requirements associated with these methods.

The title of paragraph (a) would be changed from procurement to procurement methods, and would be revised to specify the three currently allowable procurement methods: Competitive negotiation (qualifications-based selection), small purchases, and noncompetitive. The provisions of subparagraph (a)(1) would be amended to remove references to State alternative or equivalent procedures prohibited by sec. 174 of the ''2006 Appropriations Act.'' Additional provisions would be added to clarify the requirements and expectations for solicitation; request for proposal; evaluation factors; evaluation, ranking, and selection; and negotiation to ensure consistency and compliance with the provisions of the Brooks Act as required by 23 U.S.C. 112(b)(2)(A).

Subparagraph (a)(2) would be amended to clarify the requirements for use of small purchase procedures and reflect the increase in the Federal simplified acquisition threshold from $100,000 to $150,000 (as specified in the final rule published in the **Federal Register** of August 30, 2010 (75 FR 53129)). Additional revisions would

define the negotiation requirements for small purchase procedures and clarify the limitations on participation of FAHP funding in contract costs exceeding the established small purchase threshold.

The provisions of subparagraph (a)(3) would be amended to define contract negotiation requirements for noncompetitive procurement procedures and to remove references to State alternative or equivalent procedures prohibited by sec. 174 of the ''2006 Appropriations Act.''

Subparagraph (a)(4) would be removed, as State alternative or equivalent procedures are now prohibited.

Paragraph (b) would be redesignated as sec. 172.7(b)(2) and revised to clarify the methods contracting agencies may use to achieve Disadvantaged Business Enterprise (DBE) participation on engineering and design related services contracts in accordance with the requirements of 49 CFR part 26 and the agency's DBE program approved by FHWA.

Paragraph (b) of the redesignated sec. 172.7 would be amended to reference and clarify the applicability of various title 23 and 49 procurement related requirements, including the common grant rule procurement provisions, verification of suspension and debarment actions, and prevention of conflicts of interest. A requirement to develop a written code of conduct governing the performance of contracting agency employees and consultants is proposed to be included within contracting agency written policies, procedures, and contract documents to ensure consistency with the conflict of interest requirements specified in 23 CFR 1.33 and the common grant rule.

Information in paragraph (c) of the existing sec. 172.5 would be transferred to paragraph (b) of a new sec. 172.9 titled Contracts and Administration. The proposed sec. 172.9(b) would clarify the permitted and prohibited methods of payment and requirements associated with the use of lump sum and cost reimbursement contract payment methods, consistent with FAR requirements and industry guidance established in the AASHTO Guide for Consultant Contracting, 2008 Edition.

Section 172.7—Audits

This section would be redesignated as sec. 172.11 and revised. The title of this section would be changed to Allowable Costs and Oversight, and would address requirements for the allowability of contract cost and for providing assurance of compliance with the Federal cost principles.

Paragraph (a) of the proposed sec. 172.11 would clarify consultant requirements for accounting for costs, maintaining adequate records, and applying the FAR cost principles to determine the allowability of costs.

Paragraph (b) of the proposed sec. 172.11 would clarify the requirements for the allowability, acceptance, and application of elements of contract cost in accordance with the common grant rule, FAR cost principles, and requirements of 23 U.S.C. 112(b)(2). Subparagraph (b)(1) of the proposed sec. 172.11 would clarify requirements regarding cognizance, acceptance, and application of consultant indirect cost rates consistent with applicable Federal requirements and industry guidance established in the AASHTO Uniform Audit and Accounting Guide, 2010 Edition. Indirect cost rate requirements are proposed to include subconsultant rates since the Federal cost principles also apply to subconsultant costs, the qualifications of subconsultants are considered under a qualifications-based selection, and subconsultants may perform a significant portion of the contracted services. Subparagraph (b)(1)(iii) would clarify the requirement for STAs or other direct grantees to perform an evaluation of a consultant's or subconsultant's indirect cost rate prior to acceptance and application of the rate to a contract when the rate has not been established by a cognizant agency. This subparagraph would permit STAs and other direct grantees to follow a risk-based oversight process for the evaluation performed to provide assurance of indirect cost rate compliance with the FAR cost principles, as described in proposed subparagraph (c)(2).

Information from paragraphs (b) and (c) of the existing sec. 172.7 would be transferred to subparagraph (b)(1) of the proposed sec. 172.11 and revised to remove references to other State procedures prohibited by sec. 174 of the ''2006 Appropriations Act.'' Subparagraph (b)(2) of the proposed sec. 172.11 would clarify requirements for establishment of consultant direct salary or wage rates on contracts to ensure compliance with qualifications-based selection procurement requirements and the reasonableness provisions of the FAR cost principles. Subparagraph (b)(3) of the proposed sec. 172.11 would clarify requirements for the determination of fixed fees or profit in accordance with qualifications-based selection procurement requirements and industry practices. Subparagraph (b)(4) of the proposed sec. 172.11 would clarify the requirements for determining the allowability of other direct contract costs in accordance with the Federal cost principles.

Paragraph (c) of the proposed sec. 172.11 would clarify the responsibilities for contracting agencies to provide assurance of consultant cost compliance with the FAR cost principles. Subparagraph (c)(2) would permit STAs and other direct grantees written procedures to incorporate a risk-based oversight process for providing assurance of consultant cost compliance with the Federal cost principles on contracts administered by the grantee or its subgrantees. This oversight process would consist of risk assessment, mitigation, and evaluation procedures in support of the STA or other direct grantee effectively allocating resources to provide reasonable assurance of consultant compliance with the FAR cost principles.

Information in paragraph (a) of the existing sec. 172.7, performance of audits, would be transferred to subparagraph (c)(2) of sec. 172.11 and revised to remove references to other State procedures prohibited by sec. 174 of the ''2006 Appropriations Act.'' Audits performed in accordance with generally accepted government audit standards to test compliance with the FAR cost principles would be listed as an evaluation procedure under an established risk-based oversight process.

Subparagraph (c)(3) of the proposed sec. 172.11 would require consultants to certify to the contracting agency that costs included within proposals to establish indirect cost rates are allowable in accordance with the FAR cost principles prior to contracting agency acceptance of the indirect cost rates for application to contracts. Implementation of this cost certification requirement was a recommendation in the aforementioned 2009 OIG Audit Report, and is based on FHWA Order 4470.1A, FHWA Policy for Contractor Certification of Costs in Accordance with FAR to Establish Indirect Cost Rates on Engineering and Design related Services Contracts (*http://www.fhwa.dot.gov/legsregs/directives/orders/44701a.htm*).

Subparagraph (c)(4) of the proposed sec. 172.11 would require contracting agencies to pursue administrative, contractual, or legal remedies as may be appropriate when consultants knowingly charge unallowable costs to a FAHP funded contract.

Paragraph (d) of the existing sec. 172.7 would be redesignated as sec. 172.11(d) and revised to ensure consistency of terminology within the regulation.

Section 172.9—Approvals

Information in this section would be transferred to a new sec. 172.5, Program Management and Oversight, a redesignated sec. 172.7, Procurement Methods and Procedures, and a new sec. 172.9, Contracts and Administration, and revised for clarification to ensure consistency with applicable Federal laws and regulations.

Paragraph (a) of the existing sec. 172.9 would be redesignated as sec. 172.5(c) and revised to clarify the requirements for contracting agency written procedures to ensure compliance with existing Federal statutes and regulations. A new paragraph (a) of sec. 172.5 would clarify STA or other direct grantee responsibilities for management of consultant services programs and oversight of subgrantees. A new paragraph (b) of sec. 172.5 would clarify program level responsibilities of subgrantees. A new paragraph (d) of sec. 172.5 would clarify a contracting agency's ability to adopt direct Federal Government or other contracting procedures and requirements which are not in conflict with laws and regulations applicable to the FAHP. Paragraph (e) of sec. 172.5 proposes a 12-month period from the effective date of a final rule for contracting agencies to issue or update current written procedures for review and approval by the appropriate oversight agency.

Information in subparagraph (a)(5) of the existing sec. 172.9 would be expanded under a new paragraph (d) of a proposed sec. 172.9 titled Contracts and Administration. This new paragraph (d) would clarify requirements for consultant monitoring and oversight which include providing a qualified, full-time, public employee of the contracting agency in responsible charge of each contract to ensure compliance with the requirements of 23 U.S.C. 302(a) and evaluating a consultant's performance on a contract.

Paragraph (a) of the proposed sec. 172.9, Contracts and Administration, would define the various contract types and clarify the requirements associated with the use of on-call or indefinite delivery/indefinite quantity contracts in a manner that is consistent with Federal laws and regulations.

Paragraph (c) of the proposed sec. 172.9 would clarify the provisions required to be incorporated into engineering and design related services contracts when FAHP funding is used to ensure consistency and compliance with applicable Federal laws and regulations.

Paragraph (e) of the proposed sec. 172.9 would clarify the requirements associated with contract modifications to ensure modifications are warranted, properly scoped, and in compliance with applicable Federal procurement requirements.

Paragraph (b) of the existing sec. 172.9 would be redesignated as paragraph (f) of the proposed sec. 172.9. Paragraph (c) of the existing sec. 172.9 would be removed since the oversight and approval responsibility of contracts for major projects, as specified in 23 U.S.C. 106(h), should be defined within the stewardship and oversight agreements that are established between individual STAs and respective FHWA division offices.

Paragraph (d) of the existing sec. 172.9 would be redesignated as sec. 172.7(b)(5) and revised to clarify contracting agency responsibilities associated with participation of FAHP funding for consultants performing services in a management role. These revisions would ensure compliance with applicable Federal requirements regarding oversight, procurement, conflicts of interest, and cost allowability.

For ease of reference, the following distribution table is provided:

Old section	New section
172.1	172.1 Revised.
172.3	172.3 Revised.
Audit	Revised.
Cognizant agency	Revised.
Competitive negotiation.	Revised.
Contract	Added.
Contracting agencies	Revised.
Contract modification	Added.
Engineering and design related services.	Revised.
Federal cost principles.	Added.
Fixed fee	Added.
Management role	Added.
One-year applicable accounting period.	Revised.
Scope of work	Added.
State transportation agency.	Added.
172.5(a)	172.7(a) Revised.
172.5(a)(1)	172.7(a)(1) Revised.
172.5(a)(2)	172.7(a)(2) Revised.
172.5(a)(3)	172.7(a)(3) Revised.
172.5(a)(4)	Removed.
None	172.7(b) Added.
172.5(b)	172.7(b)(2) Revised.
None	172.9(a) Added.
172.5(c)	172.9(b)
None	172.9(c), (d), and (e) Added.
None	172.11(a), (b), and (c) Added.
172.7(a)	172.11(c)(2) Revised.
172.7(b)	172.11(b)(1) Revised.
172.7(c)	172.11(b)(1) Revised.
172.7(d)	172.11(d) Revised.
None	172.5(a) and (b) Added.
172.9(a)	172.5(c) Revised.
172.9(a)(5)	172.5(c)(11), (12), and 172.9(d) Revised.
None	172.5(d) and (e) Added.
172.9(b)	172.9(f) Revised.
172.9(c)	Removed.
172.9(d)	172.7(b)(5) Revised.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

The FHWA has determined that this action does not constitute a significant regulatory action within the meaning of Executive Order 12866 or within the meaning of DOT regulatory policies and procedures. The proposed amendments clarify and revise requirements for the procurement, management, and administration of engineering and design related services using FAHP funding and directly related to a construction project. Additionally, this action complies with the principles of Executive Order 13563. The proposed changes to part 172 will provide additional clarification, guidance, and flexibility to stakeholders implementing these regulations. After evaluating the costs and benefits of these proposed amendments, the FHWA anticipates that the economic impact of this rulemaking would be minimal. These changes are not anticipated to adversely affect, in any material way, any sector of the economy. In addition, these changes will not create a serious inconsistency with any other agency's action or materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. It is anticipated that the economic impact of this rulemaking will be minimal; therefore, a full regulatory evaluation is not necessary.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 60l-612), the FHWA has evaluated the effects of this proposed rule on small entities, such as local governments and businesses. Based on the evaluation, the FHWA anticipates that this action would not have a significant economic impact on a substantial number of small entities. The proposed amendments clarify and revise requirements for the procurement, management, and administration of engineering and design related services using FAHP

funding and directly related to a construction project. After evaluating the cost of these proposed amendments, as required by changes in authorizing legislation, other applicable regulations, and industry practices, the FHWA believes the projected impact upon small entities which utilize FAHP funding for consultant engineering and design related services would be negligible. Therefore, I certify that the proposed action would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This NPRM would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). The actions proposed in this NPRM would not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $143.1 million or more in any one year (2 U.S.C. 1532). Further, in compliance with the Unfunded Mandates Reform Act of 1995, FHWA will evaluate any regulatory action that might be proposed in subsequent stages of the proceeding to assess the effects on State, local, and Tribal governments and the private sector. Additionally, the definition of ''Federal Mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The FAHP permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

This proposed action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999, and it has been determined that this proposed action does not have a substantial direct effect or sufficient federalism implications on States that would limit the policymaking discretion of the States. Nothing in this proposed rule directly preempts any State law or regulation or affects the States' ability to discharge traditional State governmental functions.

Paperwork Reduction Act

Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. This proposed action does not contain a collection of information requirement for the purpose of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.).

National Environmental Policy Act

The FHWA has analyzed this proposed action for the purpose of the National Environmental Policy Act (42 U.S.C. 4321 et seq.) and has determined that this action would not have any effect on the quality of the human and natural environment because this rule would merely establish the requirements for the procurement, management, and administration of engineering and design related services using FAHP funding and directly related to a construction project.

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this proposed action under Executive Order 13175, dated November 6, 2000, and believes that this proposed action would not have substantial direct effects on one or more Indian Tribes, would not impose substantial direct compliance costs on Indian Tribal governments, and would not preempt Tribal law. This proposed rulemaking merely establishes the requirements for the procurement, management, and administration of engineering and design related services using FAHP funding and directly related to a construction project. As such, this proposed rule would not impose any direct compliance requirements on Indian Tribal governments nor would it have any economic or other impacts on the viability of Indian Tribes. Therefore, a Tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

The FHWA has analyzed this proposed action under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We have determined that this proposed action would not be a significant energy action under that order because any action contemplated would not be likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, the FHWA certifies that a Statement of Energy Effects under Executive Order 13211 is not required.

Executive Order 12630 (Taking of Private Property)

The FHWA has analyzed this proposed rule and has determined that this proposed action would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Executive Order 12988 (Civil Justice Reform)

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

Executive Order 13045 (Protection of Children)

The FHWA has analyzed this proposed action under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, and certifies that this proposed action would not cause an environmental risk to health or safety that may disproportionately affect children.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 172

Government procurement, Grant programs-transportation, Highways and roads.

Issued on: August 24, 2012.

Victor M. Mendez,

Administrator.

In consideration of the foregoing, the FHWA proposes to amend part 172 of title 23, Code of Federal Regulations, as follows:

TITLE 23—HIGHWAYS

1. Revise Part 172 to read as follows:

PART 172–PROCUREMENT, MANAGEMENT, AND ADMINISTRATION OF ENGINEERING AND DESIGN RELATED SERVICES

Sec.
172.1 Purpose and applicability.
172.3 Definitions.
172.5 Program management and oversight.
172.7 Procurement methods and procedures.
172.9 Contracts and administration.
172.11 Allowable costs and oversight.

Authority: 23 U.S.C. 106, 112, 114(a), 302, 315, and 402; 40 U.S.C. 1101 *et seq.;* 48 CFR part 31; 49 CFR 1.48(b) and part 18.

§ 172.1 Purpose and applicability.

This part prescribes the requirements for the procurement, management, and administration of engineering and design related services under 23 U.S.C. 112 and as supplemented by the common grant rule (as specified in 49 CFR part 18). The requirements of the common grant rule shall apply except where inconsistent with the requirements of this part and other laws and regulations applicable to the Federal-aid highway program (FAHP). The requirements herein apply to federally funded contracts for engineering and design related services for highway construction projects subject to the provisions of 23 U.S.C. 112(a) and are issued to ensure that a qualified consultant is obtained through an equitable qualifications-based selection procurement process, that prescribed work is properly accomplished in a timely manner, and at fair and reasonable cost.

State transportation agencies (STAs) (or other direct grantees) shall ensure that subgrantees comply with the requirements of this part and the common grant rule.

Federally funded contracts for services not defined as engineering and design related, or for services not in furtherance of a highway construction project or activity subject to the provisions of 23 U.S.C. 112(a), are not subject to the requirements of this part and shall be procured and administered under the requirements of the common grant rule and procedures applicable to such activities.

§ 172.3 Definitions.

As used in this part:

Audit means a formal examination, in accordance with professional standards, of a consultant's accounting systems, incurred cost records, and other cost presentations to test the reasonableness, allowability, and allocability of costs in accordance with the Federal cost principles (as specified in 48 CFR part 31).

Cognizant agency means any agency described below that has performed an audit in accordance with generally accepted government auditing standards to test compliance with the requirements of the Federal cost principles (as specified in 48 CFR part 31) and issued an audit report of the consultant's indirect cost rate, or any described agency that has conducted a review of an audit report and related workpapers prepared by a certified public accountant and issued a letter of concurrence with the audited indirect cost rate(s). A cognizant agency may be any of the following:

(1) Federal agency;

(2) State transportation agency of the State where the consultant's accounting and financial records are located; or

(3) State transportation agency to whom cognizance for the particular indirect cost rate(s) of a consulting firm has been delegated or transferred in writing by the State transportation agency identified in subparagraph (2) of this definition.

Competitive negotiation means qualifications-based selection procurement procedures complying with 40 U.S.C. 1101–1104, commonly referred to as the Brooks Act.

Consultant means the individual or firm providing engineering and design related services as a party to a contract.

Contract means a procurement contract or agreement between a contracting agency and consultant under a FAHP grant or subgrant and includes any procurement subcontract under a contract.

Contracting agencies means State transportation agency or a procuring agency of the State acting in conjunction with and at the direction of the State transportation agency, other direct grantees, and all subgrantees that are responsible for the procurement, management, and administration of engineering and design related services.

Contract modification means an agreement modifying the terms or conditions of an original or existing contract.

Engineering and design related services means:

(1) Program management, construction management, feasibility studies, preliminary engineering, design engineering, surveying, mapping, or architectural related services with respect to a highway construction project subject to 23 U.S.C. 112(a) (as defined in 23 U.S.C. 112(b)(2)(A)); and

(2) Professional services of an architectural or engineering nature, as defined by State law, which are required to or may logically or justifiably be performed or approved by a person licensed, registered, or certified to provide the services (as defined in 40 U.S.C. 1102(2)).

Federal cost principles means the cost principles contained in 48 CFR part 31 of the Federal Acquisition Regulations for determination of allowable costs of commercial, for-profit entities (as specified in 49 CFR 18.22(b)).

Fixed fee means a dollar amount established to cover the consultant's profit and business expenses not allocable to overhead.

Management role means acting on the contracting agency's behalf, subject to review and oversight by agency officials, to perform management services such as a program or project administration role typically performed by the contracting agency and necessary to fulfill the duties imposed by title 23 U.S.C., other Federal and State laws, and applicable regulations.

One-year applicable accounting period means the annual accounting period for which financial statements are regularly prepared by the consultant.

Scope of work means all services, work activities, and actions required of the consultant by the obligations of the contract.

State transportation agency (STA) means that department or agency maintained in conformity with 23 U.S.C. 302 and charged under State law with the responsibility for highway construction (as defined in 23 U.S.C. 101); and that is authorized by the laws of the State to make final decisions in all matters relating to, and to enter into, all contracts and agreements for projects and activities to fulfill the duties imposed by title 23 United States Code, title 23 Code of Federal Regulations, and other applicable Federal laws and regulations.

§ 172.5 Program management and oversight.

(a) *STA responsibilities.* STAs (or other direct grantees) shall develop and sustain organizational capacity and provide the resources necessary for the procurement, management, and administration of engineering and design related consultant services, reimbursed in whole or in part with FAHP funding (as specified in 23 U.S.C. 302(a)). Responsibilities shall include the following:

(1) Preparing and maintaining written policies and procedures for the procurement, management, and administration of engineering and design related consultant services in accordance with paragraph (c) of this section;

(2) Establishing a procedure for estimating staffing, resources, and costs of needed consultant services and associated agency oversight in support of project authorization requests submitted to FHWA for approval (as specified in 23 CFR 630.106);

(3) Procuring, managing, and administering engineering and design related consultant services in accordance with applicable Federal and State laws, regulations, and approved policies and procedures (as specified in 23 CFR 1.9(a)); and

(4) Administering subgrants in accordance with State laws and procedures (as specified in 49 CFR 18.37) and the requirements of 23 U.S.C.

106(g)(4)). This shall include providing oversight of the procurement, management, and administration of engineering and design related consultant services by subgrantees to assure compliance with applicable Federal and State laws and regulations. Nothing in this part shall be taken as relieving the STA of its responsibility under laws and regulations applicable to the FAHP for the work performed under any consultant agreement or contract entered into by a subgrantee.

(b) *Subgrantee responsibilities.* Subgrantees shall develop and sustain organizational capacity and provide the resources necessary for the procurement, management, and administration of engineering and design related consultant services, reimbursed in whole or in part with FAHP funding (as specified in 23 U.S.C. 106(g)(4)(A)). Responsibilities shall include the following:

(1) Adopting written policies and procedures prescribed by the awarding STA (or other direct grantee) for the procurement, management, and administration of engineering and design related consultant services in accordance with applicable Federal and State laws and regulations; or when not prescribed, shall include:

(i) Preparing and maintaining its own written policies and procedures in accordance with paragraph (c) of this section; or

(ii) Submitting documentation associated with each procurement and subsequent contract to the awarding STA (or other direct grantee) for review to assess compliance with applicable Federal and State laws, regulations, and the requirements of this part;

(2) Procuring, managing, and administering engineering and design related consultant services in accordance with applicable Federal and State laws, regulations, and approved policies and procedures (as specified in 23 CFR 1.9(a)).

(c) *Written policies and procedures.* The contracting agency shall prepare and maintain written policies and procedures for the procurement, management, and administration of engineering and design related consultant services. The STA (or other direct grantee) written policies and procedures and all revisions shall be approved by the FHWA. Written policies and procedures prepared by subgrantees shall be approved by the awarding STA (or other direct grantee). Any deviations from approved policies and procedures shall require review by FHWA, or the direct grantee as appropriate, to assess compliance with applicable requirements. These policies and procedures shall, as appropriate for each method of procurement a contracting agency proposes to use, address the following items to assure compliance with Federal and State laws, regulations, and the requirements of this part:

(1) Preparing a scope of work and evaluation factors for the ranking/selection of a consultant;

(2) Soliciting proposals from prospective consultants;

(3) Preventing, identifying, and mitigating conflicts of interest for employees of both the contracting agency and consultants (as specified in 23 CFR 1.33 and the requirements of this part).

(4) Verifying suspension and debarment actions and eligibility of consultants (as specified in 49 CFR 18.35 and 2 CFR part 180);

(5) Evaluating proposals and the ranking/selection of a consultant;

(6) Preparing an independent agency estimate for use in negotiation with the selected consultant;

(7) Selecting appropriate contract type, payment method(s), and terms and incorporating required contract provisions, assurances, and certifications in accordance with § 172.9;

(8) Negotiating a contract with the selected consultant;

(9) Establishing elements of contract costs, accepting indirect cost rate(s) for application to contracts, and assuring consultant compliance with the Federal cost principles in accordance with § 172.11;

(10) Assuring consultant costs billed are allowable in accordance with the Federal cost principles and consistent with the contract terms as well as the acceptability and progress of the consultant's work;

(11) Monitoring the consultant's work and compliance with the terms, conditions, and specifications of the contract;

(12) Preparing a consultant's performance evaluation when services are completed and using such performance data in future evaluation and ranking of consultant to provide similar services;

(13) Closing-out a contract;

(14) Retaining adequate programmatic and contract records (as specified in 49 CFR 18.42 and the requirements of this part);

(15) Determining the extent to which the consultant, which is responsible for the professional quality, technical accuracy, and coordination of services, may be reasonably liable for costs resulting from errors and omissions in the work furnished under its contract;

(16) Assessing administrative, contractual, or legal remedies in instances where consultants violate or breach contract terms and conditions, and providing for such sanctions and penalties as may be appropriate; and

(17) Resolving disputes in the procurement, management, and administration of engineering and design related consultant services.

(d) A contracting agency may formally adopt, by statute or within approved written policies and procedures as specified in paragraph (c) of this section, any direct Federal Government or other contracting regulation, standard, or procedure provided its application does not conflict with the provisions of 23 U.S.C. 112, the requirements of this part, and other laws and regulations applicable to the FAHP.

(e) Notwithstanding the foregoing, a contracting agency shall have a reasonable period of time, not to exceed 12 months from the effective date of this rule unless an extension is granted for unique or extenuating circumstances, to issue or update current written policies and procedures for review and approval in accordance with paragraph (c) of this section and consistent with the requirements of this part.

§ 172.7 Procurement methods and procedures.

(a) *Procurement methods.* The procurement of engineering and design related services funded by FAHP funds and directly related to a highway construction project subject to the provisions of 23 U.S.C. 112(a) shall be conducted in accordance with one of three methods: Competitive negotiation (qualifications-based selection) procurement, small purchase procurement for small dollar value contracts, and noncompetitive procurement where specific conditions exist allowing solicitation and negotiation to take place with a single consultant.

(1) *Competitive negotiation (qualifications-based selection).* Except as provided in (2) and (3) below, contracting agencies shall use the competitive negotiation method for the procurement of engineering and design related services when FAHP funds are involved in the contract (as specified in 23 U.S.C. 112(b)(2)(A)). The solicitation, evaluation, ranking, selection, and negotiation shall comply with the qualifications-based selection procurement procedures for architectural and engineering services codified under 40 U.S.C. 1101–1104, commonly referred to as the Brooks Act. In accordance with the requirements of the Brooks Act, the following

procedures shall apply to the competitive negotiation procurement method:

(i) *Solicitation.* The solicitation process shall be by public announcement, public advertisement, or any other public forum or method that assures qualified in-State and out-of-State consultants are given a fair opportunity to be considered for award of the contract. Procurement procedures may involve a single step process with issuance of a request for proposal (RFP) to all interested consultants or a multiphase process with issuance of a request for statements or letters of interest or qualifications (RFQ) whereby responding consultants are ranked based on qualifications and request for proposals are then provided to three or more of the most highly qualified consultants. Minimum qualifications of consultants to perform services under general work categories or areas of expertise may also be assessed through a prequalification process whereby statements of qualifications are submitted on an annual basis. Regardless of any process utilized for prequalification of consultants or for an initial assessment of a consultant's qualifications under an RFQ, a RFP specific to the project, task, or service is required for evaluation of a consultant's specific technical approach and qualifications.

(ii) *Request for proposal (RFP).* The RFP shall provide all information and requirements necessary for interested consultants to provide a response to the RFP and compete for the solicited services. The RFP shall:

(A) Provide a clear, accurate, and detailed description of the scope of work, technical requirements, and qualifications of consultants necessary for the services to be rendered. The scope of work should detail the purpose and description of the project, services to be performed, deliverables to be provided, estimated schedule for performance of the work, and applicable standards, specifications, and policies;

(B) Identify the requirements for any discussions that may be conducted with three (3) or more of the most highly qualified consultants following submission and evaluation of proposals;

(C) Identify evaluation factors including their relative weight of importance in accordance with subparagraph (a)(1)(iii) of this section;

(D) Specify the contract type and method(s) of payment to be utilized in accordance with § 172.9;

(E) Identify any special provisions or contract requirements associated with the solicited services;

(F) Require that submission of any requested cost proposals or elements of cost be in a concealed format and separate from technical/qualifications proposals as these shall not be considered in the evaluation, ranking, and selection phase; and

(G) Provide a schedule of key dates for the procurement process and establish a submittal deadline for responses to the RFP which provides sufficient time for interested consultants to receive notice, prepare, and submit a proposal, which except in unusual circumstances shall be not less than 14 days from the date of issuance of the RFP.

(iii) *Evaluation factors.* (A) Criteria used for evaluation, ranking, and selection of consultants to perform engineering and design related services must assess the demonstrated competence and qualifications for the type of professional services solicited. These qualifications-based factors may include, but are not limited to, technical approach (e.g., project understanding, innovative concepts or alternatives, quality control procedures), work experience, specialized expertise, professional licensure, staff capabilities, workload capacity, and past performance.

(B) Price shall not be used as a factor in the evaluation, ranking, and selection phase. All price or cost related items which include, but are not limited to, cost proposals, direct salaries/wage rates, indirect cost rates, and other direct costs are prohibited from being used as evaluation criteria.

(C) In-State or local preference shall not be used as a factor in the evaluation, ranking, and selection phase. State licensing laws are not preempted by this provision and professional licensure within a jurisdiction may be established as a requirement which attests to the minimum qualifications and competence of a consultant to perform the solicited services.

(D) The following nonqualifications-based evaluation criteria are permitted under the specified conditions and provided the combined total of these criteria do not exceed a nominal value of ten percent of the total evaluation criteria to maintain the integrity of a qualifications-based selection:

(1) A local presence may be used as a nominal evaluation factor where appropriate. This criteria shall not be based on political or jurisdictional boundaries and may be applied on a project-by-project basis for contracts where a need has been established for a consultant to provide a local presence, a local presence will add value to the quality and efficiency of the project, and application of this criteria leaves an appropriate number of qualified consultants, given the nature and size of the project. If a consultant outside of the locality area indicates as part of a proposal that it will satisfy the criteria in some manner, such as establishing a local project office, that commitment shall be considered to have satisfied the local presence criteria.

(2) The participation of qualified and certified Disadvantaged Business Enterprise (DBE) subconsultants may be used as a nominal evaluation criteria where appropriate in accordance with 49 CFR part 26 and a contracting agency's FHWA-approved DBE program.

(iv) *Evaluation, ranking, and selection.* (A) Consultant proposals shall be evaluated by the contracting agency based on the criteria established and published within the public solicitation.

(B) While the contract will be with the prime consultant, proposal evaluations shall consider the qualifications of the prime consultant and any subconsultants identified within the proposal with respect to the scope of work and established criteria.

(C) Following submission and evaluation of proposals, the contracting agency shall conduct interviews or other types of discussions determined appropriate for the project with at least three of the most highly qualified consultants to clarify the technical approach, qualifications, and capabilities provided in response to the RFP. Discussion requirements shall be specified within the RFP and should be based on the size and complexity of the project as defined in contracting agency written policies and procedures (as specified in § 172.5(c)). Discussions may be written, by telephone, video conference, or by oral presentation/interview. Discussions following proposal submission are not required provided proposals contain sufficient information for evaluation of technical approach and qualifications to perform the specific project, task, or service with respect to established criteria.

(D) From the proposal evaluation and any subsequent discussions which have been conducted, the contracting agency shall rank, in order of preference, at least three consultants determined most highly qualified to perform the solicited services based on the established and published criteria.

(E) Notification must be provided to responding consultants of the final ranking of the three most highly qualified consultants.

(F) The contracting agency shall retain acceptable documentation of the solicitation, proposal, evaluation, and selection of the consultant in

accordance with the provisions of 49 CFR 18.42.

(v) *Negotiation.* (A) *Independent estimate.* Prior to receipt or review of the most highly qualified consultant's cost proposal, the contracting agency shall prepare a detailed independent estimate with an appropriate breakdown of the work or labor hours, types or classifications of labor required, other direct costs, and consultant's fixed fee for the defined scope of work. The independent estimate shall serve as the basis for negotiation and ensuring the consultant services are obtained at a fair and reasonable cost.

(B) Elements of contract costs (e.g., indirect cost rates, direct salary or wage rates, fixed fee, and other direct costs) shall be established separately in accordance with § 172.11.

(C) If concealed cost proposals were submitted in conjunction with technical/qualifications proposals, only the cost proposal of the consultant with which negotiations are initiated may be considered. Concealed cost proposals of consultants with which negotiations are not initiated should be returned to the respective consultant due to the confidential nature of this data (as specified in 23 U.S.C. 112(b)(2)(E)).

(D) The contracting agency shall retain documentation of negotiation activities and resources used in the analysis of costs to establish elements of the contract in accordance with the provisions of 49 CFR 18.42. This documentation shall include the consultant cost certification and documentation supporting the acceptance of the indirect cost rate to be applied to the contract (as specified in § 172.11(c)).

(2) *Small purchases.* The small purchase method involves procurement of engineering and design related services where an adequate number of qualified sources are reviewed and the total contract costs do not exceed an established simplified acquisition threshold. Contracting agencies may use the State's small purchase procedures which reflect applicable State laws and regulations for the procurement of engineering and design related services provided the total contract costs do not exceed the Federal simplified acquisition threshold (as specified in 48 CFR 2.101). When a lower threshold for use of small purchase procedures is established in State law, regulation, or policy, the lower threshold shall apply to the use of FAHP funds. The following additional requirements shall apply to the small purchase procurement method:

(i) The scope of work, project phases, and contract requirements shall not be broken down into smaller components merely to permit the use of small purchase procedures.

(ii) A minimum of three consultants are required to satisfy the adequate number of qualified sources reviewed.

(iii) Contract costs may be negotiated in accordance with State small purchase procedures; however, the allowability of costs shall be determined in accordance with the Federal cost principles.

(iv) The full amount of any contract modification or amendment that would cause the total contract amount to exceed the established simplified acquisition threshold would be ineligible for Federal-aid funding. The FHWA may withdraw all Federal-aid from a contract if it is modified or amended above the applicable established simplified acquisition threshold.

(3) *Noncompetitive.* The noncompetitive method involves procurement of engineering and design related services when it is not feasible to award the contract using competitive negotiation or small purchase procurement methods. The following requirements shall apply to the noncompetitive procurement method:

(i) Contracting agencies may use their own noncompetitive procedures which reflect applicable State and local laws and regulations and conform to applicable Federal requirements.

(ii) Contracting agencies shall establish a process to determine when noncompetitive procedures will be used and shall submit justification to, and receive approval from, the FHWA before using this form of contracting.

(iii) Circumstances under which a contract may be awarded by noncompetitive procedures are limited to the following:

(A) The service is available only from a single source;

(B) There is an emergency which will not permit the time necessary to conduct competitive negotiations; or

(C) After solicitation of a number of sources, competition is determined to be inadequate.

(iv) Contract costs may be negotiated in accordance with contracting agency noncompetitive procedures; however, the allowability of costs shall be determined in accordance with the Federal cost principles.

(b) *Additional procurement requirements.* (1) *Common grant rule.* (i) STAs (or other direct grantees) and their subgrantees must comply with procurement requirements established in State and local laws, regulations, policies, and procedures which are not addressed by or in conflict with applicable Federal laws and regulations (as specified in 49 CFR 18.36).

(ii) When State and local procurement laws, regulations, policies, or procedures are in conflict with applicable Federal laws and regulations, contracting agencies must comply with Federal requirements to be eligible for Federal-aid reimbursement of the associated costs of the services incurred following FHWA authorization (as specified in 49 CFR 18.4).

(2) *Disadvantaged Business Enterprise (DBE) program.* (i) Contracting agencies shall give consideration to DBE consultants in the procurement of engineering and design related service contracts subject to 23 U.S.C. 112(b)(2) in accordance with 49 CFR part 26. When DBE program participation goals cannot be met through race-neutral measures, additional DBE participation on engineering and design related services contracts may be achieved in accordance with a contracting agency's FHWA approved DBE program through either:

(A) Use of an evaluation criterion in the qualifications-based selection of consultants (as specified in § 172.7(a)(1)(iii)(D)); or

(B) Establishment of a contract participation goal.

(ii) The use of quotas or exclusive set-asides for DBE consultants is prohibited (as specified in 49 CFR 26.43).

(3) *Suspension and debarment.* Contracting agencies must verify suspension and debarment actions and eligibility status of consultants and subconsultants prior to entering into an agreement or contract in accordance with 49 CFR 18.35 and 2 CFR part 180.

(4) *Conflicts of interest.* (i) Contracting agencies shall maintain a written code of standards of conduct governing the performance of their employees engaged in the award and administration of engineering and design related services contracts under this part and governing the conduct and roles of consultants in the performance of services under such contracts to prevent, identify, and mitigate conflicts of interest in accordance with 23 CFR 1.33 and the provisions of this subparagraph.

(ii) No employee, officer, or agent of the contracting agency shall participate in selection, or in the award or administration of a contract supported by Federal-aid funds if a conflict of interest, real or apparent, would be involved. Such a conflict arises when:

(A) The employee, officer, or agent;

(B) Any member of his or her immediate family;

(C) His or her partner; or

(D) An organization which employs or is about to employ, any of the above, has

a financial or other interest in the consultant selected for award.

(iii) The contracting agency's officers, employees, or agents shall neither solicit nor accept gratuities, favors, or anything of monetary value from consultants, potential consultants, or parties to subagreements. Contracting agencies may establish dollar thresholds where the financial interest is not substantial or the gift is an unsolicited item of nominal value.

(iv) Contracting agencies may provide additional prohibitions relative to real, apparent, or potential conflicts of interest.

(v) To the extent permitted by State or local law or regulations, such standards of conduct shall provide for penalties, sanctions, or other disciplinary actions for violations of such standards by the contracting agency's officers, employees, or agents, or by consultants or their agents.

(5) *Consultant services in management roles.* (i) When FAHP funds participate in the contract, the contracting agency shall receive approval from the FHWA, or the direct grantee as appropriate, before utilizing a consultant to act in a management role for the contracting agency, unless an alternate approval procedure has been approved. Use of consultants in management roles does not relieve the contracting agency of responsibilities associated with the use of FAHP funds (as specified in 23 U.S.C. 302(a) and 23 U.S.C. 106(g)(4)) and should be limited to large projects or circumstances where unusual cost or time constraints exist, unique technical or managerial expertise is required, and/or an increase in contracting agency staff is not a viable option.

(ii) Management roles may include, but are not limited to, providing oversight of an element of a highway program, function, or service on behalf of the contracting agency or may involve managing or providing oversight of a project, series of projects, and/or the work of other consultants and contractors on behalf of the contracting agency. Contracting agency written policies and procedures (as specified in § 172.5(c)) may further define allowable management roles and services a consultant may provide, specific approval responsibilities, and associated controls necessary to ensure compliance with Federal requirements.

(iii) Use of consultants in management roles requires appropriate conflicts of interest standards as specified in subparagraph (b)(4) of this section and adequate contracting agency staffing to administer and monitor the management consultant contract (as specified in § 172.9(d)). A consultant serving in a management role shall be precluded from providing services on projects, activities, or contracts under its oversight.

(iv) FAHP funds shall not participate in the costs of a consultant serving in a management role where the consultant was not procured in accordance with Federal and State requirements (as specified in 23 CFR 1.9(a)).

(v) Where benefiting more than a single Federal-aid project, allocability of consultant contract costs for services related to a management role shall be distributed consistent with the cost principles applicable to the contracting agency (as specified in 49 CFR 18.22(b)).

§ 172.9 Contracts and administration.

(a) *Contract types.* The types of contracts which shall be used are: (1) *Project-specific.* A contract between the contracting agency and consultant for the performance of services and defined scope of work related to a specific project or projects.

(2) *Multiphase.* A project-specific contract where the defined scope of work is divided into phases which may be negotiated and authorized individually as the project progresses.

(3) *On-call or indefinite delivery/indefinite quantity (IDIQ).* A contract for the performance of services for a number of projects, under task or work orders issued on an as-needed or on-call basis, for an established contract period. The procurement of services to be performed under on-call or IDIQ contracts must follow either competitive negotiation or small purchase procurement procedures (as specified in § 172.7). The solicitation and contract provisions must address the following requirements:

(i) Specify a reasonable maximum length of contract period, including the number and period of any allowable contract extensions, which shall not exceed 5 years;

(ii) Specify a maximum total contract dollar amount which may be awarded under a contract;

(iii) Include a statement of work, requirements, specifications, or other description to define the general scope, complexity, and professional nature of the services; and

(iv) If multiple consultants are to be selected and multiple on-call or IDIQ contracts awarded through a single solicitation for specific services:

(A) Identify the number of consultants that may be selected or contracts that may be awarded from the solicitation; and

(B) Specify the procedures the contracting agency will use in competing and awarding task or work orders among the selected, qualified consultants. Task or work orders shall not be competed and awarded among the selected, qualified consultants on the basis of costs under on-call or IDIQ contracts for services procured with competitive negotiation procedures. Under competitive negotiation procurement, each specific task or work order shall be awarded to the selected, qualified consultants:

(1) Through an additional qualifications-based selection procedure; or

(2) On a regional basis whereby the State is divided into regions and consultants are selected to provide on-call or IDIQ services for an assigned region(s) identified within the solicitation.

(b) *Payment methods.* (1) The method of payment to the consultant shall be set forth in the original solicitation, contract, and in any contract modification thereto. The methods of payment shall be: Lump sum, cost plus fixed fee, cost per unit of work, or specific rates of compensation. A single contract may contain different payment methods as appropriate for compensation of different elements of work.

(2) The cost plus a percentage of cost and percentage of construction cost methods of payment shall not be used.

(3) The lump sum payment method shall only be used when the contracting agency has established the extent, scope, complexity, character, and duration of the work to be required to a degree that fair and reasonable compensation, including a fixed fee, can be determined at the time of negotiation.

(4) When the method of payment is other than lump sum, the contract shall specify a maximum amount payable which shall not be exceeded unless adjusted by a contract modification.

(5) The specific rates of compensation payment method provides for reimbursement on the basis of direct labor hours at specified fixed hourly rates (including direct labor costs, indirect costs, and fee or profit) plus any other direct expenses or costs, subject to an agreement maximum amount. This payment method shall only be used when it is not possible at the time of procurement to estimate the extent or duration of the work or to estimate costs with any reasonable degree of accuracy and should be limited to contracts or components of contracts for specialized or support type services where the consultant is not in direct control of the number of hours worked, such as construction engineering and inspection. Use of this payment method

requires contracting agency management and monitoring of the consultant's level of effort and classification of employees used to perform the contracted services.

(6) Contracting agencies may withhold retainage from payments in accordance with prompt pay requirements (as specified in 49 CFR 26.29). When retainage is used, the terms and conditions of the contract must clearly define agency requirements, including periodic reduction in retention and the conditions for release of retention.

(c) *Contract provisions.* Contracts must include the following provisions:

(1) Administrative, contractual, or legal remedies in instances where consultants violate or breach contract terms and conditions, and provide for such sanctions and penalties as may be appropriate (all contracts and subcontracts);

(2) Termination for cause and for convenience by the contracting agency including the manner by which it will be effected and the basis for settlement (all contracts and subcontracts in excess of $10,000);

(3) Notice of contracting agency requirements and regulations pertaining to reporting (all contracts and subcontracts);

(4) Contracting agency requirements and regulations pertaining to copyrights and rights in data (all contracts and subcontracts);

(5) Access by grantee, the subgrantee, the FHWA, the U.S. Department of Transportation's Inspector General, the Comptroller General of the United States, or any of their duly authorized representatives to any books, documents, papers, and records of the consultant which are directly pertinent to that specific contract for the purpose of making audit, examination, excerpts, and transcriptions (all contracts and subcontracts);

(6) Retention of all required records for not less than 3 years after the contracting agency makes final payment and all other pending matters are closed (all contracts and subcontracts);

(7) Lobbying certification and disclosure (as specified in 49 CFR part 20) (all contracts and subcontracts exceeding $100,000);

(8) Standard DOT Title VI Assurances (DOT Order 1050.2) (all contracts and subcontracts);

(9) Disadvantaged Business Enterprise (DBE) assurance (as specified in 49 CFR 26.13(b)) (all contracts and subcontracts);

(10) Prompt pay requirements (as specified in 49 CFR 26.29) (all contracts and subcontracts);

(11) Determination of allowable costs in accordance with the Federal cost principles (all contracts and subcontracts);

(12) Contracting agency requirements pertaining to consultant errors and omissions (all contracts and subcontracts); and

(13) Contracting agency requirements pertaining to conflicts of interest (as specified in 23 CFR 1.33 and the requirements of this part) (all contracts and subcontracts).

(d) *Contract administration and monitoring.* (1) *Responsible charge.* A full-time, public employee of the contracting agency qualified to ensure that the work delivered under contract is complete, accurate, and consistent with the terms, conditions, and specifications of the contract shall be in responsible charge of each contract or project. While an independent consultant may be procured to serve in a program or project management role (as specified in § 172.7(b)(5)) or to provide technical assistance in review and acceptance of engineering and design related services performed and products developed by other consultants, a full-time, public employee must be designated by the contracting agency as being in responsible charge. A public employee may serve in responsible charge of multiple projects and contracting agencies may use multiple public employees to fulfill monitoring responsibilities. The public employee's responsibilities shall include:

(i) Administering inherently governmental activities including, but not limited to, contract negotiation, contract payment, and evaluation of compliance, performance, and quality of services provided by consultant;

(ii) Being familiar with the contract requirements, scope of services to be performed, and products to be produced by the consultant;

(iii) Being familiar with the qualifications and responsibilities of the consultant's staff and evaluating any requested changes in key personnel;

(iv) Scheduling and attending progress and project review meetings, commensurate with the magnitude, complexity, and type of work, to ensure the work is progressing in accordance with established scope of work and schedule milestones;

(v) Assuring consultant costs billed are allowable in accordance with the Federal cost principles and consistent with the contract terms as well as the acceptability and progress of the consultant's work;

(vi) Evaluating and participating in decisions for contract modifications; and

(vii) Documenting contract monitoring activities and maintaining adequate contract records (as specified in 49 CFR 18.42).

(2) *Performance evaluation.* The contracting agency shall prepare a final evaluation report of the consultant's performance on a contract. The report should include, but not be limited to, an evaluation of the timely completion of work, adherence to contract scope and budget, and quality of the work. The consultant shall be provided a copy of the report and shall be provided an opportunity to provide written comments to be attached to the report. Additional interim performance evaluations should be considered based on the scope, complexity, and size of the contract as a means to provide feedback, foster communication, and achieve desired changes or improvements. Completed performance evaluations should be archived for consideration as an element of past performance in the future evaluation of the consultant to provide similar services.

(e) *Contract modification.* (1) Contract modifications are required for any amendments to the terms of the existing contract that change the cost of the contract; significantly change the character, scope, complexity, or duration of the work; or significantly change the conditions under which the work is required to be performed.

(2) A contract modification shall clearly define and document the changes made to the contract, establish the method of payment for any adjustments in contract costs, and be in compliance with the terms and conditions of the contract and original procurement.

(3) Contract modifications shall be negotiated following the same procedures as the negotiation of the original contract.

(4) Only the type of services and work included within the scope of services of the original solicitation from which a qualifications-based selection was made may be added to a contract. Services outside of the scope of work established in the original request for proposal must be procured under a new solicitation, performed by contracting agency staff, or performed under a different contract established for the services desired.

(5) Overruns in the costs of the work shall not automatically warrant an increase in the fixed fee portion of a cost plus fixed fee reimbursed contract. Permitted changes to the scope of work or duration may warrant consideration

for adjustment of the fixed fee portion of cost plus fixed fee or lump sum reimbursed contracts.

(f) *Contracts.* Contracts and contract settlements involving engineering and design related services for projects that have not been assumed by the State under 23 U.S.C. 106(c), that do not fall under the small purchase procedures (as specified in § 172.7(a)(2)), shall be subject to the prior approval by FHWA, unless an alternate approval procedure has been approved by FHWA.

§ 172.11 Allowable costs and oversight.

(a) *Allowable costs.* (1) Costs or prices based on estimated costs for contracts shall be eligible for Federal-aid reimbursement only to the extent that costs incurred or cost estimates included in negotiated prices are allowable in accordance with the Federal cost principles.

(2) Consultants shall be responsible for accounting for costs appropriately and for maintaining records, including supporting documentation, adequate to demonstrate that costs claimed have been incurred, are allocable to the contract, and comply with Federal cost principles.

(b) *Elements of contract costs.* The following requirements shall apply to the establishment of the specified elements of contract costs:

(1) *Indirect cost rates.* (i) Indirect cost rates shall be updated on an annual basis in accordance with the consultant's annual accounting period and in compliance with the Federal cost principles.

(ii) Contracting agencies shall accept a consultant's or subconsultant's indirect cost rate(s) established for a 1-year applicable accounting period by a cognizant agency that has:

(A) Performed an audit in accordance with generally accepted government auditing standards to test compliance with the requirements of the Federal cost principles and issued an audit report of the consultant's indirect cost rate(s); or

(B) Conducted a review of an audit report and related workpapers prepared by a certified public accountant and issued a letter of concurrence with the related audited indirect cost rate(s).

(iii) When the indirect cost rate has not been established by a cognizant agency in accordance with subparagraph (1)(ii) herein, a STA (or other direct grantee) shall perform an evaluation of a consultant's or subconsultant's indirect cost rate prior to acceptance and application of the rate to contracts administered by the grantee or its subgrantees. The evaluation performed by STAs (or other direct grantees) to establish or accept an indirect cost rate(s) shall provide assurance of compliance with the Federal cost principles and may consist of the following:

(A) Performing an audit in accordance with generally accepted government auditing standards and issuing an audit report;

(B) Reviewing and accepting an audit report and related workpapers prepared by a certified public accountant or another STA;

(C) Establishing a provisional indirect cost rate for the specific contract and adjusting contract costs based upon an audited final rate; or

(D) Conducting other evaluations in accordance with a risk-based oversight process as specified in subparagraph (c)(2) of this section and within the agency's approved written policies and procedures (as specified in § 172.5(c)).

(iv) A lower indirect cost rate may be accepted for use on a contract if submitted voluntarily by a consultant; however, the consultant's offer of a lower indirect cost rate shall not be a condition or qualification to be considered for the work or contract award.

(v) Once accepted in accordance with subparagraphs (1)(ii)–(iv) herein, contracting agencies shall apply such indirect cost rate(s) for the purposes of contract estimation, negotiation, administration, reporting, and contract payment and the indirect cost rate(s) shall not be limited by administrative or de facto ceilings of any kind.

(vi) A consultant's accepted indirect cost rate for its 1-year applicable accounting period shall be applied to contracts; however, once an indirect cost rate is established for a contract, it may be extended beyond the 1-year applicable period, through the duration of the specific contract, provided all concerned parties agree. Agreement to the extension of the 1-year applicable period shall not be a condition or qualification to be considered for the work or contract award.

(vii) *Disputed rates.* If an indirect cost rate established by a cognizant agency in subparagraph (1)(ii) herein is in dispute, the contracting agency does not have to accept the rate. A contracting agency may perform its own audit or other evaluation of the consultant's indirect cost rate for application to the specific contract, until or unless the dispute is resolved. A contracting agency may alternatively negotiate a provisional indirect cost rate for the specific contract and adjust contract costs based upon an audited final rate. Only the consultant and the parties involved in performing the indirect cost audit may dispute the established indirect cost rate. If an error is discovered in the established indirect cost rate, the rate may be disputed by any prospective contracting agency.

(2) *Direct salary or wage rates.* (i) Compensation for each employee or classification of employee must be reasonable for the work performed in accordance with the Federal cost principles.

(ii) To provide for fair and reasonable compensation, considering the classification, experience, and responsibility of employees necessary to provide the desired engineering and design related services, contracting agencies may establish consultant direct salary or wage rate limitations or ''benchmarks'' based upon an objective assessment of the reasonableness of proposed rates performed in accordance with the reasonableness provisions of the Federal cost principles.

(iii) When an assessment of reasonableness in accordance with the Federal cost principles has not been performed, contracting agencies shall use and apply the consultant's actual direct salary or wage rates for estimation, negotiation, administration, and payment of contracts and contract modifications.

(3) *Fixed fee.* (i) The determination of the amount of fixed fee shall consider the scope, complexity, contract duration, degree of risk borne by the consultant, amount of subcontracting, and professional nature of the services as well as the size and type of contract.

(ii) The establishment of fixed fee shall be project or task order specific.

(iii) Fixed fees in excess of 15 percent of the total direct labor and indirect costs of the contract may be justified only when exceptional circumstances exist.

(4) *Other direct costs.* The Federal cost principles shall be used in determining the reasonableness, allowability, and allocability of other direct contract costs.

(c) *Oversight.* (1) *Agency controls.* Contracting agencies shall provide reasonable assurance that consultant costs on contracts reimbursed in whole or in part with FAHP funding are allowable in accordance with the Federal cost principles and consistent with the contract terms considering the contract type and payment method(s). Contracting agency written policies, procedures, contract documents, and other controls (as specified in § 172.5(c) and § 172.9) shall address the establishment, acceptance, and administration of contract costs to assure compliance with the Federal cost

principles and requirements of this section.

(2) *Risk-based analysis.* The STAs (or other direct grantees) may employ a risk-based oversight process to provide reasonable assurance of consultant compliance with Federal cost principles on FAHP funded contracts administered by the grantee or its subgrantees. If employed, this risk-based oversight process shall be incorporated into STA (or other direct grantee) written policies and procedures (as specified in § 172.5(c)). In addition to ensuring allowability of direct contract costs, the risk-based oversight process shall address the evaluation and acceptance of consultant and subconsultant indirect cost rates for application to contracts. A risk-based oversight process shall consist of the following:

(i) *Risk assessments.* Conducting and documenting an annual assessment of risks of noncompliance with the Federal cost principles per consultant doing business with the agency, considering the following factors:

(A) Consultant's contract volume within the State;

(B) Number of States in which the consultant operates;

(C) Experience of consultant with FAHP contracts;

(D) History and professional reputation of consultant;

(E) Audit history of consultant;

(F) Type and complexity of consultant accounting system;

(G) Size (number of employees and/or annual revenues) of consultant;

(H) Relevant experience of certified public accountant performing audit of consultant;

(I) Assessment of consultant's internal controls;

(J) Changes in consultant organizational structure; and

(K) Other factors as appropriate.

(ii) *Risk mitigation and evaluation procedures.* Allocating resources, as considered necessary based on the results of the annual risk assessment, to provide reasonable assurance of compliance with the Federal cost principles through application of the following types of risk mitigation and evaluation procedures appropriate to the consultant and circumstances:

(A) Audits performed in accordance with generally accepted government audit standards to test compliance with the requirements of the Federal cost principles;

(B) Certified public accountant or other STA workpaper reviews;

(C) Desk reviews;

(D) Other analytical procedures;

(E) Consultant cost certifications in accordance with subparagraph (c)(3) herein; and

(F) Training on the Federal cost principles.

(iii) *Documentation.* Maintaining adequate documentation of the risk-based analysis procedures performed to support the allowability and acceptance of consultant costs on FAHP funded contracts.

(3) *Consultant cost certification.* (i) Indirect cost rate proposals for the consultant's 1-year applicable accounting period shall not be accepted and no agreement shall be made by a contracting agency to establish final indirect cost rates, unless the costs have been certified by an official of the consultant as being allowable in accordance with the Federal cost principles. The certification requirement shall apply to all indirect cost rate proposals submitted by prime and subconsultants for acceptance by a STA (or other direct grantee).

(ii) Consultant official shall be an individual executive or financial officer of the consultant's organization at a level no lower than a Vice President or Chief Financial Officer, or equivalent, who has the authority to represent the financial information utilized to establish the indirect cost rate proposal submitted for acceptance.

(iii) The certification of final indirect costs shall read as follows:

Certificate of Final Indirect Costs

This is to certify that I have reviewed this proposal to establish final indirect cost rates and to the best of my knowledge and belief:

1. All costs included in this proposal (identify proposal and date) to establish final indirect cost rates for (identify period covered by rate) are allowable in accordance with the cost principles of the Federal Acquisition Regulation (FAR) of title 48, Code of Federal Regulations (CFR), part 31; and

2. This proposal does not include any costs which are expressly unallowable under applicable cost principles of the FAR of 48 CFR part 31.

Firm: _____

Signature: _____

Name of Certifying Official: _____

Title: _____

Date of Execution: _____

(4) *Sanctions and penalties.* Contracting agency written policies, procedures, and contract documents (as specified in § 172.5(c) and § 172.9(c)) shall address the range of administrative, contractual, or legal remedies that may be assessed in accordance with Federal and State laws and regulations where consultants violate or breach contract terms and conditions. Where consultants knowingly charge unallowable costs to a FAHP funded contract:

(i) Contracting agencies shall pursue administrative, contractual, or legal remedies and provide for such sanctions and penalties as may be appropriate; and

(ii) Consultants are subject to suspension and debarment actions (as specified in 2 CFR part 180), potential cause of action under the False Claims Act (as specified in 32 U.S.C. 3729–3733), and prosecution for making a false statement (as specified in 18 U.S.C. 1020).

(d) *Prenotification; confidentiality of data.* The FHWA, grantees, and subgrantees of FAHP funds may share audit information in complying with the grantee's or subgrantee's acceptance of a consultant's indirect cost rates pursuant to 23 U.S.C. 112 and this part provided that the consultant is given notice of each use and transfer. Audit information shall not be provided to other consultants or any other government agency not sharing the cost data, or to any firm or government agency for purposes other than complying with the grantee's or subgrantee's acceptance of a consultant's indirect cost rates pursuant to 23 U.S.C. 112 and this part without the written permission of the affected consultants. If prohibited by law, such cost and rate data shall not be disclosed under any circumstance; however, should a release be required by law or court order, such release shall make note of the confidential nature of the data.

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BILLING CODE 4910–22–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1610

RIN 3046–AA90

Availability of Records

AGENCY: Equal Employment Opportunity Commission

ACTION: Notice of proposed rulemaking.

SUMMARY: The Equal Employment Opportunity Commission (''EEOC'' or ''Commission'') proposes to revise its Freedom of Information Act (FOIA) regulations in order to implement the Openness Promotes Effectiveness in our National Government Act of 2007 (OPEN Government Act) and the Electronic FOIA Act of 1996 (E–FOIA Act); to reflect the reassignment of FOIA responsibilities in the Commission's field offices from the Regional Attorneys

to the District Directors; and to consolidate Commission public reading areas in offices where there are adequate FOIA personnel to provide satisfactory service.

DATES: Written comments must be received on or before November 5, 2012.

ADDRESSES: Written comments should be submitted to Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street NE., Suite 6NE03F, Washington, DC 20507. As a convenience to commenters, the Executive Secretariat will accept comments by facsimile (''FAX'') machine. The telephone number of the FAX receiver is (202) 663–4114. (This is not a toll-free FAX number). Only comments of six or fewer pages will be accepted via FAX transmittal to ensure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTY). (These are not toll-free telephone numbers.) You may also submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments. Copies of comments submitted by the public will be available for review at the Commission's library, 131 M Street NE., Suite 4NW08R, Washington, DC 20507, between the hours of 9:30 a.m. and 5:00 p.m. or can be reviewed at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Stephanie D. Garner, Assistant Legal Counsel, Gary J. Hozempa, Senior Attorney, or Draga G. Anthony, Attorney Advisor, Office of Legal Counsel, U.S. Equal Employment Opportunity Commission at (202) 663–4640 (voice) or (202) 663–7026 (TTY). These are not toll-free telephone numbers. This notice is also available in the following formats: large print, Braille, audiotape, and electronic file on computer disk. Requests for this document in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 663–4191 (voice) or (202) 663–4494 (TTY), or to the Publications Information Center at 1–800–669–3362.

SUPPLEMENTARY INFORMATION: The proposed rule updates the Commission's FOIA regulations to reflect current Commission practice in responding to FOIA requests as reflected in the OPEN Government Act and the E–FOIA Act, and the Commission's transfer of FOIA responsibilities from its Regional Attorneys to its District Directors. The proposed rule also consolidates Commission public reading rooms in offices where there are adequate FOIA personnel and streamlines the Commission's FOIA regulations by removing excess verbiage.

The OPEN Government Act

The OPEN Government Act, Public Law 110–175, 121 Stat. 2524, was enacted into law on December 31, 2007 to make it easier for a requester to access agency records, and to require agencies to be more responsive, transparent, and accountable to the public in responding to FOIA requests. The Act addresses many aspects of agency FOIA administration, including:

- Time limits for agencies to act on FOIA requests;
- Recovery of attorney's fees and litigation costs in FOIA-related lawsuits;
- Disciplinary actions for arbitrary and capricious rejection of FOIA requests;
- Use of individualized identification numbers to track FOIA requests;
- Proper fee charges for FOIA requests from news media;
- Enhanced requirements for agencies' annual FOIA reports to Congress;
- Appointment of a Chief FOIA Officer in an agency;
- Appointment of a FOIA Public Liaison in an agency;
- Disclosure of records maintained for an agency by a private entity pursuant to a records management contract; and
- A new requirement that the amount of material deleted from a document produced pursuant to FOIA must be specifically identified at the site of the deletion, together with the exemption authorizing that deletion.

To conform the Commission's FOIA regulations to the requirements of the Act, the proposed rule revises the following sections of 29 CFR part 1610:

—Section 1610.1 (adds definitions for ''agency record,'' ''news,'' and ''representative of the news media'' based on the Act);
—Section 1610.5 (identifies the acceptable methods of submitting a FOIA request to the Commission [in person or via mail, email, Internet, or facsimile machine] including the required identification of the submission as a FOIA request and other content required for efficient processing);
—Section 1610.6 (provides that FOIA requests which seek documents in the Commission's custody, but that originated in another agency, will be referred to the originating agency for its decision, and that the requester will be informed of the referral);
—Section 1610.7 (lists the proper Commission offices to receive FOIA requests);
—Section 1610.9 (explains the prospective processing time for FOIA requests and the period for which the time schedule for responding to a FOIA request is delayed when the Commission requires clarification by the requester, and provides that requests misdirected to the wrong EEOC–FOIA office shall be forwarded to the correct EEOC–FOIA office within 10 business days);
—Section 1610.10 (clarifies that the Commission will provide a written response to a FOIA request regardless of whether the request is granted or denied and regardless of whether there are documents responsive to the request);
—Section 1610.11 (provides that FOIA appeals misdirected to Commission District Offices shall be forwarded from those offices to the Legal Counsel within 10 business days);
—Section 1610.15 (states that the Commission will not charge search fees if the Commission's response to the FOIA is untimely, absent unusual or exceptional circumstances);
—Section 1610.18 (states that data underlying annual FOIA reports shall be available to the public);
—Section 1610.21 (specifies the content of the Commission's annual FOIA report to Congress).

The E-FOIA ACT

The Electronic FOIA Act of 1996 (E-FOIA) specifies that, after November 1996, information made available to the public for inspection and copying pursuant to FOIA must also be made available in electronic format. To coordinate the Commission's FOIA regulations with the E-FOIA, the proposed rule revises §§ 1610.18 and 1610.21 to state that the information identified therein shall be available in electronic as well as paper form. The E-FOIA Act also allows an agency to adopt a multi-track system for processing FOIA requests. EEOC therefore proposes to revise § 1610.9(a) in order to implement a multi-track system.

EEOC FOIA Transfer of Responsibility

The Commission transferred FOIA responsibility from EEOC Regional Attorneys to EEOC District Directors in 2007. To coordinate the Commission's FOIA regulations with the EEOC's current delegation of responsibility for FOIA processing as reflected in EEOC Order 150.001, the proposed rule revises

the following sections of 29 CFR part 1610:

—Sections 1610.7, 1610.8, 1610.9, 1610.10, 1610.11, 1610.13 and 1610.14 (revise all prior references to EEOC Regional Attorneys so that those references now are to EEOC District Directors).

In order to consolidate the Commission's public reading area functions in offices with adequate personnel to service the public, the proposed rule revises § 1610.04 by requiring the Commission's Headquarters library and District Offices to maintain public reading areas.

Editorial Revisions

The Commission also wishes to update and clarify its FOIA regulations. To accomplish these goals, the proposed rule removes or revises the following sections of 29 CFR part 1610:

—Section 1610.4 (updates the addresses of Commission offices, deletes references to materials no longer published, and deletes unnecessary verbiage);

—Sections 1610.6, 1610.7, 1610.10, 1610.13 and 1610.19 (delete unnecessary verbiage);

—Section 1610.20 (removed because its language was duplicative of other Commission FOIA regulations).

Regulatory Procedures

Executive Order 12866

The proposed rule has been drafted and reviewed in accordance with Executive Order 12866, 58 FR 51735 (Sept. 30, 2003), section 1(b), Principles of Regulation, and Executive Order 13563, 76 FR 3821 (January 1, 2011), Improving Regulation and Regulatory Review. The rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866.

Paperwork Reduction Act

The proposed rule contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Regulatory Flexibility Act

The Commission certifies under 5 U.S.C. 605(b) that the proposed rule will not have a significant economic impact on a substantial number of small entities because the proposed revisions do not impose any burdens upon FOIA requestors, including those that might be small entities. Therefore, a regulatory flexibility analysis is not required by the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

The proposed rule will not result in the expenditure by State, local, or tribal governments in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

List of Subjects in 29 CFR Part 1610

Freedom of information.

Dated: August 23, 2012.

For the Commission.

Jacqueline A. Berrien,

Chair.

Accordingly, part 1610 is proposed to be amended as follows:

PART 1610—AVAILABILITY OF RECORDS

1. The authority citation for 29 CFR part 1610 continues to read as follows:

Authority: 42 U.S.C. 2000e–12(a), 5 U.S.C. 552 as amended by Pub. L. 93–502, Pub. L. 99–570, and Pub. L. 105–231; for § 1610.15, non-search or copy portions are issued under 31 U.S.C. 9701.

2. Amend § 1610.1 by adding new paragraphs (j), (k), and (l) to read as follows:

§ 1610.1 Definitions.

* * * * *

(j) *Agency record* includes any information maintained for an agency by an entity under Government contract, for the purposes of records management.

(k) *News* refers to information about current events that would be of current interest to the public.

(l) *Representative of the news media* refers to any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. Examples of news media entities are television or radio stations broadcasting to the public at large and publishers of periodicals (but only if such entities qualify as disseminators of ''news'') who make their products available for purchase by, subscription by, or free distribution to, the general public. As methods of news delivery evolve (for example, the implementation of electronic dissemination of newspapers through telecommunication services), such alternative media shall be considered to be news-media services. A freelance journalist shall be regarded as working for a news-media entity if the journalist can demonstrate a solid basis for expecting publication through that entity, whether or not the journalist is actually employed by the entity. A publication contract would present a solid basis for such an expectation; the Commission may also consider the past publication record of the requester in making such a determination.

3. Revise § 1610.4 to read as follows:

§ 1610.4 Public reference facilities and current index.

(a) The Commission will maintain in a public reading area located in the Commission's library at 131 M Street NE., Washington, DC 20507, the materials which are required by 5 U.S.C. 552(a)(2) and 552(a)(5) to be made available for public inspection and copying. Any such materials created on or after November 1, 1996 may also be accessed through the Internet at *http://www.eeoc.gov.* The Commission will maintain and make available for public inspection and copying in this public reading area a current index providing identifying information for the public as to any matter which is issued, adopted, or promulgated after July 4, 1967, and which is required to be indexed by 5 U.S.C. 552(a)(2). The Commission in its discretion may, however, include precedential materials issued, adopted, or promulgated prior to July 4, 1967. The Commission will also maintain on file in this public reading area all material published by the Commission in the **Federal Register** and currently in effect.

(b) The Commission offices designated in § 1610.4(c) shall maintain and make available for public inspection and copying a copy of:

(1) The Commission's notices and regulatory amendments which are not yet published in the Code of Federal Regulations;

(2) The Commission's annual reports;

(3) The Commission's Compliance Manual;

(4) Blank forms relating to the Commission's procedures as they affect the public;

(5) The Commission's Orders (agency directives);

(6) ''CCH Equal Employment Opportunity Commission Decisions'' (1973 and 1983); and

(7) Commission awarded contracts.

(c) The Commission's District Offices with public reading areas are:

Atlanta District Office, 100 Alabama Street SW., Suite 4R30, Atlanta, GA 30303 (includes the Savannah Local Office).

Birmingham District Office, Ridge Park Place, 1130 22nd Street South, Suite 2000, Birmingham, AL 35205–2397

(includes the Jackson Area Office and the Mobile Local Office).

Charlotte District Office, 129 West Trade Street, Suite 400, Charlotte, NC 28202 (includes the Raleigh Area Office, the Greensboro Local Office, the Greenville Local Office, the Norfolk Local Office, and the Richmond Local Office).

Chicago District Office, 500 West Madison Street, Suite 2000, Chicago, IL 60661 (includes the Milwaukee Area Office and the Minneapolis Area Office).

Dallas District Office, 207 S. Houston Street, 3rd Floor, Dallas, TX 75202–4726 (includes the San Antonio Field Office and the El Paso Area Office).

Houston District Office, 1201 Louisiana Street, 6th Floor, Houston, TX 77002 (includes the New Orleans Field Office).

Indianapolis District Office, 101 West Ohio Street, Suite 1900, Indianapolis, IN 46204–4203 (includes the Detroit Field Office, the Cincinnati Area Office, and the Louisville Area Office).

Los Angeles District Office, 255 E. Temple Street, 4th Floor, Los Angeles, CA 90012 (includes the Fresno Local Office, the Honolulu Local Office, the Las Vegas Local Office, and the San Diego Local Office).

Memphis District Office, 1407 Union Avenue, 9th Floor, Memphis, TN 38104 (includes the Little Rock Area Office, and the Nashville Area Office).

Miami District Office, Miami Tower, 100 SE 2nd Street, Suite 1500, Miami, FL 33131 (includes the Tampa Field Office and the San Juan Local Office).

New York District Office, 33 Whitehall Street, 5th Floor, New York, NY 10004 (includes the Boston Area Office, the Newark Area Office, and the Buffalo Local Office).

Philadelphia District Office, 801 Market Street, 13th Floor, Philadelphia, PA 19107–3127 (includes the Baltimore Field Office, the Cleveland Field Office, and the Pittsburgh Area Office).

Phoenix District Office, 3300 N. Central Avenue, Suite 690, Phoenix, AZ 85012–2504 (includes the Denver Field Office, and the Albuquerque Area Office).

San Francisco District Office, 350 Embarcadero, Suite 500, San Francisco, CA 94105–1687 (includes the Seattle Field Office, the Oakland Local Office, and the San Jose Local Office).

St. Louis District Office, Robert A. Young Building, 1222 Spruce Street, Room 8100, St. Louis, MO 63103 (includes the Kansas City Area Office, and the Oklahoma City Area Office).

4. Amend § 1610.5 by revising paragraph (a), redesignating paragraphs (b) and (c) as (d) and (e), and adding new paragraphs (b) and (c) to read as follows:

§ 1610.5 Request for records.

(a) A written request for inspection or copying of a record of the Commission may be presented in person, or by mail, or by fax, or by email, or through *https://egov.eeoc.gov/foia/* to the Commission employee designated in § 1610.7. Every request, regardless of format, must contain the requester's name and may identify a non-electronic mailing address. In-person requests must be presented during business hours on any business day.

(b) A request must be clearly and prominently identified as a request for information under the ''Freedom of Information Act.'' If submitted by mail, or otherwise submitted under any cover, the envelope or other cover must be similarly identified.

(c) A respondent must always provide a copy of the ''Filed'' stamped court complaint when requesting a copy of a charge file. The charging party must provide a copy of the ''Filed'' stamped court complaint when requesting a copy of the charge file if the Notice of Right to Sue has expired.

* * * * *

5. Revise § 1610.6 to read as follows:

§ 1610.6 Records of other agencies.

Requests for records that originated in another Agency and are in the custody of the Commission will be referred to that Agency and the person submitting the request shall be so notified. The decision made by that Agency with respect to such records will be honored by the Commission.

6. Amend § 1610.7 by revising the introductory sentence of paragraph (a), revising paragraphs (b) and (c), and removing paragraphs (d) and (e) to read as follows:

§ 1610.7 Where to make request; form.

(a) Requests for the following types of records shall be submitted to the District Director for the pertinent district, field, area, or local office, at the district office address listed in § 1610.4(c) or, in the case of the Washington Field Office, shall be submitted to the Field Office Director at 131 M Street NE., Fourth Floor, Washington, DC 20507.

(1) * * *

(b) A request for any record which does not fall within the ambit of subparagraph (a) of this section, or a request for any record the location of which is unknown to the person making the request, shall be submitted in writing to the Assistant Legal Counsel, FOIA Programs, U.S. Equal Employment Opportunity Commission, by mail to 131 M Street NE., Suite 5NW02E, Washington, DC 20507, or by fax to (202) 663–4679, or by email to *FOIA@eeoc.gov,* or by Internet to *https://egov.eeoc.gov/foia/*.

(c) Any Commission officer or employee who receives a written Freedom of Information Act request shall promptly forward it to the appropriate official specified in paragraph (a) or (b) of this section. Any Commission officer or employee who receives an oral request under the Freedom of Information Act shall inform the person making the request that it must be in writing and also inform such person of the provisions of this subpart.

7. Revise § 1610.8 to read as follows:

§ 1610.8 Authority to determine.

The Assistant Legal Counsel, FOIA Programs, the District Director, or the District Director's designee, when receiving a request pursuant to these regulations, shall grant or deny such request. That decision shall be final, subject only to administrative review as provided in § 1610.11 of this subpart.

8. Amend § 1610.9 by redesignating paragraphs (a) through (c) as paragraphs (d) through (f), adding new paragraphs (a), (b), (c), and (g), and revising newly redesignated paragraphs (d) through (f) to read as follows:

§ 1610.9 Responses: timing.

(a) The EEOC utilizes a multi track system for responding to FOIA requests. After review, a FOIA request is placed on one of three tracks: the simple track, the complex track, or the expedited track. A FOIA request is assigned to the simple track if it will be processed in fewer than 10 business days. A FOIA request requiring more than 10 business days to process will be assigned to the complex track. A FOIA request which has been granted expedited processing will be assigned to the expedited track.

(b) The Assistant Legal Counsel, FOIA Programs, the District Director, or the District Director's designee shall, within 10 days from receipt of a request, notify the requester in writing of the date EEOC received the request, the expected date of issuance of the determination, the individualized FOIA tracking number assigned to the request, and the telephone number or Internet site where requesters may inquire about the status of their request.

(c) If a FOIA request is submitted to the incorrect EEOC–FOIA office, that office shall forward the misdirected request to the appropriate EEOC–FOIA

office within 10 business days. If a misdirected request is forwarded to the correct EEOC–FOIA office more than 10 business days after its receipt by the EEOC, then, pursuant to 5 U.S.C. § 552(a)(6)(A), the statutory 20 business days to respond to the request is reduced by the number of days in excess of 10 that it took the EEOC to forward the request to the correct EEOC–FOIA office.

(d) Within 20 business days after receipt of the request, the Assistant Legal Counsel, FOIA Programs, the District Director, or the District Director's designee shall either grant or deny the request for agency records, unless additional time is required for one of the following reasons:

(1) It is necessary to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(2) It is necessary to search for, collect, and appropriately examine a voluminous number of separate and distinct records which are demanded in a single request; or

(3) It is necessary to consult with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial interest therein.

(e) When additional time is required for one of the reasons stated in paragraph (d) of this Section, the Assistant Legal Counsel, FOIA Programs, District Director, or the District Director's designee shall, within the statutory 20 business day period, issue to the requester a brief written statement of the reason for the delay and an indication of the date on which it is expected that a determination as to disclosure will be forthcoming. If more than 10 additional business days are needed, the requester shall be notified and provided an opportunity to limit the scope of the request or to arrange for an alternate time frame for processing the request.

(f)(1) A request for records may be eligible for expedited processing if the requester demonstrates a compelling need. For the purposes of this section, compelling need means:

(i) That the failure to obtain the records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) That the requester is a representative of the news media as described in § 1610.1(l) and there is an urgency to inform the public concerning actual or alleged Federal government activity.

(2) A requester who seeks expedited processing must submit a statement, certified to be true and correct to the best of that person's knowledge and belief, explaining in detail the basis for requesting expedited processing. A determination on the request for expedited processing will be made and the requester notified within 10 calendar days. The Legal Counsel or designee, or the Assistant Legal Counsel, FOIA Programs, as appropriate, shall promptly respond to any appeal of the denial of a request for expedited processing.

(g) The Commission may toll the statutory time period to issue its determination on a FOIA request one time during the processing of the request to obtain clarification from the requester. The statutory time period to issue the determination on disclosure is tolled until EEOC receives the information reasonably requested from the requester. The agency may also toll the statutory time period to issue the determination to clarify with the requester issues regarding fees. There is no limit on the number of times the agency may request clarifying fee information from the requester.

9. Amend § 1610.10 by revising paragraphs (b) and (c) to read as follows:

§ 1610.10 Responses: form and content.

* * * * *

(b) A reply either granting or denying a written request for a record shall be in writing, signed by the Assistant Legal Counsel, FOIA Programs, the District Director, or the District Director's designee, and shall include:

(1) His or her name and title;

(2) A reference to the specific exemption under the Freedom of Information Act authorizing the withholding of the record and a brief explanation of how the exemption applies to the record withheld, or a statement that, after diligent effort, the requested records have not been found or have not been adequately examined during the time allowed under § 1610.9 (d), and that the denial will be reconsidered as soon as the search or examination is complete; and

(3) A written statement that the denial may be appealed to the Legal Counsel, or Assistant Legal Counsel, FOIA Programs, as appropriate, within 30 calendar days of receipt of the denial or partial denial.

(c) When a request for records is denied, the Commission shall provide to the requester a written statement identifying the estimated volume of denied material unless providing such estimate would harm an interest protected by the exemptions in 5 U.S.C. 522(b). When a reasonably segregable portion of a record is provided, the amount of information deleted from the released portion and, to the extent technically feasible, the place in the record where such deletion was made, and the exemption upon which the deletion was based, shall be indicated on the record provided to the requester.

* * * * *

10. Revise § 1610.11 to read as follows:

§ 1610.11 Appeals to the Legal Counsel from initial denials.

(a) When the Assistant Legal Counsel, FOIA Programs, the District Director, or the District Director's designee has denied a request for records in whole or in part, the requester may appeal within 30 calendar days of receipt of the determination letter. The appeal must be in writing addressed to the Legal Counsel, or the Assistant Legal Counsel, FOIA Programs, as appropriate, Equal Employment Opportunity Commission, 131 M Street NE., Suite 5NW02E, Washington, DC 20507, and clearly labeled as a ''Freedom of Information Act Appeal.'' Any appeal of a determination issued by a District Director or the District Director's designee must include a copy of the District Director's or the District Director's designee's determination. If a FOIA appeal is misdirected to a District Office, the District Office shall forward the appeal to the Legal Counsel, or the Assistant Legal Counsel, FOIA Programs, as appropriate, within 10 business days.

(b) The Legal Counsel or designee, or the Assistant Legal Counsel, FOIA Programs, as appropriate, shall act upon the appeal within 20 business days of its receipt, and more rapidly if practicable. If the decision is in favor of the person making the request, the decision shall order that records be promptly made available to the person making the request. The Legal Counsel or designee, or the Assistant Legal Counsel, FOIA Programs, as appropriate, may extend the 20 business day period in which to render a decision on an appeal for that period of time which could have been claimed and used by the Assistant Legal Counsel, FOIA Programs, the District Director, or the District Director's designee under § 1610.9, but which was not in fact used in making the original determination.

(c) The decision on appeal shall be in writing and signed by the Legal Counsel or designee, or the Assistant Legal Counsel, FOIA Programs, as appropriate. A denial in whole or in part of a request on appeal shall set forth the exemption relied on, a brief

explanation of how the exemption applies to the records withheld, and the reasons for asserting it, if different from those described by the Assistant Legal Counsel, FOIA Programs, the District Director, or the District Director's designee under § 1610.9. The decision on appeal shall indicate that the person making the request may, if dissatisfied with the decision, file a civil action in the United States District Court for the district in which the person resides or has his principal place of business, for the district where the records reside, or for the District of Columbia.

(d) No personal appearance, oral argument or hearing will ordinarily be permitted in connection with an appeal to the Legal Counsel or the Assistant Legal Counsel, FOIA Programs.

(e) On appeal, the Legal Counsel or designee, or the Assistant Legal Counsel, FOIA Programs, as appropriate, may reduce any fees previously assessed.

(f) In the event that the Commission terminates its proceedings on a charge after the District Director or the District Director's designee denies a request, in whole or in part, for the charge file but during consideration of the requester's appeal from that denial, the request may be remanded for redetermination. The requester retains a right to appeal to the Assistant Legal Counsel, FOIA Programs, from the decision on remand.

11. Revise § 1610.13 to read as follows:

§ 1610.13 Maintenance of files.

The Legal Counsel or designee, the Assistant Legal Counsel, FOIA Programs, and the District Directors or designees shall maintain files containing all material required to be retained by or furnished to them under this subpart. The material shall be filed by individual request.

12. Amend § 1610.14 by revising paragraph (a) to read as follows:

§ 1610.14 Waiver of user charges.

(a) Except as provided in paragraph (b) of this section, the Legal Counsel or designee, the Assistant Legal Counsel, FOIA Programs, and the District Directors or designees shall assess fees where applicable in accordance with § 1610.15 for search, review, and duplication of records requested. They shall also have authority to furnish documents without any charge or at a reduced charge if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

* * * * *

13. Amend § 1610.15 by adding paragraph (g) to read as follows:

§ 1610.15 Schedule of fees and method of payment for services rendered.

* * * * *

(g) A search fee will not be charged to requesters specified in paragraphs (a)(1) and (a)(3) of this section, and a duplication fee will not be charged to requesters specified in paragraph (a)(2) of this section, if the Commission issues an untimely determination and the untimeliness is not due to unusual or exceptional circumstances.

14. Amend § 1610.18 by revising the introductory text and adding paragraph (h) to read as follows:

§ 1610.18 Information to be disclosed.

The Commission will provide the following information to the public. This information will also be made available electronically:

* * * * *

(h) Underlying annual FOIA report data.

15. Amend § 1610.19 by removing paragraph (b)(2), redesignating paragraph (b)(3) as paragraph (b)(2), and removing the word ''working'' wherever it appears in paragraphs (d) and (e) and add in its place the word ''business.''

16. Remove and reserve § 1610.20.

§ 1610.20 [Removed and Reserved]

17. Revise § 1610.21 to read as follows:

§ 1610.21 Annual report.

The Legal Counsel shall, on or before February 1, submit individual Freedom of Information Act reports for each principal agency FOIA component and one for the entire agency covering the preceding fiscal year to the Attorney General of the United States. The reports shall include those matters required by 5 U.S.C. 552(e), and shall be made available electronically on the agency Web site.

[FR Doc. 2012–21495 Filed 8–31–12; 8:45 am]

BILLING CODE 6570–01–P

DEPARTMENT OF EDUCATION

34 CFR Subtitle A

[DOCKET ID ED–2012–OII–0013]

RIN 1855–AA08

Proposed Priorities, Requirements, Definitions, and Selection Criteria—Supporting Effective Educator Development

[CFDA Number: 84.367D.]

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Proposed priorities, requirements, definitions, and selection criteria.

SUMMARY: The Assistant Deputy Secretary for Innovation and Improvement proposes priorities, requirements, definitions, and selection criteria under the Supporting Effective Educator Development (SEED) Grant program. We may use these priorities, requirements, definitions, and selection criteria for competitions of the SEED Grant program for fiscal year (FY) 2012 and later years. We intend for the priorities, requirements, definitions, and selection criteria to help national not-for-profit organizations to build evidence on how best to recruit, train, and support effective teachers and school leaders; recruit and prepare effective science, technology, engineering, and mathematics teachers; and invest in efforts that enhance the teaching and school leadership professions.

DATES: We must receive your comments on or before October 4, 2012.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by email. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID and the phrase ''Supporting Effective Educator Development'' at the top of your comments.

- *Federal eRulemaking Portal:* Go to www.regulations.gov to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''How To Use This Site.'' A direct link to the docket page is also available at *www.ed.gov/programs/innovation/index.html.*
- *Postal Mail, Commercial Delivery, or Hand Delivery.* If you mail or deliver your comments about these proposed

priorities, requirements, definitions, and selection criteria, address them to Office of Innovation and Improvement (Attention: Supporting Effective Educator Development Comments), U.S. Department of Education, 400 Maryland Avenue SW., room 4C131, Washington, DC 20202.

• **Privacy Note:** The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Richard Wilson Telephone: (202) 453–6709 or by email: *seed@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priorities, requirements, definitions, and selection criteria, we urge you to identify clearly the specific proposed priority, requirement, definition, or selection criterion that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from the proposed priorities, requirements, definitions, and selection criteria. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the Department's programs and activities.

During and after the comment period, you may inspect all public comments about this notice by accessing Regulations.gov. You may also inspect the comments in person, in room 4W335, 400 Maryland Avenue SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in the **SUMMARY** section of this notice.

Purpose of Program: The SEED Grant program provides funding for grants to national not-for-profit organizations for projects that support teacher or principal training or professional enhancement activities and are supported by at least moderate evidence of effectiveness (as defined in this notice).

Program Authority: Department of Education Appropriations Act, 2012 (Pub. L. 112–74, Title III, Division F).

Proposed Priorities

This notice contains seven proposed priorities.

Background

The Statutory Context

The Department of Education Appropriations Act, 2012, requires the Secretary to reserve up to 1.5 percent of the funds for the Elementary and Secondary Education Act's (ESEA) Title II, Part A programs for competitive awards to national not-for-profit organizations for teacher or principal training or professional enhancement activities.

Overview of the SEED Grant program

Reforming and improving schools with high concentrations of high-need students is a key priority for the Department. Strengthening teacher and principal leadership is an essential part of any strategy to make a difference in these schools. Research shows that teachers are a critical element in improving student learning.[1] Additionally, there is compelling evidence that strong principals have positive, although indirect, effects on student learning.[2] The Department is using the SEED Grant program as a mechanism to identify and support projects that will strengthen teaching and school leadership specifically for high-need schools. As proposed in this notice, applicants must demonstrate how they will build evidence on how best to recruit, prepare, and support effective teachers and principals.

The following priorities focus on this goal.

Proposed Priority 1: Teacher or Principal Recruitment, Selection, and Preparation

Background

This proposed priority would support projects that will recruit, select, and prepare teachers, principals, or both who are able to increase student achievement and student learning, particularly in high-need schools. Although we included a similar priority in our September 8, 2011, notice inviting applications (76 FR 55658–55664) (2012 SEED NIA), that priority focused only on teachers. The Department of Education Appropriations Act, 2012, provides that projects may serve principals, teachers, or both and, therefore, we are modifying this priority accordingly. Additionally, we propose to include a more explicit focus on schools with high concentrations of high-need students (as defined in this notice) and to provide more direction on required project activities.

Proposed Priority 1

Under this proposed priority, the Secretary would fund projects that will create or expand practices and strategies that increase the number of highly effective teachers (as defined in this notice) or highly effective principals (as defined in this notice) by recruiting, selecting, and preparing talented individuals to work in schools with high concentrations of high-need students (as defined in this notice). Projects would include activities that focus on creating or expanding high-performing teacher preparation programs, principal preparation programs, or both. Activities may include but are not limited to expanding clinical experiences, re-designing and implementing program coursework to align with State standards and district requirements for their P–12 teachers, providing induction and other support for program participants in their classrooms and schools, and developing strategies for tracking the effect of program graduates on the achievement of their students or their schools.

In addition, an applicant would need to propose a plan demonstrating a

[1] Lee S. Shulman, *Knowledge and Teaching: Foundations of the New Reform,* Harvard Educational Review, Vol. 57, No. 1 (February 1987), pages 1–22; Eric A. Hanushek, John F. Kain, & Steven G. Rivkin. *Teachers, Schools, and Academic Achievement* (NBER Working Paper No. 6691) (1998), National Bureau of Economic Research, Retrieved April 25, 2012, from *http://www.nber.org/papers/w6691.pdf;* Thomas J. Kane & Douglas O. Staiger, *Gathering Feedback for Teaching: Combining High-Quality Observations with Student Surveys and Achievement Gains,* Bill & Melinda Gates Foundation (January, 2012).

[2] Kyla L. Wahlstom, Karen Seashore-Louis, Kenneth Leithwood, & Stephen E. Anderson, *Learning from Leadership: Investigating the Links to Improved Student Learning,* Center for Applied Research and Educational Improvement, University of Minnesota, Ontario Institute for Studies in Education at the University of Toronto, sponsored by the Wallace Foundation (July, 2010).

rigorous, competitive selection process to determine which aspiring teachers or principals participate in the applicant's proposed activities.

Proposed Priority 2: Professional Development for Teachers of English Language Arts With a Specific Focus on Writing

Background

This proposed priority is based on Absolute Priority 2 published in the 2012 SEED NIA. We propose changing the priority by requiring that the professional development be aligned with State standards. We also propose to require that the professional development align with district needs and include a rigorous evaluation of the effectiveness of teachers who participate in the professional development.

Proposed Priority 2

Under this proposed priority, the Secretary would fund projects designed to improve student literacy and writing skills by creating or expanding practices and strategies that increase the number of highly effective teachers (as defined in this notice) of English language arts by improving their knowledge, understanding, and teaching of English language arts, with a specific focus on teaching writing. Projects would focus on increasing student achievement (as defined in this notice) in English language arts by providing high-quality professional development to teachers in schools with high concentrations of high-need students (as defined in this notice).

An applicant would be required to describe the need of the proposed districts to be served for teacher professional development in English language arts and demonstrate alignment of its proposed project with State standards.

In addition, applicants would have to describe how they plan to measure the impact the professional development has on the effectiveness of teachers served by the project. Applicants would need to determine teacher effectiveness through a rigorous, transparent, and fair evaluation in which performance is differentiated using multiple measures of effectiveness and based in significant part on student growth (as defined in this notice).

Proposed Priority 3: Advanced Certification and Advanced Credentialing

Background

This proposed priority would support projects that will develop or enhance systems to develop and recognize teachers, principals, or both who will serve as models, coaches, and mentors from whom other teachers, principals, or both can learn and strengthen their practices. We propose changing this priority from Absolute Priority 3 in the 2012 SEED NIA by encouraging applicants to target services to teachers, principals, or both who are working or agree to work in schools with high concentrations of high-need students (as defined in this notice). We also propose adding requirements for the selection of participants and the evaluation of outcomes or effectiveness of participants.

Proposed Priority 3

Under this proposed priority, the Secretary would fund projects that will create or expand practices and strategies that increase the number of highly effective teachers (as defined in this notice), highly effective principals (as defined in this notice), or both, who work in schools with high concentrations of high-need students (as defined in this notice).

Applicants would be required to focus their proposed projects on encouraging and supporting teachers, principals, or both, who seek a nationally recognized, standards-based advanced certificate or advanced credential through high-quality professional enhancement projects designed to improve teaching and learning for teachers who would take on career ladder positions (as defined in this notice), principals, or both who would serve as models, mentors, and coaches for other teachers, principals, or both working in schools with high concentrations of high-need students (as defined in this notice).

In addition, effectiveness of teachers or principals who receive advanced certification or credentialing would need to be determined through a rigorous, transparent, and fair evaluation in which performance is differentiated using multiple measures of effectiveness and based in significant part on student growth (as defined in this notice).

Finally, an applicant would need to propose a plan demonstrating a rigorous, competitive selection process to determine which teachers or principals participate in the applicant's proposed activities.

Proposed Priority 4: Promoting Science, Technology, Engineering, and Mathematics (STEM) Education

Background

This proposed priority would support projects that will improve professional development for STEM teachers and increase the number of STEM teachers from traditionally underrepresented groups. Improving STEM education is critical in developing a globally competitive workforce.

This priority was not used in the 2012 SEED NIA. We propose adding this priority because it would respond to the high demand for highly effective STEM teachers, particularly in high-need schools. We also note that this proposed priority is based on the notice of final supplemental priorities and definitions for discretionary grant programs, published in the **Federal Register** on December 15, 2010 (75 FR 78486–78511), and corrected on May 12, 2011 (76 FR 27637–27641) (Supplemental Priorities). However, in both subsections (a) and (b) of this proposed priority, we removed the term ''other educators'' because the appropriations language for the SEED Grant program allows projects that provide services only to teachers, principals, or both.

Proposed Priority 4

Under this proposed priority, the Secretary would fund projects that address one or both of the following priority areas:

(a) Increasing the opportunities for high-quality preparation of, or professional development for, teachers of STEM subjects.

(b) Increasing the number of individuals from groups traditionally underrepresented in STEM, including minorities, individuals with disabilities, and women, who are teachers of STEM subjects and have increased opportunities for high-quality preparation or professional development.

In addition, applicants would have to describe how they plan to measure the impact the proposed project activities have on teacher effectiveness. Applicants would need to determine teacher effectiveness through a rigorous, transparent, and fair evaluation in which performance is differentiated using multiple measures of effectiveness and based in significant part on student growth (as defined in this notice).

Proposed Priority 5: Professional Development for Teachers of Core Academic Subjects

Background

This proposed priority would support projects that will provide professional development to teachers of core academic subjects, including special education teachers, to help them continue to improve their pedagogy, increase their knowledge of core subjects, and become highly effective

teachers in schools with high concentrations of high-need students (as defined in this notice). We propose adding this priority to support the creation and expansion of high-quality professional development projects that strengthen instruction and raise student achievement across core academic subjects. The priority would require that the professional development be aligned with State standards. We also propose to include requirements for the selection of participants that align with district needs and for the evaluation of the effectiveness of participants.

Proposed Priority 5

Under this proposed priority, the Secretary would fund projects that will create or expand practices and strategies that increase the number of highly effective teachers (as defined in this notice) by providing professional development opportunities to teachers, including special education teachers, in schools with high concentrations of high-need students (as defined in this notice). Projects would focus on increasing student achievement (as defined in this notice) in core academic subjects by providing high-quality professional development to teachers. The academic subjects that may be addressed through professional development under this priority include foreign languages, civics and government, economics, arts, history, physical education, geography, environmental education, and financial literacy.

Applicants would be required to describe the need of the proposed districts to be served for teacher professional development in the selected high-need core academic subjects and to demonstrate alignment of its proposed project with State standards.

In addition, applicants would have to describe how they plan to measure the impact the professional development has on teacher effectiveness. Applicants would need to determine teacher effectiveness through a rigorous, transparent, and fair evaluation in which performance is differentiated using multiple measures of effectiveness and based in significant part on student growth (as defined in this notice).

Proposed Priority 6: Improving Efficiency

Background

This proposed priority would support projects that identify cost-effective strategies to improve project outcomes. In order to meet this priority, applicants would be required to demonstrate how they will efficiently improve educational outcomes, including student achievement. We propose changing the language in this priority from the Competitive Preference Priority 2 in the 2012 SEED NIA in order to emphasize the use of cost-effective strategies.

Proposed Priority 6

Under this proposed priority, the Secretary would fund projects that will identify strategies for providing cost-effective, high-quality services at the State, regional, or local level by making better use of available resources. Such projects may include innovative and sustainable uses of technology, modification of school schedules and teacher compensation systems, use of open educational resources (as defined in this notice), or other strategies.

Proposed Priority 7: Supporting Practices and Strategies for Which There Is Strong Evidence of Effectiveness

Background

This proposed priority would support projects that are supported by strong evidence. The Department firmly believes that the strongest available evidence should inform educational funding and policy decisions. Creating a larger pool of evidence-supported implementation sites will provide more opportunities to scale up projects that have a history of success and to improve educational outcomes for more students. We propose to leave this priority unchanged from the 2012 SEED NIA; however, we propose a slightly different definition of ''strong evidence of effectiveness'', as explained in the *Definitions* section of this notice.

Proposed Priority 7

Under this proposed priority, the Secretary would fund projects that are supported by strong evidence of effectiveness (as defined in this notice).

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, as specified by 34 CFR 75.105(c)(3), we would consider only applications that meet the priority.

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority preference over other applications (34 CFR 75.105(c)(1)).

Proposed Requirements

The Secretary proposes the following requirements for the SEED Grant program. We may apply these requirements in any year in which this program is in effect.

Eligible applicants: To be eligible for a SEED Grant program grant, an entity must be a national not-for-profit organization (as defined in this notice). Each applicant must provide in its application documentation that it is a national not-for-profit organization (as defined in this notice).

Evidence of effectiveness: To be eligible for funding, an applicant must demonstrate that its proposed project is supported by at least moderate evidence of effectiveness (as defined in this notice).

Each applicant must provide in its application documentation that its proposed project is supported by at least moderate evidence of effectiveness. An applicant that applies for Proposed Priority 7 also must provide documentation that its proposed project is supported by strong evidence of effectiveness. An applicant must ensure that all evidence is available to the Department from publically available sources and provide links, references, or copies of the evidence in the application. If the Department determines that an applicant has provided insufficient evidence that its proposed project meets the definition of ''moderate evidence of effectiveness,'' or ''strong evidence of effectiveness,'' the applicant will not have an opportunity to provide additional evidence to support its application.

Evaluations: An applicant receiving funds under this program must comply with the requirements of any evaluation of the program conducted by the Department. In addition, an applicant receiving funds under this program must make broadly available through formal (e.g., peer-reviewed journals) or informal (e.g., newsletters) mechanisms, and in print or electronically, the results of any evaluations it conducts of its funded activities.

Proposed Definitions

The Secretary proposes the following definitions for this competition. We propose to modify the definition of ''national not-for-profit organization'' from the definition used in the 2012 SEED NIA to add more objective criteria for determining what type of organizations meet the definition. Additionally, the definitions relating to levels of evidence have both been changed to align more closely with other Department definitions of levels of evidence. We may apply one or more of these definitions in any year in which this program is in effect.

Career ladder positions means school-based instructional leadership positions designed to improve instructional practice, which teachers may voluntarily accept, such as positions described as master teacher, mentor teacher, demonstration or model teacher, or instructional coach, and for which teachers are selected based on criteria that are predictive of the ability to lead other teachers.

High-need students means students at risk of educational failure, such as students who are living in poverty, who are English learners, who are far below grade level or who are not on track to becoming college- or career-ready by graduation, who have left school or college before receiving, respectively, a regular high school diploma or a college degree or certificate, who are at risk of not graduating with a diploma on time, who are homeless, who are in foster care, who are pregnant or parenting teenagers, who have been incarcerated, who are new immigrants, who are migrant, or who have disabilities.

Highly effective principal means a principal whose students, overall and for each subgroup as described in section 1111(b)(2)(C)(v)(II) of the Elementary and Secondary Education Act, as amended (ESEA) (i.e., economically disadvantaged students, students from major racial and ethnic groups, students with disabilities, and students with limited English proficiency), achieve high rates (e.g., one and one-half grade levels in an academic year) of student growth. Eligible applicants may include multiple measures, provided that principal effectiveness is evaluated, in significant part, based on student growth. Supplemental measures may include, for example, high school graduation rates; college enrollment rates; evidence of providing supportive teaching and learning conditions, support for ensuring effective instruction across subject areas for a well-rounded education, strong instructional leadership, and positive family and community engagement; or evidence of attracting, developing, and retaining high numbers of effective teachers.

Highly effective teacher means a teacher whose students achieve high rates (e.g., one and one-half grade levels in an academic year) of student growth. Eligible applicants may include multiple measures, provided that teacher effectiveness is evaluated, in significant part, based on student growth. Supplemental measures may include, for example, multiple observation-based assessments of teacher performance or evidence of leadership roles (which may include mentoring or leading professional development learning communities) that increase effectiveness of other teachers in the school or local educational agency (LEA).

Large sample means a sample of 350 or more students (or other single analysis units) who were randomly assigned to a treatment or control group, or 50 or more groups (such as classrooms or schools) that contain 10 or more students (or other single analysis units) and that were randomly assigned to a treatment or control group.

Moderate evidence of effectiveness means one of the following conditions is met:

(1) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse Evidence Standards without reservations;[3] found a statistically significant favorable impact on a relevant outcome (as defined in this notice) (with no statistically significant unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse); and includes a sample that overlaps with the populations or settings proposed to receive the process, product, strategy, or practice.

(2) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse Evidence Standards with reservations,[4] found a statistically significant favorable impact on a relevant outcome (as defined in this notice) (with no statistically significant unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse), includes a sample that overlaps with the populations or settings proposed to receive the process, product, strategy, or practice, and includes a large sample (as defined in this notice) and a multi-site sample (as defined in this notice) (**Note:** multiple studies can cumulatively meet the large and multi-site sample requirements as long as each study meets the other requirements in this paragraph).

Multi-site sample means more than one site, where site can be defined as an LEA, locality, or State.

National level describes the level of scope or effectiveness of a process, product, strategy, or practice that is able to be effective in a wide variety of communities, including rural and urban areas, as well as with different groups (e.g., economically disadvantaged, racial and ethnic groups, migrant populations, individuals with disabilities, English learners, and individuals of each gender).

National not-for-profit organization means an entity that meets the definition of ''nonprofit'' under 34 CFR 77.1(c) and is of national scope, meaning that the entity provides services in multiple States to a significant number or percentage of recipients and is supported by staff or affiliates in multiple States.

Open educational resources means teaching, learning, and research resources that reside in the public domain or have been released under an intellectual property license that permits their free use or repurposing by others.

Relevant outcome means the student outcome or outcomes (or the ultimate outcome if not related to students) that the proposed project is designed to improve, consistent with the specific goals of a program.

Strong evidence of effectiveness means that one of the following conditions is met:

(1) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse Evidence Standards without reservations;[5] found a statistically

[3] *See* What Works Clearinghouse Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.*

[4] *See* What Works Clearinghouse Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.*

[5] *See* What Works Clearinghouse Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.*

significant favorable impact on a relevant outcome (as defined in this notice) (with no statistically significant unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse); includes a sample that overlaps with the populations and settings proposed to receive the process, product, strategy, or practice; and includes a large sample (as defined in this notice) and a multi-site sample (as defined in this notice) (Note: multiple studies can cumulatively meet the large and multi-site sample requirements as long as each study meets the other requirements in this paragraph).

(2) There are at least two studies of the effectiveness of the process, product, strategy, or practice being proposed, each of which meets the What Works Clearinghouse Evidence Standards with reservations,[6] found a statistically significant favorable impact on a relevant outcome (as defined in this notice) (with no statistically significant unfavorable impacts on that outcome for relevant populations in the studies or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse), includes a sample that overlaps with the populations and settings proposed to receive the process, product, strategy, or practice, and includes a large sample (as defined in this notice) and a multi-site sample (as defined in this notice).

Student achievement means—

(a) For tested grades and subjects: (1) A student's score on the State's assessments under the ESEA; and, as appropriate, (2) other measures of student learning, such as those described in paragraph (b) of this definition, provided they are rigorous and comparable across schools.

(b) For non-tested grades and subjects: alternative measures of student learning and performance, such as student scores on pre-tests and end-of-course tests; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across schools.

Student growth means the change in student achievement (as defined in this notice) for an individual student between two or more points in time. An applicant may also include other measures that are rigorous and comparable across classrooms.

[6] *See* What Works Clearinghouse Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.*

Proposed Selection Criteria

Background

The proposed selection criteria are intended to ensure that applicants can demonstrate that they have the experience and capacity to expand or develop practices and strategies to recruit, select, and prepare or provide professional enhancement activities for teachers, principals, or both.

In the absence of specific selection criteria for the SEED Grant program, the Department would use the general selection criteria in 34 CFR 75.210 of the Education Department General Administrative Regulations (EDGAR) in selecting grant recipients. While many of the selection criteria subfactors are taken directly from EDGAR at 34 CFR 75.210, they have been combined in some cases or organized under different criteria in other cases. In addition, some subfactors have been edited to focus on that which would affect the ability of the applicant to implement an effective project that meets the SEED Grant program's purposes.

Under the proposed selection criteria, the Secretary would assess the extent to which an applicant would be able to sustain a project once Federal funding through the SEED Grant program is no longer available. Thus, eligible applicants should propose activities that they will be able to sustain without funding from the program and should include in their management plan the specific steps they will take for sustained implementation of the proposed project.

Proposed Selection Criteria

The Secretary proposes the following selection criteria for evaluating an application under the SEED Grant program. We may apply one or more of these criteria, as well as other criteria or factors established in 34 CFR 75.210, in any year in which this program is in effect. In the notice inviting applications or the application package, or both, we will announce the maximum possible points assigned to each criterion.

(a) *Significance.* The Secretary considers the significance of the proposed project. In determining the significance of the proposed project, the Secretary considers:

(1) The significance of the proposed project on a national level (as defined in this notice).

(2) The potential contribution of the proposed project to the development and advancement of teacher and school leadership theory, knowledge, and practices.

(3) The importance or magnitude of the results or outcomes likely to be attained by the proposed project, especially improvements in teaching and student achievement.

(b) *Quality of the Project Design and Services.* The Secretary considers the quality of the design and services of the proposed project. In determining the quality of the design and services of the proposed project, the Secretary considers:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified, aligned, and measurable.

(2) The extent to which the proposed project is part of a comprehensive effort to improve teaching and learning and support rigorous academic standards for students.

(3) The extent to which the training or professional development services to be provided by the proposed project will be of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(c) *Quality of the Management Plan and Personnel.* The Secretary considers the quality of the management plan for the proposed project and of the personnel who will carry out the proposed project. In determining the quality of the management plan and the project personnel, the Secretary considers:

(1) The qualifications, including relevant training and experience, of the project director, key project personnel, and project consultants or subcontractors.

(2) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(3) The extent to which the time commitments of the project director and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(4) The extent to which the proposed management plan includes sufficient and reasonable resources to effectively carry out the proposed project, including the project evaluation.

(d) *Sustainability.* The Secretary considers the adequacy of resources to continue the proposed project after the grant period ends. In determining the adequacy of resources and the potential for utility of the proposed project's activities and products by other organizations, the Secretary considers:

(1) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the period of Federal financial assistance.

(2) The extent to which the proposed project is likely to yield findings and products (such as information, materials, processes, or techniques) that may be used by other agencies and organizations.

(3) The extent to which the applicant will disseminate information about results and outcomes of the proposed project in ways that will enable others, including the public, to use the information or strategies.

(e) *Quality of the Project Evaluation.* The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers one or more of the following factors:

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(2) The extent to which the evaluation includes the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data.

(3) The extent to which the evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(4) The extent to which the proposed project plan includes sufficient resources to carry out the project evaluation effectively.

Note: We encourage applicants to review the following technical assistance resources on evaluation: (1) What Works Clearinghouse Procedures and Standards Handbook: *http://ies.ed.gov/ncee/wwc/references/idocviewer/doc.aspx?docid=19&tocid=1;* and (2) IES/NCEE Technical Methods papers: *http://ies.ed.gov/ncee/tech_methods/.*

Final Priorities, Requirements, Definitions, and Selection Criteria

We will announce the final priorities, requirements, definitions, and selection criteria in a notice in the **Federal Register**. We will determine the final priorities, requirements, definitions, and selection criteria after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use these priorities, requirements, definitions, and selection criteria, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3 (f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practical—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavior changes.''

We are taking this proposed regulatory action only on a reasoned determination that the benefits justify the costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. The Department believes that this proposed regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Summary of Costs and Benefits

The costs of carrying out activities would be paid for with program funds and with matching funds provided by private-sector partners. Thus, the costs of implementation would not be a burden for any eligible applicants, including small entities.

Paperwork Reduction Act of 1995

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program 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 ensure that: the public understands the Department's collection instructions, respondents can provide the requested data 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.

We estimate that each applicant would spend approximately 176 hours of staff time to address the proposed requirements and selection criteria, prepare the application, and obtain necessary clearances. The total number of hours for all expected applicants is an estimated 2,640 hours. We estimate the total cost per hour of the applicant-level staff who will carry out this work to be $57 per hour. The total estimated cost for all applicants is estimated to be $150,480.

Under the PRA, the Department has submitted to OMB for its review a copy of the information collection (including the burden estimates) for the SEED discretionary grant application using the proposed priorities, requirements, definitions, and selection criteria. Through this NPP, OII seeks comment on this information collection. If you want to comment on the proposed information collection, please send your comments to the Office of Information and Regulatory Affairs, OMB, Attention:

Desk Officer for U.S. Department of Education. Send these comments by email to *OIRA_DOCKET@omb.eop.gov* or by fax to (202) 395–6974. You may also send a copy of these comments to the Department contact named in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

In preparing your comments you may want to review the ICR, which we maintain in the Education Department Information Collection System (EDICS) at *http://edicsweb.ed.gov*. Click on Browse Pending Collections. This proposed collection is identified as proposed collection (04833) 1855-New. This ICR is also available on OMB's RegInfo Web site at *www.reginfo.gov.*

We consider your comments on this proposed collection of information in—

- Deciding whether the proposed collection is necessary for the proper performance of our functions, including whether the information will have practical use;
- Evaluating the accuracy of our estimate of the burden of the proposed collection, including the validity of our methodology and assumptions;
- Enhancing the quality, usefulness, and clarity of the information we collect; and
- Minimizing the burden on those who must respond. This includes exploring the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

OMB is required to make a decision concerning the collection of information contained in these proposed priorities, requirements, and selection criteria between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, to ensure that OMB gives your comments full consideration, it is important that OMB receives your comments on the proposed collection within 30 days after publication. This does not affect the deadline for your comments to us on the proposed priorities, requirements, definitions, and selection criteria.

Please note that a Federal agency cannot conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number. We will provide the OMB control number when we publish the notice of final priorities, requirements, definitions, and selection criteria.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR Part 79. One of the objectives of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism. The Executive Order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: August 30, 2012.

James H. Shelton, III,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2012–21814 Filed 8–31–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–YELL–10569; 2310–0070–422]

36 CFR Part 7

RIN 1024–AE10

Special Regulations; Areas of the National Park System, Yellowstone National Park

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: This rule would implement an amended Record of Decision for the 2011 Winter Use Plan/Environmental Impact Statement and would govern winter visitation and certain recreational activities in Yellowstone National Park for the 2012–2013 winter season. The rule proposes to retain, for one additional year, the regulation and management framework that have been in place for the past three winter seasons (2009–2010, 2010–2011 and 2011–2012). Specifically, the rule would retain provisions that require most recreational snowmobiles operating in the park to meet certain National Park Service air and sound emissions requirements; require snowmobiles and snowcoaches in Yellowstone to be accompanied by a commercial guide; set daily entry limits on the numbers of snowmobiles (up to 318) and snowcoaches (up to 78) that may enter the park; and prohibit traveling off designated oversnow routes.

DATES: Comments must be received by October 4, 2012.

ADDRESSES: You may submit your comments, identified by Regulation Identifier Number (RIN) 1024–AE10, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Yellowstone National Park, Winter Use Proposed Rule, P.O. Box 168, Yellowstone National Park, WY 82190.
- *Hand Deliver to:* Management Assistant's Office, Headquarters Building, Mammoth Hot Springs, Yellowstone National Park, Wyoming.

All submissions received must include the agency name and RIN. For additional information see ''Public Participation'' under **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: Wade Vagias, Management Assistant's Office, Headquarters Building, Yellowstone National Park, 307–344–2035 or at the address listed in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION:

Background

The National Park Service (NPS) has managed winter use in Yellowstone National Park for several decades. A detailed history of the winter use issue, past planning efforts, and litigation is provided on the park's Web site, *http://www.nps.gov/yell/parkmgmt/timeline.htm.* The park has most recently operated under a temporary one-year rule (76 FR 77131). That rule, which expired by its own terms on March 15, 2012, had extended for one

winter season the daily entry limits and operational requirements for snowmobiles and snowcoaches adopted by the 2009 interim plan, which had been in effect for the prior two winter seasons.

On July 5, 2011, the NPS published a proposed long-term rule to implement the preferred alternative identified in the Draft Environmental Impact Statement (DEIS) (76 FR 39048). Under that alternative, the NPS proposed providing four different use-level combinations for snowmobiles and snowcoaches, which would vary according to a seasonal schedule. The NPS had intended to issue a record of decision and finalize a long-term rule for Yellowstone winter use by December 2011. However, some of the more than 59,000 public comments received on the DEIS raised reasonable questions as to long-term management strategies and environmental impacts, and the NPS decided to delay implementation of a long-term rule in order to prepare a Supplemental Environmental Impact Statement (SEIS) further analyzing the impacts of winter use under various long-term management options.

Accordingly, in its December 2011 Record of Decision (ROD) (76 FR 77249), the NPS announced its decision to select and implement Alternative 8 in the Final Environmental Impact Statement (FEIS). Alternative 8 extended for one additional winter season—the 2011–2012 season—the daily entry limits and operating requirements of the 2009 rule, which allowed up to 318 commercially guided, best available technology snowmobiles and 78 commercially guided snowcoaches in the park per day, as well as authorizing a variety of non-motorized uses. The DEIS and FEIS contained and analyzed an alternative—identified as Alternative 2—implementing those limits and operating requirements indefinitely into the future. On December 12, 2011, the NPS published a final rule to implement Alternative 8 (76 FR 77131). The NPS believed that the additional time afforded by a new one-season rule would allow it to complete the SEIS, decide on a long-term plan for managing winter use, and promulgate a new long-term rule before the beginning of the 2012–2013 winter season.

On June 29, 2012, the NPS released the Draft SEIS and published a Notice of Availability in the **Federal Register** (77 FR 38824). Public comment on the Draft SEIS closed on August 20, 2012. The response from the public and stakeholders has been robust. A majority of the substantive comments have addressed the proposal in the Draft SEIS's preferred alternative to manage snowmobiles and snowcoaches by a new concept known as ''transportation events.'' Numerous commenters have requested additional time to consider this new management concept and to respond substantively to it. Accordingly, the NPS has decided to reopen public comment on the Draft SEIS for an additional 30 days. Mindful of the short amount of time left before the December 15, 2012, opening of the 2012–2013 winter season and desiring to take the time necessary to make a reasoned, sustainable long-term decision on winter use, the NPS has decided to amend the December 2011 ROD. Utilizing the analyses contained in Alternative 2 in the 2011 FEIS and updated information gathered during the 2011–2012 winter season, the NPS is promulgating this new rule to extend for one additional winter season the 2011–2012 daily entry limits and operating requirements. The purpose of this publication is to solicit public comment on the NPS's decision to amend the December 2011 ROD and on the new proposed one-season rule.

Section by Section Analysis

The NPS is proposing to revise § 7.13 paragraphs (l)(3)(ii) and (l)(4)(vi) and the introductory text of paragraphs (l)(7)(i) and (l)(8)(i) by replacing the terms ''the winter season of 2011–2012'' and ''the winter of 2011–2012'' with the terms ''the winter season of 2012–2013'' and ''the winter of 2012–2013.'' This would be the only change to the existing regulations.

Compliance With Other Laws and Executive Orders

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is significant because it will raise novel legal or policy issues.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (RFA)

This rule will not have a significant economic effect on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*).

The NPS used two separate baselines for its regulatory flexibility analysis. If no new rule were passed, Baseline 1 would be defined by the no-action alternative in the EIS. Under this baseline, no motorized oversnow vehicles would be allowed in the park. In addition, the NPS defined a second baseline, Baseline 2. Baseline 2 represents the continuation of the same levels of use allowed under the 2009 interim regulation in place for the past three winter seasons. Under Baseline 2, there would be a zero net change between the past three years and the actions being implemented under this rule, because the rule extends the management framework in place the past three winter seasons for one additional year. A regulatory flexibility analysis is included in the report titled ''Economic Analysis of Winter Use Regulations in Yellowstone National Park'' (RTI International, 2011). The NPS has reviewed the economic analysis contained in that report and has concluded that it still is relevant and that its results would apply to the additional year.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the SBREFA. This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This rule has no effect on methods of manufacturing or production and specifically affects the Greater Yellowstone Area, not national or U.S.-based enterprises.

Unfunded Mandates Reform Act (UMRA)

This rule does not impose an unfunded mandate on State, local, or

tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required. The rule addresses public use of national park lands, and imposes no requirements on other agencies or governments.

Takings (Executive Order 12630)

Under the criteria in section 2 Executive Order 12630, this rule does not have significant takings implications. Access to private property located adjacent to the park will be afforded the same access during winter as before this rule. No other property is affected. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. It addresses public use of national park lands, and imposes no requirements on other agencies or governments. A Federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's tribal consultation policy is not required. Numerous tribes in the area were consulted in the development of the previous winter use planning documents.

Paperwork Reduction Act (PRA)

This rule does not contain any new collection of information that requires approval by the Office of Management and Budget (OMB) under the PRA of 1995 (44 U.S.C. 3501 *et seq.*). OMB has approved the collection requirement associated with Commercial Services and has assigned OMB control number 1024–0129 (expires 09/30/2013). 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.

National Environmental Policy Act (NEPA)

This winter use plan and rule constitute a major Federal action with the potential to significantly affect the quality of the human environment. The NPS prepared the 2011 Winter Use Plan/Environmental Impact Statement under the National Environmental Policy Act of 1969. The NPS is reexamining the analyses contained in the 2011 EIS, as well as new data from the 2011–2012 winter season, and intends to amend the December 2011 ROD (76 FR 77249) to authorize extending the current winter use management frame work for an additional year. The EIS is available for review at *http://parkplanning.nps.gov/yell.*

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive Order 13211, a statement of Energy Effects is not required.

Clarity of This Regulation

We are required by Executive Orders 12866 (section 1 (b)(12)), 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

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.

Length of the Comment Period

This proposed rule is available for public review and comment for a period of 30 days. Under more typical circumstances the NPS would normally provide a 60-day comment period. In this case, new issues raised in the course of preparing the 2011 EIS necessitated the completion of a Supplemental EIS, resulting in the need for an expedited rulemaking process to authorize winter use during the upcoming winter season. For this regulation, we have determined that in order for a final rule to become effective by December 15, 2012, it is necessary to reduce the normal review and comment period to 30 days.

Good cause exists for the shortened comment period for the following reasons:

(1) The NPS has received voluminous public comment on previous rulemaking efforts regarding winter use of the park, including efforts in 2000, 2003, 2004, 2007, 2008, and 2011. Those rulemaking efforts addressed many of the same issues as are addressed in this rulemaking, and a relatively small number of new issues are being raised.

(2) Since at least December 2011 the NPS has in good faith publicly stated that the 2012–2013 winter season for Yellowstone would commence on or about December 15, 2012, and the public and businesses have made decisions based on the widespread public knowledge of this opening date.

(3) Many persons planning to visit the park have already made travel plans in anticipation of the park being open for snowmobile and snowcoach use, such as reserving time off from work, booking airfares and hotel accommodations, making reservations for snowmobile or snowcoach tours, and the like. The Christmas-New Year period is one of the

most heavily visited times of the winter season. If the park does not open as scheduled on December 15, 2012, it would create unnecessary hardship for visitors who have already planned trips, and would likely result in economic losses for some visitors if reservations had to be cancelled. Significant revenue loss for businesses in and around the park would also occur. Many businesses in the gateway communities surrounding the park, and the people who rely upon them for their livelihoods, are highly dependent upon the park being open for the entire duration of the approximately 90-day season.

(4) Snowmobile and snowcoach operators have made business decisions and investments for the winter season premised on an opening date of December 15, 2012. Such actions include purchasing new snowmobiles and snowcoaches for their fleets, making offers of employment, preparing advertising and other materials, and purchasing snowmobile accessories such as suits, helmets, boots, mittens, etc. A late opening would shorten an already-brief winter season, thereby depriving these businesses and others that depend on the winter season (such as hotels, restaurants, service stations, and other hospitality-oriented businesses) of revenue that is important to their livelihoods.

List of Subjects in 36 CFR Part 7

National Parks, Reporting and recordkeeping requirements.

In consideration of the forgoing, the NPS proposes to amend 36 CFR part 7 as set forth below:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

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

Authority: 16 U.S.C. 1, 3, 9a, 462(k); Sec. 7.96 also issued under DC Code 10–137 (2001) and DC Code 50–2201 (2001).

2. In § 7.13 revise paragraphs (l)(3)(ii), (l)(4)(vi), (l)(7)(i) introductory text, and (l)(8)(i) introductory text to read as follows:

§ 7.13 Yellowstone National Park.

* * * * *

(l) * * *

(3) * * *

(ii) The authority to operate a snowmobile in Yellowstone National Park established in paragraph (l)(3)(i) of this section is in effect only through the winter season of 2012–2013.

* * * * *

(4) * * *

(vi) The authority to operate a snowcoach in Yellowstone National Park established in paragraph (l)(4)(i) of this section is in effect only through the winter season of 2012–2013.

* * * * *

(7) * * *

(i) You may operate your snowmobile only upon designated oversnow routes established within the park in accordance with § 2.18(c) of this chapter. The following oversnow routes are designated for snowmobile use through the winter of 2012–2013:

* * * * *

(8) * * *

(i) Authorized snowcoaches may be operated on the routes designated for snowmobile use in paragraphs (l)(7)(i)(A) through (l)(7)(i)(O) of this section. The restricted hours of snowmobile use described in paragraphs (1)(7)(i)(M) through (1)(7)(i)(O) do not apply to snowcoaches. Snowcoaches may also be operated on the following additional oversnow routes through the winter of 2012–2013:

* * * * *

Dated: August 30, 2012.

Michael Bean,

Acting Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2012–21828 Filed 8–31–12; 8:45 am]

BILLING CODE 4312–CT–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. 2012–3]

Registration of Copyright: Definition of Claimant

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of Proposed Rulemaking: Extension of Reply Comment Period.

SUMMARY: The Copyright Office is extending the reply comment period on the proposed rule to amend its regulations governing the definition of a ''claimant'' for purposes of copyright registration by eliminating the footnote to the definition of a ''claimant'' in § 202.3(a)(3)(ii).

DATES: Reply comments must be received in the Copyright Office no later than 5:00 p.m. Eastern Daylight Time (EDT) on October 4, 2012.

ADDRESSES: The Copyright Office strongly prefers that comments be submitted electronically. A comment page containing a comment form is posted on the Copyright Office Web site at *http://www/copyright.gov/docs/claimantfn*. The online form contains fields for required information including the name and organization of the commenter, as applicable, and the ability to upload comments as an attachment. To meet accessibility standards, all comments must be uploaded in a single file in either the Adobe Portable Document File (PDF) format that contains searchable, accessible text (not an image); Microsoft Word; WordPerfect; Rich Text Format (RTF); or ASCII text file format (not a scanned document). The maximum file size is 6 megabytes (MB). The names of the submitter and, if applicable, the organization should appear on both the form and the face of the comments. All comments will be posted publicly on the Copyright Office Web site exactly as they are received, along with names and organizations. If electronic submission of comments is not feasible, please contact the Copyright Office at 202–707–8380 for special instructions.

FOR FURTHER INFORMATION CONTACT: Robert Kasunic, Deputy General Counsel, Copyright Office, GC/I&R, P.O. Box 70400, Washington, DC 20024. Telephone: (202) 707–8380. Fax: (202) 707–8366.

SUPPLEMENTARY INFORMATION: On May 17, 2012, the Copyright Office published a Notice of Proposed Rulemaking seeking comments on its proposal to amend the definition of a ''claimant'' by removing the footnote to the definition in § 202.3(a)(3)(ii). In response to this Notice, the Copyright Office received three comments that are posted on the Office's Web site at: *http://www.copyright.gov/docs/claimantfn/comments/index.html.*

At the conclusion of the comment period, the online comment submission form was removed from the Web site and was not replaced with a reply comment submission form during the established reply comment period. Although the Office is not aware of any attempts to submit a reply comment, the Copyright Office is extending the reply comment period in this rulemaking for an additional 30 days as a result of the error with the submission form, and invites replies to the initial comments submitted.

Dated: August 29, 2012.

David O. Carson,

General Counsel.

[FR Doc. 2012–21703 Filed 8–31–12; 8:45 am]

BILLING CODE 1410–30–P

POSTAL SERVICE

39 CFR Part 111

Retirement of *FASTforward* Technology

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: The Postal Service proposes to revise the *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) 602.5.0 to terminate the use of *FASTforward®* technology as a Move Update option for commercial First-Class Mail®, First-Class Package Service™, Standard Mail®, and Parcel Select Lightweight™ mailings.

DATES: We must receive comments on or before October 4, 2012.

ADDRESSES: Mail or deliver written comments to the Manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW., Room 4446, Washington DC 20260–5015. You may inspect and photocopy all written comments at USPS® Headquarters Library, 475 L'Enfant Plaza SW., 11th Floor N, Washington DC by appointment only between the hours of 9 a.m. and 4 p.m., Monday through Friday by calling 1–202–268–2906 in advance. Email comments, containing the name and address of the commenter, may be sent to: *MailingStandards@usps.gov,* with a subject line of ''*FASTforward* Discontinuation'' Faxed comments are not accepted.

FOR FURTHER INFORMATION CONTACT: Charles Hunt at 901–681–4651, or Bill Chatfield at 202–268–7278.

SUPPLEMENTARY INFORMATION: *FASTforward,* a licensed hardware/software change-of-address system, was developed in 1996 to enable Multi-Line Optical Character Reader (MLOCR) users a means to meet the Move Update requirement for their commercial mailings. Using the best technology then available, most of the *FASTforward* ''black boxes'' were 386/486 processors using secured cards and cabling operations. By 2009, many of the original black boxes were failing, and finding replacement parts became difficult. In February 2009, the USPS™ announced its intention to retire the *FASTforward* system by the end of FY2012 and migrate the licensees to the newer, more robust NCOALink® MPE (Mail Processing Equipment) licensed software system.

In August 2011, the USPS established an ad hoc workgroup consisting of postal personnel, MLOCR manufacturers, mailers, and representatives of the National Association of Presort Mailers (NAPM). The workgroup has worked to resolve all issues, enabling a smooth migration from the antiquated *FASTforward* system to the newer NCOALink MPE system.

NCOALink MPE licensees will have the option of upgrading their agreement to provide an electronic list of COA information to the mail owner, in addition to directly applying new addresses on mailpieces. However, use of the NCOALink MPE process to apply updated addresses on mailpieces will suffice by itself to meet the Move Update standard.

The Postal Service recognizes that not all affected mailers may have been able to participate in the workgroup. Also, the fees for use of NCOALink MPE system may be higher for some mailers than the fees for *FASTforward.* Therefore, the Postal Service invites comments on the proposal by means of this notice. The termination date for *FASTforward* would be January 27, 2013. Mailers may begin to use the NCOALink MPE system at any time as a method of meeting the Move Update standards.

The Postal Service accordingly proposes the following changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), which is incorporated by reference in the Code of Federal Regulations. See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is proposed to be amended as follows:

PART 111—[AMENDED]

1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

2. Revise the following sections of the *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM):

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM):

* * * * *

500 Additional Mailing Services

* * * * *

507 Mailer Services

* * * * *

4.0 Address Correction Services

* * * * *

[Delete current 4.3, FASTforward, in its entirety.]

[Renumber current 4.4 as new 4.3.]

* * * * *

600 Basic Standards for All Mailing Services

* * * * *

602 Addressing

* * * * *

5.0 Move Update Standards

* * * * *

5.2 USPS-Approved Methods

The following methods are authorized for meeting the Move Update standard:

* * * * *

[Revise item 5.2b as follows:]

b. National Change of Address Linkage System (NCOALink). This includes both pre-mail NCOALink processing systems and the physical mailpiece processing equipment system: National Change of Address Linkage System Mail Processing Equipment (NCOALink MPE). See the NCOALink page (NCOALink MPE Solutions) on *ribbs.usps.gov* for more information on the MPE application.

[Delete item 5.2c in its entirety and redesignate current items 5.2d and 5.2e as new 5.2c and 5.2d respectively.]

* * * * *

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes if our proposal is adopted.

Stanley F. Mires,

Attorney, Legal Policy and Legislative Advice.

[FR Doc. 2012–21738 Filed 8–31–12; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

39 CFR Part 966

Rules of Practice in Proceedings Relative to Administrative Offsets Initiated Against Former Employees of the Postal Service

AGENCY: Postal Service.

ACTION: Proposed rule.

SUMMARY: This document proposes revisions to the rules of practice of the Judicial Officer in proceedings relative to administrative offsets initiated against former employees of the Postal Service. These revisions would update the rules to reflect changes in the Postal

Service's debt collection regulations and procedures. This document also proposes minor revisions to eliminate outdated provisions and conform the rules to the Judicial Officer's existing practice.

DATES: Comments must be received on or before October 4, 2012.

ADDRESSES: Mail or deliver written comments to the Office of the Judicial Officer, United States Postal Service, 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201–3078. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, at the above address.

FOR FURTHER INFORMATION CONTACT: Administrative Judge Gary E. Shapiro, 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201–3078; Telephone: (703) 812–1900.

SUPPLEMENTARY INFORMATION:

A. Executive Summary

The rules of practice in proceedings relative to administrative offsets initiated against former employees of the Postal Service are set forth in 39 CFR part 966. The Postal Service is concurrently revising its regulations pertaining to collecting debts from former employees contained in the Postal Service Employment and Labor Relations Manual (ELM). These ELM revisions conform existing Postal Service regulations to the requirements of the Debt Collection Act. The revisions proposed in this document would revise 39 CFR part 966 to bring its provisions into accord with the Postal Service's revised regulations for collecting debts from former employees by administrative offset. In addition, minor changes would be made to eliminate outdated provisions and conform these rules to the existing practice of the Judicial Officer.

B. Summary of Proposed Changes

Changes to § 966.2(a) cross reference the Postal Service's new ELM provisions pertaining to administrative offsets and also clarify that such offsets are taken pursuant to the statutory authority of 31 U.S.C. 3716. Changes to § 966.2(b) clarify that the regulations contained in 39 CFR part 966 are intended to be consistent with the Federal Claims Collection Standards promulgated jointly by the Department of Justice and the Treasury, found at 31 CFR parts 900–904.

Changes to § 966.3 update the definitions of part 966 to refer to the Postal Service Accounting Service Center (ASC) or successor installation instead of the area Postmaster/Installation head. The definition of ''reconsideration'' in paragraph (i) is thus revised to refer to action taken by the ASC. These changes accurately reflect the Postal Service's current practices for collecting debts from former employees, as collections from former employees are normally handled through the ASC. Definitions are also updated to include the Federal Claims Collection Standards, referenced elsewhere in the revised regulations. Changes to paragraph (j) are non-substantive and provide the parties with useful contact information.

Changes to § 966.4 revise the procedures for filing a petition for a hearing under part 966. These revisions align these regulations with the Postal Service's revised ELM regulations pertaining to collecting debts from former employees by administrative offset, the Postal Service's current debt collection procedures, and current practice before the Judicial Officer. Paragraphs (a)(2) and (3) are revised to cross reference and incorporate the Postal Service's ELM provisions, as well as the relevant section of the Debt Collection Act, that detail the notice and due process rights former Postal Service employees are afforded prior to the collection of a debt by administrative offset. Changes to these paragraphs clarify that a former employee may petition for review under part 966 either after receiving the required notice and requesting and receiving a reconsideration determination from the ASC, or after requesting reconsideration but not receiving a determination within 60 days from the request. Changes to paragraph (b) detail those situations whereby the Postal Service may take an administrative offset without affording an opportunity for pre-deprivation review to the former employee. In accordance with the Judicial Officer's current practice and applicable law, these changes further clarify that where prior notice and an opportunity for review are omitted and the circumstances outlined in revised paragraphs (b)(2), (3) and/or (4) do not apply, the former employee may submit a petition for review under part 966 following the offset. Changes to paragraph (c) clarify the procedural time limits for filing a petition for review under revised part 966. In conformance with revisions made elsewhere to part 966, ''Accounting Service Center'' is substituted for ''Postmaster/Installation Head'' in paragraph (d)(4). The remaining revisions to paragraph (d) are intended to modernize requirements for the content of hearing petitions.

In § 966.6, paragraph (a) is revised to reflect the Recorder's correct hours, delete the requirement that parties submit documents in triplicate, and clarify that parties should serve papers directly with each other unless otherwise directed by the Hearing Official. Paragraph (c) explicitly requires that parties discuss extensions of time with the opposing party, as is the current practice. Paragraph (d) clarifies that the General Counsel may delegate cases to a designee and establishes a notice of appearance requirement in order to reduce the possibility of misdirected orders. In addition, paragraph (d) is revised to allow for non-attorney representatives. In current practice, former employees are often represented by non-attorneys.

Section 966.7 is revised to simplify the answer's content, eliminate the need for the Postal Service's representative to provide certain information prematurely, and require that the answer clearly explain the basis and calculation of the debt at issue.

Changes to § 966.8(a)(3), (6), and (7) conform the regulations to the existing practice of the Judicial Officer. Changes to § 966.8(a)(9) similarly reflect the Judicial Officer's existing practice and provide notice to parties that time extensions will not be automatically granted.

Changes to § 966.9 update the regulation to reflect the existing practice of the Judicial Officer pertaining to hearing transcripts, as well as the Hearing Official's ability, in case of a party's unexcused absence, to continue with a hearing at the Hearing Official's discretion.

Section 966.11 is revised to provide that the Initial Decision of the presiding Administrative Judge may become the final determination of the Postal Service without any further order by the Judicial Officer, so long as no appeal has been filed and the Judicial Officer has not decided to review the decision on his or her own motion.

Formerly, § 966.12 detailed only circumstances under which the Petitioner could be found in default and administrative offset could thus be initiated. As revised, § 966.12 provides for circumstances under which either party may be found in default. This change is in accordance with existing practice and decisions of the Judicial Officer.

Section 966.13 is revised to reflect more accurately the definition of ''ex parte'' discussions in the context of proceedings brought under part 966.

Sections 966.5 and 966.10, dealing respectively with the effect of filing a petition, and the initial decision of the Hearing Official, are retained without change.

C. Effective Dates and Applicability

These revised rules would begin to govern proceedings under part 966 docketed on or after 30 days from their publication in final form.

List of Subjects in 39 CFR Part 966

Administrative practice and procedure, claims, Government employees, wages.

For the reasons stated in the preamble, the Postal Service proposes to amend 39 CFR part 966 as set forth below:

PART 966—RULES OF PRACTICE IN PROCEEDINGS RELATIVE TO ADMINISTRATIVE OFFSETS INITIATED AGAINST FORMER EMPLOYEES OF THE POSTAL SERVICE

1. The authority citation for 39 CFR part 966 is revised to read as follows:

Authority: 31 U.S.C. 3716; 39 U.S.C. 204, 401, 2601.

2. Section 966.2 is revised to read as follows:

§ 966.2 Scope of Rules.

(a) The rules in this part apply to any petition filed by a former postal employee:

(1) To challenge the Postal Service's determination that he or she is liable to the Postal Service for a debt incurred in connection with his or her Postal Service employment, that the Postal Service intends to collect by administrative offset pursuant to the authority of 31 U.S.C. 3716 and in accordance with the regulations contained in the Employee and Labor Relations Manual, sections 470 and 480; and/or

(2) To challenge the administrative offset schedule proposed by the Postal Service for collecting any such debt.

(b) The regulations in this part are consistent with the provisions of the Federal Claims Collection Standards pertaining to administrative offset.

3. Section 966.3 is revised to read as follows:

§ 966.3 Definitions.

(a) *Accounting Service Center* refers to the United States Postal Service Eagan Accounting Service Center or its successor installation.

(b) *Administrative offset* refers to the withholding of money payable by the Postal Service or the United States to, or held by the Postal Service or the United States for, a former employee in order to satisfy a debt determined to be owed by the former employee to the Postal Service.

(c) *Debt* refers to any amount determined by the Postal Service to be owed to the Postal Service by a former employee.

(d) *Federal Claims Collection Standards* or *FCCS* refers to regulations promulgated by the Department of Justice and the Department of the Treasury and codified at 31 CFR parts 900–904.

(e) *Former employee* refers to an individual whose employment with the Postal Service has ceased. An employee is considered formally separated from the Postal Service rolls as of close of business on the effective date of his or her separation.

(f) *General Counsel* refers to the General Counsel of the Postal Service, and includes a designated representative.

(g) *Hearing Official* refers to an Administrative Law Judge qualified to hear cases under the Administrative Procedure Act, an Administrative Judge appointed under the Contract Disputes Act of 1978, or any other qualified person licensed to practice law designated by the Judicial Officer to preside over a hearing conducted pursuant to this part.

(h) *Judicial Officer* refers to the Judicial Officer, Associate Judicial Officer, or Acting Judicial Officer of the Postal Service.

(i) *Reconsideration* refers to the review of an alleged debt and/or the proposed offset schedule conducted by the Accounting Service Center at the request of a former employee alleged to be indebted to the Postal Service.

(j) *Recorder* refers to the Recorder, Judicial Officer Department, United States Postal Service, 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201–3078. The recorder's telephone number is (703) 812–1900, and the Judicial Officer's Web site is *http://about.usps.com/who-we-are/judicial/welcome.htm.* The fax number is (703) 812–1901.

4. Section 966.4 is revised to read as follows:

§ 966.4 Petition for a hearing and supplement to petition.

(a) A former employee who is alleged to be responsible for a debt to the Postal Service may petition for a hearing under this part, provided:

(1) Liability for the debt and/or the proposed offset schedule has not been established under part 452.3 or part 462.3 of the Employee & Labor Relations Manual (ELM);

(2) The former employee has received a Notice from the Accounting Service Center in compliance with section 472.1 of the ELM and the administrative offset provisions of the FCCS, informing the former employee of the debt and an offset schedule to satisfy the debt, the former employee's rights under 31 U.S.C. 3716(a), the right to request reconsideration of the debt and/or offset schedule from the Accounting Service Center, and the right to request review under this part; and

(3) The former employee has requested reconsideration of the Postal Service's determination of the existence or amount of the alleged debt and/or the offset schedule proposed by the Postal Service within thirty (30) calendar days of receiving the notice referenced in paragraph (a)(2), and either has received a reconsideration determination, or within sixty (60) calendar days from the reconsideration request has not received a reconsideration determination.

(b) Notwithstanding the provisions of this part, the Postal Service may omit the procedures for notice and reconsideration in this part under certain circumstances as set forth below:

(1) If the Postal Service first learns of the existence of the amount owed by the former employee when there is insufficient time before payment would be made to the former employee to allow for prior notice and an opportunity for review under this part. When prior notice and an opportunity for review are omitted, the Postal Service will give the former employee notice and an opportunity for review as soon as practicable and will promptly refund any money ultimately found not to have been owed. In such circumstances whereby prior notice and an opportunity for pre-deprivation review are omitted, the former employee may submit a petition for review under this part.

(2) If an agency (including the Postal Service) has already given the former employee any of the required notice and review opportunities set forth in the FCCS with respect to a particular debt. In such a situation, the Postal Service need not duplicate such notice and review opportunities before taking an administrative offset.

(3) If a former bargaining unit employee of the Postal Service pursues, in accordance with the applicable provisions of his or her CBA, a grievance concerning the Postal Service's claim, including, but not limited to, the existence of a debt owed to the Postal Service, the amount of such debt, and/or the proposed repayment schedule, and none of the circumstances set forth in ELM section 483.1 apply;

(4) If otherwise allowed by law, including, but not limited to, the administrative offset provisions of the FCCS.

(c) Within thirty (30) calendar days after the date of receipt of the Accounting Service Center's decision upon reconsideration, after the expiration of sixty (60) calendar days after a request for reconsideration where a reconsideration determination is not made, or following an administrative offset taken without prior notice and opportunity for reconsideration pursuant to paragraph (b)(1) of this section, the former employee must file a written, signed petition, requesting a written or oral hearing, with the Recorder, Judicial Officer Department, United States Postal Service, 2101 Wilson Boulevard, Suite 600, Arlington, VA 22201–3078.

(d) The petition must include the following:

(1) The words, ''Petition for Review Under 39 CFR Part 966'';

(2) The former employee's name;

(3) The former employee's home address, email address (if available), and telephone number, and any other address and telephone number at which the former employee may be contacted about these proceedings;

(4) A statement of the date the former employee received the Accounting Service Center's decision upon reconsideration of the alleged debt and a copy of the decision;

(5) A statement of the grounds upon which the former employee objects to the Postal Service's determination of the debt or to the administrative offset schedule proposed by the Postal Service for collecting any such debt. This statement should identify with reasonable specificity and brevity the facts, evidence, and legal arguments, if any, which support the former employee's position; and

(6) Copies of all records in the former employee's possession which relate to the debt and which the former employee may enter into the record of the hearing.

(e) The former employee may, if necessary, file with the Recorder additional information as a supplement to the petition at any time prior to the filing of the answer to the petition under § 966.7, or at such later time as permitted by the Hearing Official upon a showing of good cause.

5. Section 966.6 is revised to read as follows:

§ 966.6 Filing, docketing and serving documents; computation of time; representation of parties.

(a) *Filing.* All documents required under this part must be filed by the former employee or the General Counsel with the Recorder. (The Recorder's normal business hours are between 8:45 a.m. and 4:45 p.m., eastern standard or daylight saving time as appropriate during the year.) Unless otherwise directed by the Hearing Official, the party filing any document shall send a copy thereof to the opposing party.

(b) *Docketing.* The Recorder will maintain a docket record of proceedings under this part and will assign each petition a docket number. After notification of the docket number, the former employee and General Counsel should refer to it on any further filings regarding the petition.

(c) *Time computation.* A filing period under the rules in this part excludes the day the period begins, and includes the last day of the period unless the last day is a Saturday, Sunday, or legal holiday, in which event the period runs until the close of business on the next business day. Requests for extensions of time shall be made in writing stating good cause therefor, shall represent that the moving party has contacted the opposing party about the request, or made reasonable efforts to do so, and shall indicate whether the opposing party consents to the extension.

(d) *Representation of parties.* After the filing of the petition, further document transmittals for, or communications with, the Postal Service shall be through its representative, the General Counsel, or designee. The representative of the Postal Service, as designated by the General Counsel, shall file a notice of appearance as soon as practicable, and no later than the date for filing the answer. If a former employee has a representative, further transmissions of documents and other communications by and with the former employee shall be made through his or her representative rather than directly with the former employee.

6. Section 966.7 is revised to read as follows:

§ 966.7 Answer to petition.

Within thirty (30) days after the date of receipt of the petition, the General Counsel shall file an answer to the petition, and attach all available relevant records and documents in support of the Postal Service's claim, or the administrative offset schedule proposed by the Postal Service for collecting any such claim. The answer shall provide a clear and detailed description of the basis for the Postal Service's determination of the alleged debt and its calculation of the amount of the alleged debt and/or its proposed offset schedule, as appropriate.

7. Section 966.8 is revised to read as follows:

§ 966.8 Authority and responsibilities of Hearing Official or Judicial Officer.

(a) In processing a case under this part, the Hearing Official's authority includes, but is not limited to, the following:

(1) Ruling on all offers, motions, or requests by the parties;

(2) Issuing any notices, orders, or memoranda to the parties concerning the hearing procedures;

(3) Conducting telephone conferences with the parties to expedite the proceedings (a memorandum of a telephone conference will be transmitted to both parties). The Hearing Official's Memorandum of Telephone Conference serves as the official record of that conference;

(4) Determining if an oral hearing is necessary, the type of oral hearing that would be appropriate, and setting the place, date, and time for such hearing;

(5) Administering oaths or affirmations to witnesses;

(6) Conducting the hearing in a manner to maintain discipline and decorum while assuring that relevant, reliable, and probative evidence is elicited on the disputed issues, and that irrelevant, immaterial, or repetitious evidence is excluded. The Hearing Official in his or her discretion may examine witnesses to ensure that a satisfactory record is developed;

(7) Establishing the record in the case. Except as the Hearing Official may otherwise order in his or her discretion, no proof shall be received in evidence after completion of an oral hearing or, in cases submitted on the written record, after notification by the Hearing Official that the case is ready for decision. The weight to be attached to any evidence of record will rest within the sound discretion of the Hearing Official. The Hearing Official may require either party, with appropriate notice to the other party, to submit additional evidence on any relevant matter;

(8) Issuing an initial decision or one on remand; and

(9) Granting reasonable time extensions or other relief for good cause shown.

(b) The Judicial Officer, in addition to possessing such authority as is described elsewhere in this part, shall possess all of the authority and responsibilities of a Hearing Official.

8. Section 966.9 is revised to read as follows:

§ 966.9 Opportunity for oral hearing.

An oral hearing generally will be held only in those cases which, in the opinion of the Hearing Official, cannot be resolved by a review of the

documentary evidence, such as when the existence, or amount, of a debt turns on issues of credibility or veracity. An oral hearing includes an in-person hearing, a telephonic hearing, or a hearing by video conference. When the Hearing Official determines that an oral hearing is not necessary, the decision shall be based solely on written submissions. The Hearing Official shall arrange for the recording and transcription of an oral hearing, which shall serve as the official record of the hearing. The unexcused absence of a party at the time and place set for hearing may not be occasion for delay at the discretion of the Hearing Official. In the event of such absence, the hearing may proceed without the participation of the absent party.

9. Section 966.11 is revised to read as follows:

§ 966.11 Appeal.

The initial or tentative decision will become the final agency decision thirty (30) days after its issuance unless, before the expiration of that time, a party files an appeal with the Judicial Officer, or the Judicial Officer, in his or her sole discretion, elects to conduct a review of the decision on his or her own initiative. During such review or appeal consideration, the Judicial Officer will accept all findings of fact in the original decision unless clearly erroneous. If following appeal or review, the Judicial Officer affirms the original decision, that decision becomes the final agency decision with no further right of appeal within the agency.

10. Section 966.12 is revised to read as follows:

§ 966.12 Waiver of rights.

(a) The Hearing Official may determine that the former employee has waived the right to a hearing, and that administrative offset may be initiated if the former employee files a petition for hearing after the period prescribed in these Rules and fails to demonstrate to the satisfaction of the Hearing Official good cause for the delay; or has filed a withdrawal of the former employee's previous petition for a hearing.

(b) The Hearing Official may determine that the Postal Service has waived the alleged debt at issue, and that the administrative offset may not be initiated if the Postal Service fails to file the answer within the period prescribed by the Rules and fails to demonstrate to the satisfaction of the Hearing Official good cause for the delay; or has filed a withdrawal of the debt determination at issue.

(c) In addition, whenever a record discloses the failure of either party to file documents required by these rules, respond to notices or correspondence from the Hearing Official, comply with orders of the Hearing Official, participate in conferences, fail to treat the proceedings with the proper decorum, or otherwise indicate an intention not to continue the prosecution or defense of a petition, the Hearing Official may issue an order requiring the offending party to show cause why the petition should not be dismissed or granted, as appropriate. If the offending party shall fail to show cause, the Hearing Official may take such action as he or she deems reasonable and proper under the circumstances, including dismissal or granting of the petition as appropriate.

11. Section 966.13 is revised to read as follows:

§ 966.13 Ex parte communications.

Ex parte communications are not allowed between a party and the Hearing Official or the Official's staff. For these purposes, ex parte communication means an oral or written communication, not on the public record, with one party only with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports or procedural matters. A memorandum of any communication between the Hearing Official and a party will be transmitted to both parties.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2012–21617 Filed 8–31–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 122

[EPA–HQ–OW–2012–0195; FRL–9722–5]

RIN 2040–AF42

Notice of Proposed Revisions to Stormwater Regulations To Clarify That an NPDES Permit Is Not Required for Stormwater Discharges From Logging Roads

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: The EPA is proposing revisions to its Phase I stormwater regulations to clarify that stormwater discharges from logging roads do not constitute stormwater discharges associated with industrial activity and that a National Pollutant Discharge Elimination System (NPDES) permit is not required for these stormwater discharges.

DATES: Comments must be received on or before October 4, 2012.

ADDRESSES: You may submit comments, identified by docket number EPA–HQ–OW–2012–0195, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Mail: Water Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, Attention Docket ID No. EPA–HQ–OW–2012–0195.
- Hand Delivery/Courier: EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OW–2012–0195. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket, visit the

EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information may not be publicly available, i.e., CBI or other information whose disclosure is restricted by statue. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Water Docket, EPA Docket Center, EPA/DC, EPA West, Room B102, 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 Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: For further information on this notice, you may contact Jeremy Bauer, EPA Headquarters, Office of Water, Office of Wastewater Management via email at *bauer.jeremy@epa.gov* or telephone at 202–564–2775.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Applicability

This notice does not impose requirements on any entity. The action proposed is intended to clarify the status of stormwater discharges from logging roads. Those with an interest in such discharges may be interested in this proposed action. If you have questions regarding the applicability of this notice, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Copies of This Document and Other Information

This document is available for download at *http://www.epa.gov/npdes/stormwater/forestroads* or under docket EPA–HQ–OW–2012–0195.

II. Background

A. Purpose

The EPA is issuing this notice to address the stormwater discharges identified under *Northwest Environmental Defense Center* v. *Brown,* 640 F.3d 1063 (9th Cir. 2011) (NEDC).

This notice proposes adding language to existing stormwater regulations to clarify that, for the purposes of assessing whether stormwater discharges are ''associated with industrial activity,'' the only facilities under SIC code 2411 that are ''industrial'' are: rock crushing, gravel washing, log sorting, and log storage. The effect of this would be to clarify, contrary to the Ninth Circuit's decision in NEDC, that discharges of stormwater from silviculture facilities other than the four specifically named silviculture facilities identified above do not require an NPDES permit.[1]

B. Statutory Authority and Regulatory History

The objective of the Clean Water Act is to restore and maintain the chemical, physical, and biological integrity of the nation's waters. 33 U.S.C. 1251(a). To that end, the Act provides that the discharge of any pollutant by any person shall be unlawful, except in compliance with other provisions of the statute. Generally, the Act provides for a permit program for the addition to waters of the United States of a pollutant from a point source, defined as ''any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged.'' 33 U.S.C. 1362(14). In 1987 Congress amended the Clean Water Act with the addition of section 402(p), which required NPDES permits for certain categories of stormwater point source discharges and allowed EPA discretion to determine how pollution from other stormwater discharges would be addressed.

For the initial phase, section 402(p)(1) created a temporary moratorium on NPDES permits for stormwater discharges from point sources except for those listed in section 402(p)(2), which includes discharges for which a permit had already been issued; discharges from large municipal separate storm sewer systems; and ''industrial discharges.'' Congress did not define industrial discharges, allowing the EPA to define the term. For subsequent phases, section 402(p)(5) directs the EPA to conduct studies, in consultation with the states, for ''identifying those stormwater discharges or classes of stormwater discharges for which permits are not required''; ''determining to the maximum extent practicable, the nature and extent of pollutants in such discharges''; and ''establishing procedures and methods to control stormwater discharges to the extent necessary to mitigate impacts on water quality.'' Section 402(p)(6) directs the Agency to issue regulations, in consultation with state and local officials, based on such studies. The section allows the EPA flexibility in issuing regulations to address designated stormwater discharges where appropriate and does not require the use of NPDES permits or any specific regulatory approach. Specifically, the section states that the regulations ''shall establish priorities, establish requirements for state stormwater management programs, and establish expeditious deadlines'' and may include ''performance standards, guidelines, guidance, and management practices and treatment requirements, as appropriate.'' 33 U.S.C. 1342(p)(6). This flexibility is unique to stormwater discharges and is different than the treatment of stormwater discharges listed in section 402(p)(2)(B) of the Act, which requires a permit for a stormwater discharge ''associated with industrial activity.''

Prior to the 1987 Amendments, there were numerous questions regarding the appropriate means of regulating stormwater discharges within the NPDES program due to the water quality impacts of stormwater, the variable nature of stormwater, the large number of stormwater discharges, and the limited resources of permitting agencies. The EPA undertook numerous regulatory actions, which resulted in extensive litigation, in an attempt to address these unique discharges.

EPA's Silvicultural Rule (40 CFR 122.27) predates the 1987 amendments to the Clean Water Act that created section 402(p) for stormwater controls. The Agency defined silvicultural point source as part of the Silvicultural Rule to specify which silvicultural discharges were to be included in the NPDES program. The rule defines silvicultural point source to mean any ''discernible, confined and discrete conveyance related to rock crushing, gravel washing, log sorting, or log storage facilities which are operated in connection with silvicultural activities and from which pollutants are discharged into waters of the United States'' and further explains that ''the term does not include non-point source silvicultural activities such as nursery operations, site preparation, reforestation and subsequent cultural

[1] This rulemaking responds to the uncertainty created by the Ninth Circuit's holding in *NEDC* that certain channeled discharges of stormwater from logging roads constitute point source discharges, bringing them within the Section 402 NPDES permitting framework. This proposed rule, by clarifying what constitutes a discharge ''associated with industrial activity,'' makes clear that such discharges do not require NPDES permits even if they are point source discharges. Nothing in this proposed rule should be construed as conceding that discharges of stormwater from logging roads constitute point source discharges, a question on which the Supreme Court has granted review for the October 2012 term.

treatment, thinning, prescribed burning, pest and fire control, harvesting operations, surface drainage, or road construction and maintenance from which there is natural runoff.''

In 1990, following the 1987 amendments that directed the Agency to develop regulations requiring permits for large municipal separate storm sewer systems and stormwater ''discharges associated with industrial activity,'' the EPA promulgated the Phase I stormwater regulations. (55 FR 47990, November 16, 1990). The EPA defined in the Phase I regulations ''storm water discharge associated with industrial activity'' which is not defined by the Act. In describing the scope of the term ''associated with industrial activity,'' several members of Congress explained in the legislative history that the term applied if a discharge was ''directly related to manufacturing, processing or raw materials storage areas at an industrial plant.'' (Vol. 132 Cong. Rec. H10932, H10936 (daily ed. October 15, 1986); Vol. 133 Cong. Rec. H176 (daily ed. January 8, 1987)). The Phase I rule clarified the regulatory definition of ''associated with industrial activity'' by adopting the language used in the legislative history and supplementing it with a description of various types of areas (e.g., material handling sites, sites used for the storage and maintenance of material handling equipment, etc.) that are directly related to an industrial process and to industrial facilities identified by the EPA. The supplemental language in the Phase I rule also includes the term ''immediate access road.'' The EPA considers ''immediate access roads'' to refer to roads which are exclusively or primarily dedicated for use by the industrial facility. *See* 55 FR 47990, 48009 (Nov. 16, 1990). These ''immediate access roads'' do not include public access roads that are state, county, or federal roads such as highways or Bureau of Land Management roads which happen to be used by the facility. *See id.* The Phase I regulation defines the term ''storm water discharge associated with industrial activity'' to include stormwater discharges from facilities identified in the rule by standard industrial classification or ''SIC'' code at 40 CFR 122.26(b)(14). The Agency specified in the Phase I rule that the term does not include discharges from facilities or activities excluded from the NPDES program under other parts of the EPA's regulations, including the Silvicultural Rule. As discussed above, the EPA had previously specified under the Silvicultural Rule which silvicultural discharges were to be included in the NPDES program (40 CFR 122.27). The EPA intended to regulate those same ''silvicultural point source[s]'' under the Phase I rule (i.e., rock crushing, gravel washing, log sorting, and log storage facilities) and to exclude from the Phase I regulation stormwater runoff from other silvicultural activities. For the ''silvicultural point source[s]'' (i.e., rock crushing, gravel washing, log sorting, and log storage facilities) regulated under the Phase I rule, the term ''storm water discharge associated with industrial activity'' includes ''immediate access roads'' (40 CFR 122.26(b)(14)(ii)). Unlike ''immediate access roads'' associated with industrial facilities, many logging roads have multiple uses, including recreation and general transportation, and commonly extend over long distances (i.e.; may not provide ''immediate access'' to an industrial site). The intent of the EPA in this notice of proposed rulemaking is that the NPDES program requirements be implemented with regard to ''immediate access roads'' in the same way they were implemented prior to the decision by the Ninth Circuit.

In developing the second phase of stormwater regulations, the EPA submitted to Congress in March 1995 a report that presented the nature of stormwater discharges from municipal and industrial facilities that were not already regulated under the Phase I regulations (U.S. Environmental Protection Agency, Office of Water. 1995. Storm Water Discharges Potentially Addressed by Phase II of the National Pollutant Discharge Elimination System Storm Water Program: Report to Congress. Washington, DC EPA 833–K–94–002). On December 8, 1999, the EPA promulgated the Phase II stormwater regulations to address stormwater discharges from small municipal separate storm sewer systems and construction sites that disturb one to five acres. (64 FR 68722, December 8, 1999). The EPA retains the authority to designate additional stormwater discharges for regulation at a later date under either CWA section 402(p)(2)(E) or 402(p)(6).

The Phase II regulations for stormwater controls were challenged in *Environmental Defense Center* v. *US EPA,* 344 F.3d 832 (9th Cir. 2003) (*EDC* v. *EPA*). In that case, petitioners contended that the EPA arbitrarily failed to regulate discharges from forest roads under the Phase II rule. The court held that the EPA failed to consider the petitioners' comments and remanded the issue to the EPA ''so that it may consider in an appropriate proceeding Petitioner's contention that § 402(p)(6) requires the EPA to regulate forest roads. The EPA may then either accept Petitioners' arguments in whole or in part, or reject them on the basis of valid reasons that are adequately set forth to permit judicial review.'' Id. at 863.

More recently, in *Northwest Environmental Defense Center* v. *Brown,* 640 F.3d 1063 (9th Cir. 2011) (*NEDC*), a citizen suit was filed alleging violations of the Clean Water Act for discharging stormwater from ditches alongside two logging roads in state forests without a permit. The court held that because the stormwater runoff from the two roads in question is collected by and then discharged from a system of ditches, culverts and channels, there was a point source discharge of industrial stormwater for which an NPDES permit is required. As discussed above, the Agency specified in the Phase I rule that the term ''storm water discharge associated with industrial activity'' does not include discharges from facilities or activities excluded from the NPDES program under other parts of the EPA's regulations, including the aforementioned Silvicultural Rule. The EPA intends through this regulation to more clearly limit Phase I applicability to only those silvicultural facilities that are ''rock crushing, gravel washing, log sorting, and log storage facilities.''

In response to the partial remand under *EDC* v. *EPA,* the Agency continues to review available information on the water-quality impacts of stormwater discharges from forest roads, which include logging roads as discussed above, as well as existing practices to control those discharges and is considering a range of options to address such discharges, which could include designating a subset of stormwater discharges from forest roads for regulation under the Agency's section 402(p) rulemaking authority. The EPA believes that the broad range of flexible approaches under section 402(p)(6) may be well suited to address the complexity of forest road ownership, management, and use. EPA is currently evaluating comments on its *Notice of Intent to Revise Stormwater Regulations To Specify That an NPDES Permit is Not Required for Stormwater Discharges From Logging Roads and To Seek Comment on Approaches for Addressing Water Quality Impacts From Forest Road Discharges* (77 FR 30473, May 23, 2012), as it considers possible next steps.

In the interim, the EPA notes that Congress has directed that permits are not required for stormwater discharges

for logging roads. Under the Consolidated Appropriations Act of 2012, until September 30, 2012, the Administrator may not require an NPDES permit or directly or indirectly require any state to require a permit, for discharges of stormwater runoff from roads, the construction, use, or maintenance of which are associated with silvicultural activities.

III. Proposed Revisions and Rationale

A. Proposed Revisions

The EPA is proposing to revise 40 CFR 122.26(b)(14)(ii) to clarify that for the purposes of defining stormwater discharges associated with industrial activity, the only activities under SIC code 2411 that are ''industrial'' are rock crushing, gravel washing, log sorting, and log storage. This revision does not remove any existing exemptions. Though the existing language in 40 CFR 122.26(b)(14)(ii) excepts SIC code 2434, wood kitchen cabinets, the wood kitchen cabinets category remains covered in a separate subsection. *See id.* at 122.26(b)(14)(xi) (listing ''Facilities covered under Standard Industrial Classifications 20, 21, 22, 23, 2434 * * *'' as engaging in industrial activity for purposes of the industrial stormwater regulations.)

B. Rationale

The EPA did not intend logging roads themselves to be regulated as industrial facilities. However, in light of *NEDC,* the EPA proposes the addition of language to 40 CFR 122.26(b)(14) to clarify the Agency's intent.

The EPA believes that stormwater discharges from forest roads, including logging roads, should be evaluated under section 402(p)(6) of the Clean Water Act because the section allows for a broad range of flexible approaches that may be better suited to address the complexity of forest road ownership, management, and use.

C. Request for Comment

The EPA requests comment on whether the proposed language sufficiently clarifies that discharges of stormwater from logging roads do not require an NPDES permit. The EPA does not think that changes to 40 CFR 122.27 are necessary to accomplish the goal of clarifying the scope of stormwater discharges associated with industrial activity, but welcomes comments on this point and reserves the option of making changes to that section as appropriate to clearly articulate the Agency's intent.

Although the EPA has conducted a preliminary review of the comments submitted in response to the ''Notice of Intent to Revise Stormwater Regulations To Specify That an NPDES Permit is Not Required for Stormwater Discharges From Logging Roads and To Seek Comment on Approaches for Addressing Water Quality Impacts From Forest Road Discharges'' (77 FR 30473, May 23, 2012), the Agency does not plan to respond to these comments when taking final action on the rule proposed in today's notice. If you submitted comments in response to the earlier Federal Register Notice that you believe to be relevant to the rule proposed today, please resubmit your comments in accordance with the process outlined above.

IV. Economic Impact

The proposed action clarifies existing regulations and has no economic, public health, or environmental impacts.

V. Statutory and Executive Order Review

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

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action.'' Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) requires the EPA to estimate the burden on regulated entities to comply with information collection requirements of the EPA's regulations. This proposed action would clarify existing regulations and would have no impact on existing information collection requirements.

C. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business ''as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201;'' (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. Rather, the proposed rule will clarify that stormwater discharges from logging roads do not constitute stormwater discharges associated with industrial activity and that an NPDES permit is not required for these stormwater discharges. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for state, local, or tribal governments or the private sector. This action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This proposed action would not have Federalism implications. This proposed action would clarify existing regulations and would have no economic impact. Thus, it would not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132.

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

This proposed action would not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). Thus, Executive Order 13175 does not apply to this proposed action.

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

The proposed action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866. Moreover, this proposed action would clarify existing regulations and would have no economic, public health, or environmental impacts.

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

The proposed action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Additionally, the proposed change does not involve the installation of treatment or other components that use a measurable amount of energy.

I. National Technology Transfer and Advancement Act

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

The proposed action would clarify existing regulations and would make no change to existing standards.

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

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

The EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The proposed action would clarify existing regulations and would have no economic, public health, or environmental impacts.

List of Subjects 40 CFR Part 122

Environmental protection, water pollution control.

Dated: August 24, 2012.

Lisa P. Jackson,

Administrator.

For the reasons set out in the preamble, 40 CFR part 122 is proposed to be amended as follows:

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

1. The authority citation for part 122 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

Subpart B—[Amended]

2. Section 122.26 is amended by revising paragraph (b)(14)(ii) to read as follows:

§ 122.26 Storm water discharges (applicable to State NPDES programs, see § 123.25).

* * * * *

(b) * * *

(14) * * *

(ii) Facilities classified within Standard Industrial Classification 24, Industry Group 241 that are rock crushing, gravel washing, log sorting, or log storage facilities operated in connection with silvicultural activities defined in 40 CFR 122.27(b)(2)–(3) and Industry Groups 242 through 249; 26 (except 265 and 267), 28 (except 283), 29, 311, 32 (except 323), 33, 3441, 373; (not included are all other types of silviculture facilities);

* * * * *

[FR Doc. 2012–21432 Filed 8–31–12; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 77, No. 171

Tuesday, September 4, 2012

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Shasta-Trinity National Forest; California; East McCloud Plantations Thinning Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service will prepare an environmental impact statement (EIS) to evaluate and disclose the predicted effects of the East McCloud Plantations Thinning project, which would treat conifer plantations on approximately 9,266 acres to improve forest health and increase resiliency to natural events such as drought, insect and disease infestations and severe wildfire. Treatments would include commercial and non-commercial thinning and hazardous fuels reduction using mechanical and hand methods. Proposed connected actions include road maintenance and reconstruction of National Forest System, new road construction and addition of new roads and selected existing unauthorized routes to the Forest Transportation System to support future management activities. The project is located in Siskiyou and Shasta Counties, California, on the northeast corner of the Shasta-McCloud Management Unit of the Shasta-Trinity National Forest. The project's legal description is: Portions of Township (T.) 39 North (N.), Range (R.) 1–3 East (E.); T. 40 N., R. 2, 3 E.; T. 41 N., R. 2–4 E.; T. 42 N., R. 3, 4 E., MBM. The project area is approximately 18 miles northeast of the town of McCloud, California, and 70 miles northeast of Redding, California.

DATES: Comments concerning the scope of the analysis must be received by October 3, 2012. The draft environmental impact statement is expected in July 2013 and the final environmental impact statement is expected November 2013.

ADDRESSES: Send written comments to Nisha van Hees, USDA Forest Service, Shasta McCloud Management Unit, 204 West Alma Street, Mount Shasta, California 96067. Comments may also be sent via email to *comments-pacificsw-shasta-trinity-mtshasta-mccloud@fs.fed.us* or via facsimile to (530) 926–9678. Verbal comments must be received in person at the Mt. Shasta Ranger Station, 204 West Alma Street in Mt. Shasta, California, or by telephone at (503) 926–9664 during normal business hours (8:00 a.m.–4:30 p.m.).

FOR FURTHER INFORMATION CONTACT: Nisha van Hees, TSI Program Manager/District Culturist, at 530–926–9664.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

Past reforestation activities in the project area have resulted in hundreds of dense conifer plantations which will soon reach or already exceed site capability to sustain healthy and vigorous trees. Competition for limited water, sunlight, and nutrients as well as high tree density have resulted in decreasing growth rates and increasing susceptibility to major insect attacks and other factors such as drought, root disease, storm damage, mistletoe infestations and severe wildfire. Recent drought conditions in the western United States have put additional environmental stress on plantations that are growing at high stand densities such as those in the project area.

Current conditions cannot sustain plantation capacity to meet the future stand growth, production, and development potential needed to meet the goals and future desired conditions directed in the Shasta-Trinity National Forest's Land and Resource Management Plan (Forest Plan). The Forest Service proposes to reduce competition in selected plantations at this time to promote the development of mature forests and reduce the probability of density- and drought-related mortality in the plantations.

Approximately one hundred years of fire suppression have contibuted to the current conditions of overcrowding and trending towards slow tree growth, low stand health, and density-related mortality. The project area is susceptible to uncharacteristically severe, stand-destroying wildfire due to the increasing surface fuel accumulation, tree density and number of dead trees in the canopy. The exclusion of fire has also resulted in understory vegetation extending into the forest canopy creating fuel ladders into the overstory vegetation. In the case of a wildfire during the summer season, fire behavior modeling predicts rates of spread, flame lengths, and resistance to control that would contribute to significant mortality and post-fire damage in plantations. The project is needed at this time to restore and sustain healthy, disturbance-resilient ecosystems by reducing woody fuels, forest densities and landscape homogeneity.

Proposed Action

The proposed action would treat conifer plantations ranging from 4–55 years of age; ranging in size from approximately one-third to 300 acres, using the following silvicultural prescriptions: (1) Thin from below on 5,173 acres using mechanical and hand methods; (2) Thin from below combined with mastication to remove 55–90 percent of the brush on 2,333 acres; (3) Mastication only on 1,760 acres in areas with small diameter trees and dense or large brush (all acres are approximate).

About 93 percent of the proposed treatment acres are outside the designated Late Successional Reserves (LSR). Thinning outside of the LSR would include retention of tall healthy trees with large crowns. Minimum spacing would leave 45–100 trees per acre depending on age, species, site quality, and average tree size. Within the LSR, thinning would vary to further enhance valuable habitat components such as species and structural diversity. Variable spacing that includes tree retention based on habitat value would leave 45–120 trees per acre across 90 percent of unit areas. About 10 percent of each unit would remain untreated.

In all management prescriptions, the proposed action would radial thin around rust-resistant sugar pine and some hardwoods, including black oak; remove most competing conifers in and near aspen clones; and prune residual trees at variable heights. Most of the

plantations include islands of residual trees that pre-date the plantations which would be left untreated to provide diverse structure and habitat within the plantations.

About 80% of the treatment acres would have wood products removed using whole-tree-yarding to designated landings.

One or more of these secondary treatments, depending on site conditions, would follow the primary silvicultural treatments: (1) Masticate competing brush; (2) pile and burn activity fuels; (3) lop and scatter activity fuels; and (4) pull slash back or chip within 50 feet of National Forest System roads. Secondary treatments address predicted wildfire behavior by reducing hazardous fuels conditions.

The project would be accomplished under several Service and Timber Sale Contracts over a period of several years, dependent upon funding. Plantations to be treated are generally put together in contracts of 300 to 600 acres in size and located close to one another to be operationally and economically feasible. Additional vegetation and road treatments would be completed with Forest Service employees and agency owned machinery (i.e., force account), Youth Conservation Corp Crews, California Conservation Corp Crews and/or volunteers as funding allows. Treatment activities and road actions would occur between approximately May 1 and October 15 each year. Plantations with poor stand health and vigor and/or high fuel hazards would be treated first. Commercial removal units would be scheduled as soon as possible. Upon award, the average Service Contract vegetation treatment and related road closures would generally be completed within 18 months. Timber Sale Contracts can take anywhere from 1 to 5 years from award to completion. Associated road closures would occur upon completion of an activity in each contract/sale area boundary.

Road management activities necessary to implement the proposed action and also needed for future management activities include: 126 miles of road maintenance and 36 miles of reconstruction on National Forest System (NFS) roads. Existing unauthorized routes totaling 33 miles are proposed to be added to the NFS (these routes are currently open roads that are not part of the National Forest system under the Shasta-Trinity National Forests Motorized Travel Management, Final Environmental Impact Statement, 2010); and construction of 24 segments totaling 5.5 miles of new roads that would be added to the system.

Eighteen miles of existing unauthorized routes and 3.5 miles of new temporary roads would be decommissioned within 1–3 years of project conclusion.

Approximately 462 landings up to one-half acre in size (or up to one-quarter acre in the LSR) would be located within or near plantation boundaries where wood products would be removed.

Landings and skid trails would be rehabilitated when no longer needed for this project. Maintenance Level 1 (intermittent use) roads would be closed within 1–3 years of each contracts completion, until needed for future management activities.

The Proposed Action implements the Forest Plan standards and guides, management recommendations in the Forestwide Late Successional Reserve Assessment, the Forest's Fire Management Plan, and Regional Ecosystem Office guidance. Additional site-specific project design features and best management practices would be used to further protect resources. Coordination and consultation with the U.S. Fish and Wildlife Service will continue and consultation with the State Historic Preservation Office and Tribes is planned.

Responsible Official

J. Sharon Heywood, Forest Supervisor, Shasta-Trinity National Forest.

Nature of Decision To Be Made

The Forest Supervisor will decide whether to implement the proposed action, take an alternative action that meets the purpose and need, or take no action.

Permits or Licenses Required

A permit would be required from the State of California prior to burning piles. Storm Water Permits: The appropriate regulatory agencies will be consulted regarding national or state required permits associated with roads used in project implementation. Required permits will be obtained prior to implementation.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Include the following information with your comments: your name, address, email (optional), and telephone number; the project name: East McCloud Plantations Thinning Project; and site-specific comments about the proposed action, along with supporting information you believe will help identify issues, develop alternatives, or predict environmental effects of this proposal. The most useful comments provide new information or describe unwanted environmental effects potentially caused by the proposed action. If you reference scientific literature in your comments, you must provide a copy of the entire reference you have cited and include rationale as to how you feel it is pertinent to the East McCloud Plantations Thinning Project.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however.

Dated: August 21, 2012.

J. Sharon Heywood,

Forest Supervisor.

[FR Doc. 2012–21712 Filed 8–31–12; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Missoula County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Lolo National Forest's Missoula County Resource Advisory Committee (RAC) will meet on Monday, September 24, 2012 from 4:00 p.m. to 6:00 p.m., in Missoula, Montana. The purpose of the meeting is to review and vote on submitted proposals, and receive public comment on the meeting subjects and proceedings.

DATES: Monday, September 24, 2012 from 4 p.m. to 6 p.m.

ADDRESSES: Missoula County Courthouse, Room Admin B14; 199 W Pine St. Missoula, Mt 59802.

FOR FURTHER INFORMATION CONTACT: Boyd Hartwig; Address: Lolo National Forest, Building 24A Fort Missoula, Missoula, Montana 59804; Phone: 406–329–1024 email: *bchartwig@fs.fed.us.*

SUPPLEMENTARY INFORMATION: Agenda items to be covered include: (1) Review

of individual member proposal rankings (2) brief discussion of proposals (3) vote on proposals in order of ranking (4) receive public comment (5) review old business. There will be an open comment period for the public at the start of the meeting.

Dated: August 27, 2012.

Paul Matter,

Missoula District Ranger.

[FR Doc. 2012–21646 Filed 8–31–12; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Delta-Bienville Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Delta-Bienville Resource Advisory Committee will meet in Forest, Mississippi. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose of the meeting is to discuss the progress and status of approved and completed RAC projects.

DATES: The meeting will be held on September 20, 2012, and will begin at 6:00 p.m.

ADDRESSES: The meeting will be held at the Bienville Ranger District Work Center, Hwy 501 South, 935A South Raleigh St., Forest, Mississippi 39074. Written comments should be sent to Michael T. Esters, Bienville Ranger District Office, 3473 Hwy 35 South, Forest, Mississippi 39074. Comments may also be sent via email to *mesters@fs.fed.us,* or via facsimile to 601 469–2513.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Bienville Ranger District Office, 3473 Hwy 35 South, Forest, Mississippi 39074. Visitors are encouraged to call ahead to 601 469–3811 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Nefisia Kittrell, RAC coordinator, USDA, Bienville Ranger District Office, 3473 Hwy 35 South, Forest, Mississippi; (601) 469–3811; Email *nkittrell@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) The purpose of the meeting is to discuss the progress and status of approved and completed RAC projects. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: August 28, 2012.

Michael T. Esters,

Designated Federal Officer.

[FR Doc. 2012–21647 Filed 8–31–12; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Amador County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Amador County Resource Advisory Committee will meet in Sutter Creek, California. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 112–141) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is to discuss the committee's processes and procedures, review applications, and make recommendations for projects to be approved.

DATES: The meeting will be held September 20, 2012, 6 p.m.

ADDRESSES: The meeting will be held at the Amador County Public Health Building, Conference Room A; 10877 Conductor Road, Sutter Creek, CA.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Eldorado National Forest Headquarters Office; 100 Forni Road, Placerville, CA. Please call ahead to (530) 622–5061 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Frank Mosbacher, Resource Advisory Committee Coordinator, Forest headquarters, 100 Forni Road, Placerville, CA (530) 621–5268, TTY (530) 642–5122, *fmosbacher@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The following business will be conducted: review and discuss the committee's processes and procedures, review project proposals, and make recommendations for projects to be approved. The full agenda will be posted on the Web at: *https://fsplaces.fs.fed.us/fsfiles/unit/wo/secure_rural_schools.nsf/Web_Agendas?OpenView&Count=1000&RestrictToCategory=Amador+County.* Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 18, 2012 to be scheduled on the agenda. Written comments and requests for time for oral comments must be sent to Frank Mosbacher, RAC Coordinator; 100 Forni Road; Placerville, CA 95667 or by email to *fmosbacher@fs.fed.us,* or via facsimile to 530–621–5297. A summary of the meeting will be posted at *https://fsplaces.fs.fed.us/fsfiles/unit/wo/secure_rural_schools.nsf/Web_Agendas?OpenView&Count=1000&RestrictToCategory=Amador+County* within 21 days of the meeting.

Meeting Accommodations: If you require sign language interpreting, assistive listening devices or other reasonable accommodation please request this in advance of the meeting by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 28, 2012.

Kathryn D. Hardy,

Forest Supervisor, Eldorado National Forest.

[FR Doc. 2012–21648 Filed 8–31–12; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Ashley Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Ashley Resource Advisory Committee will meet in Vernal, Utah. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub.L 110–343) and in compliance with the Federal Advisory Committee Act. The purpose of the meeting is conduct introductions, approve meeting minutes, review available short form project proposals, set the next meeting date, time and location and receive public comment on the meeting subjects and proceedings.

DATES: The meetings will be held September 19, 2012, from 6 p.m. to 9 p.m.

ADDRESSES: The meeting will be held in the Supervisor's Office conference room at the Ashley National Forest Supervisor's Office, 355 North Vernal Avenue in Vernal, Utah. Written comments should be sent to Ashley National Forest, 355 North Vernal Avenue, Vernal, UT 84078. Comments may also be sent via email to *ljhaynes@fs.fed.us,* or via facsimile to 435–781–5142.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Ashley National Forest, 355 North Vernal Avenue, Vernal, UT.

FOR FURTHER INFORMATION CONTACT: Louis Haynes, RAC Coordinator, Ashley National Forest, (435) 781–5105; email: *ljhaynes@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) Welcome and roll call; (2) Approval of meeting minutes; (3) Evaluation and voting to recommend project funding; (4) review of next meeting purpose, location, and date; (5) Receive public comment. Persons who wish to bring related matters to the attention of the Committee may file written statements with the committee staff before or after the meeting. Public input sessions will be provided and individuals who made written requests by September 15, 2012 will have the opportunity to address the committee at these meetings.

Dated: August 27, 2012.

John R. Erickson,

Forest Supervisor.

[FR Doc. 2012–21527 Filed 8–31–12; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

West Virginia Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The West Virginia Resource Advisory Committee will meet in Elkins, West Virginia. The committee is meeting as authorized under the one year extension of the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose is to recommend 2012 funding projects to the Deciding Federal Official.

DATES: The meetings will be held on September 17, 2012, and if necessary to complete business, also on September 21, 2012. Meetings will begin at 10:00 a.m.

ADDRESSES: The meetings will be held at the Monongahela National Forest Supervisor's Office, 200 Sycamore Street, Elkins, WV 26241. Written comments should be sent to Kate Goodrich-Arling at the same address. Comments may also be sent via email to *kgoodricharling@fs.fed.us,* or via facsimile to 304–637–0582.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Monongahela National Forest, 200 Sycamore Street, Elkins, WV 26241.

FOR FURTHER INFORMATION CONTACT: Kate Goodrich-Arling, RAC coordinator, USDA, Monongahela National Forest, 200 Sycamore Street, Elkins, WV 26241; (304) 636–1800; Email *kgoodricharling@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: All WV RAC meetings are open to the public. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting. Persons with special needs or to request a sign language interpreter, should contact Kate Goodric-Arling at the above number or addresses by September 10, 2012.

Dated: August 28, 2012.

DeVela J. Clark,

Deputy Forest Supervisor.

[FR Doc. 2012–21714 Filed 8–31–12; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Sabine Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Sabine Resource Advisory Committee will meet in Hemphill, Texas. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L 110–343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is to further discuss and finalize approved Title II Projects.

DATES: The meeting will be held on Thursday, September 13, 2012, 3:30 p.m.

ADDRESSES: The meeting will be held at the Sabine NF Office, 5050 State Hwy 21 East, Hemphill, TX 75948.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at 5050 State Hwy 21 East, Hemphill, TX 75948. Please call ahead to (409) 625–1940 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: William E. Taylor, Jr., Designated Federal Officer, Sabine National Forest, 5050 State Hwy. 21 E., Hemphill, TX 75948: Telephone: 936–639–8501 or email at: *etaylor@fs.fed.us.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–

800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The following business will be conducted: The purpose of the meeting is to further discuss and finalize approved Title II Projects. Please visit *http://fido.gov/facadatabase/default.asp* to view the full agenda or where more information is available. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 7, 2012 to be scheduled on the agenda. Written comments and requests for time for oral comments must be sent to 5050 State Hwy 21 East, Hemphill, TX 75948 or by email to *etaylor@fs.fed.us* or via facsimile to 409–625–1953. A summary of the meeting will be posted at *http://fido.gov/facadatabase/default.asp* within 21 days of the meeting.

Meeting Accommodations: If you require sign language interpreting, assistive listening devices or other reasonable accommodation please request this in advance of the meeting by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: August 27, 2012.

William E. Taylor, Jr.,

Designated Federal Officer, Sabine National Forest RAC.

[FR Doc. 2012–21525 Filed 8–31–12; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

International Trade Administration

Proposed Information Collection; Comment Request; Interim Procedures for Considering Requests and Comments From the Public Under the Commercial Availability Provision of the United States-Korea Free Trade Agreement

AGENCY: International Trade Administration, Department of 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.

DATES: Written comments must be submitted on or before November 5, 2012.

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 and instructions should be directed to Maria D'Andrea, Office of Textiles and Apparel, U.S. Department of Commerce, Tel. (202) 482–4058, *maria_dandrea@ita.doc.gov,* Fax. (202) 482–0667.

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States and Korea negotiated the US-Korea Free Trade Agreement (the ''Agreement'') which was implemented into U.S. law pursuant to the United States-Korea Free Trade Agreement Implementation Act (''the Act''). Under the provisions of the Act, textile and apparel goods must contain fibers, yarns, and fabrics produced in Korea or the United States to receive duty-free tariff treatment. The Agreement also provides for the establishment of a list of specific fibers, yarns, and fabrics that are not available in commercial quantities in a timely manner from producers in the United States. Articles containing these commercially unavailable fibers, yarns, and fabrics are also entitled to duty-free or preferential duty treatment despite not being produced in the United States.

The list of commercially unavailable fabrics, yarns, and fibers may be changed pursuant to the commercial availability provision of the Agreement and the Act. Under Section 202(o) of the Act (''the commercial availability provision''), interested entities from Korea or the United States have the right to request that a specific fiber, yarn, or fabric be added to, or removed from, the list of commercially unavailable fibers, yarns, and fabrics. This right becomes effective when the Agreement enters into force.

Section 202(o)(3)(F) of the Act requires that the President establish procedures for parties to follow when exercising the right to make these requests. The President delegated the responsibility for publishing the procedures and administering commercial availability requests to the Committee for the Implementation of Textile Agreements (CITA), which issues procedures and acts on requests through the Office of Textiles and Apparel (''OTEXA'').

The intent of these procedures is to foster the trade in U.S. and Korean textile and apparel articles by allowing non-originating fibers, yarns, and fabrics to be placed on or removed from a list of items not available in commercial quantities, on a timely basis, and in a manner that is consistent with normal business practice. To this end, these procedures are intended to facilitate the transmission, on a timely basis, of requests for commercial availability determinations and offers to supply the products that are the subject of the requests; have the market indicate the availability of the supply of the subject products; make available promptly, to interested entities and parties, information received regarding the requests for products and offers to supply; ensure wide participation by interested entities and parties; provide careful scrutiny of information provided to substantiate order requests and responses of offers to supply; and provide timely public dissemination of information used by CITA in making commercial availability determinations.

For a fiber, yarn or fabric to be added to Appendix 4–B–1, an interested entity must submit to CITA a Request for a Commercial Availability Determination (''Request'') which states that the subject product is not commercially available in the United States within a commercially reasonable timeframe (i.e., timely). In support of its claim, the requestor must provide information to CITA regarding its attempts to source the subject product in the United States, and why it determined that the product is not available in a timely manner. Potential suppliers from the United States may submit a Response with an Offer to Supply (''Response''), asserting their capability and capacity to supply the subject product. These Responses must include information supporting the capability and capacity assertion. If the requestor disputes a responder's assertions, the requestor may submit a Rebuttal comment offering its contention, along with supporting information and documentation.

The information collected by CITA from Requests, Responses and Rebuttals will be used to determine whether the subject product is available in commercial quantities in a timely manner in the United States under the commercial availability provision of the Act. Requests, Responses, and Rebuttals must identify confidential information.

Entities submitting confidential information in their Requests, Responses, or Rebuttals to CITA must submit both a public and a confidential version of their submissions. If the submissions are accepted, the public submissions or public versions of submissions will be posted on the dedicated commercial availability section of the OTEXA's Web site. Business confidential information will not be shared with the public. Requestors and potential suppliers of the product named in the Request may use the public version as a basis for Responses and Rebuttals.

Each submission containing factual information for CITA's consideration must be accompanied by the appropriate certification regarding the accuracy of the factual information. With each electronic and original signed submission that contains factual information, an interested entity must file a certification of due diligence, attesting to the accuracy and authenticity of the submission. If the interested entity has legal counsel or other representative, the legal counsel or other representative must also file a certification of due diligence with each electronic and original signed submissions that contains factual information. Accurate representations of material facts submitted to CITA for the Commercial Availability Proceeding are vital to the integrity of this process and are necessary for CITA's effective administration of the statutory scheme. Each submission containing factual information for CITA's consideration must be accompanied by the appropriate certification regarding the accuracy of the factual information. Any submission that lacks the applicable certifications will be considered an incomplete submission that CITA will reject and return to the submitter. CITA may verify any factual information submitted by interested entities in a Commercial Availability Proceeding.

II. Method of Collection

All submissions for a commercial availability proceeding pursuant to these procedures (e.g., Commercial Availability Request, Response, Rebuttal, and Request to Remove) must be in English. If any attachments are in a language other than English, a complete translation must be provided. Each submission must be submitted to the Chairman of CITA, in care of the U.S. Department of Commerce's Office of Textiles and Apparel in two forms: email and an original signed submission. An email version of the submission must be either in PDF or Word format, must contain an adequate public summary of any business confidential information and the due diligence certification, and should be sent to *OTEXA.KOREA@trade.gov.* The email version of the submission will be posted for public review on KOREA FTA Commercial Availability Web site. No business confidential information should be submitted in the email version of any document.

Brackets must be placed around all business confidential information contained in submissions. Documents containing business confidential information must have a bolded heading stating ''Confidential Version.'' Attachments considered business confidential information must have a heading stating ''Business Confidential Information.'' Documents, including those submitted via email, provided for public release must have a bolded heading stating ''Public Version'' and all the business confidential information must be deleted from public versions, and substituted with an adequate public summary.

III. Data

OMB Control Number: 0625–0270.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Individuals or households; Business or other for-profit organizations).

Estimated Number of Respondents: 16.

Estimated Time Per Response: 8 hours for Request for Commercial Availability Determination; 2 hours for Response to a Request; and 1 hour for Rebuttal.

Estimated Total Annual Burden Hours: 89.

Estimated Total Annual Cost to Public: $3,440.

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: August 29, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–21692 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–801, A–427–801]

Ball Bearings and Parts Thereof From France and Italy: Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from interested parties, the Department of Commerce (the Department) initiated administrative reviews of the antidumping duty orders on ball bearings and parts thereof from France and Italy. The period of review is May 1, 2011, through September 14, 2011. As a result of the withdrawals of the requests for review, the Department is rescinding these reviews.

DATES: *Effective Date:* September 4, 2012.

FOR FURTHER INFORMATION CONTACT: Sandra Dreisonstok or Minoo Hatten, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0768 or (202) 482–1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 10, 2012, the Department published a notice of initiation of the administrative reviews of the antidumping duty orders on ball bearings and parts thereof from France and Italy in accordance with section 751(a) of the Tariff Act of 1930 (the Act) and 19 CFR 351.221(c)(1)(i). *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocations in Part,* 77 FR 40565 (July 10, 2012).

Rescission of Reviews

In accordance with 19 CFR 351.213(d)(1), the Department will rescind an administrative review, ''if a party that requested a review withdraws the request within 90 days of the date

of publication of notice of initiation of the requested review.'' The following companies timely filed requests for review and submitted timely withdrawals of their requests between June 29 and July 24, 2012:

Country	Company
France	Kongskilde Limited, NTN–SNR Roulements, S.A., SKF France S.A. and SKF Aerospace France S.A.S.
Italy	SKF Industrie S.p.A. and Somecat S.p.A., Schaeffler Italia SpA.

Because we received no other requests for review of these companies, and because all parties withdrew their requests for review within 90 days of the date of publication of the notice of initiation, we are rescinding the administrative reviews of the orders with respect to all companies. This rescission is in accordance with 19 CFR 351.213(d)(1). The Department intends to issue appropriate assessment instructions to U.S. Customs and Border Protection within 15 days after publication of this notice.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) 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 doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is published in accordance with section 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: August 28, 2012.

Gary Taverman,

Senior Advisor for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–21731 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–909]

Certain Steel Nails From the People's Republic of China: Preliminary Results and Partial Rescission of the Third Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''Department'') is conducting the third administrative review of the antidumping duty order on certain steel nails from the People's Republic of China (''PRC'') for the period August 1, 2010, through July 31, 2011. The Department has preliminarily determined that sales have been made below normal value (''NV'') by certain respondents examined in this administrative review. If these preliminary results are adopted in our final results of this review, the Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries of subject merchandise during the period of review.

DATES: *Effective Date:* September 4, 2012.

FOR FURTHER INFORMATION CONTACT: Alexis Polovina or Jamie Blair-Walker, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3927 or (202) 482–2615, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department received timely requests from Petitioner [1] and other companies, in accordance with 19 CFR 351.213(b), during the anniversary month of August, to conduct reviews of certain companies exporting steel nails from the PRC. On October 3, 2011, the Department initiated this review with respect to all 383 requested companies.[2]

On December 22, 2011, Qingdao JISCO Co., Ltd., a Chinese producer of subject merchandise and its Korean parent company, ECO System Corporation d/b/a JISCO Corporation (collectively, ''JISCO''), withdrew its request for an administrative review.[3] On January 3, 2012, the Department received a timely [4] letter from Petitioner to withdraw its request for review of numerous companies.[5]

On March 30, 2012, the Department published a notice [6] extending the time period for issuing the preliminary results by 120 days to August 30, 2012. From October 11, 2011, to December 5, 2011, the Department received timely separate rate applications, certifications and no shipment letters from many companies. On December 13, 2011, the Department received an untimely no shipment certification from Hebei Minmetals Co., Ltd. (''Hebei'').[7] Pursuant to 19 CFR 351.302(d)(1)(i), the Department rejected the untimely no shipment certification from Hebei on July 16, 2012.[8]

Between December 20, 2011, and July 25, 2012, The Stanley Works (Langfang) Fastening Systems Co., Ltd. (''Stanley Langfang''), and Stanley Black & Decker (''SBD'') (collectively ''Stanley'') submitted responses to the Department's original and supplemental questionnaires. Between March 8, 2012, and July 20, 2012, the Department received responses to its original and supplemental questionnaires from Tianjin Jinghai County Hongli Industry and Business Co., Ltd. (''Hongli'').

Period of Review

The period of review (''POR'') is August 1, 2010, through July 31, 2011.

Scope of the Order

The merchandise covered by this order includes certain steel nails having a shaft length up to 12 inches. Certain steel nails include, but are not limited to, nails made of round wire and nails that are cut. Certain steel nails may be of one piece construction or constructed

[1] Mid Continent Nail Corporation (''Petitioner'').

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocations in Part,* 76 FR 61076 (October 3, 2011) (''*Initiation Notice*'').

[3] *See* submission from JISCO Corporation regarding Steel Nails from the People's Republic of China: Withdrawal of Request for Administrative Review, dated December 22, 2011.

[4] The deadline for submitting requests was January 1, 2012, but due to the federal holiday, the deadline was automatically extended to the following business day.

[5] *See* submission from Petitioner regarding Certain Steel Nails from the People's Republic of China: Withdrawal of Requests for Administrative Review, dated January 3, 2012.

[6] *See Certain Steel Nails From the People's Republic of China: Extension of Time Limit for the Preliminary Results of the Third Antidumping Duty Administrative Review,* 77 FR 19190 (March 30, 2012).

[7] The deadline to submit separate rate applications, certifications and no shipment letters was December 2, 2011, 60 days following the publication of the *Initiation Notice.*

[8] *See* letter to Hebei from Matthew Renkey regarding Certain Steel Nails from the People's Republic of China (''PRC''): Rejection of Untimely Certification of No Shipments, dated July 16, 2012.

of two or more pieces. Certain steel nails may be produced from any type of steel, and have a variety of finishes, heads, shanks, point types, shaft lengths and shaft diameters. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, whether by electroplating or hot dipping one or more times), phosphate cement, and paint. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted shank styles. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the fastener using a tool that engages with the head. Point styles include, but are not limited to, diamond, blunt, needle, chisel and no point. Finished nails may be sold in bulk, or they may be collated into strips or coils using materials such as plastic, paper, or wire. Certain steel nails subject to this order are currently classified under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings 7317.00.55, 7317.00.65 and 7317.00.75.

Excluded from the scope of this order are steel roofing nails of all lengths and diameter, whether collated or in bulk, and whether or not galvanized. Steel roofing nails are specifically enumerated and identified in ASTM Standard F 1667 (2005 revision) as Type I, Style 20 nails. Also excluded from the scope are the following steel nails: (1) Non-collated (*i.e.,* hand-driven or bulk), two-piece steel nails having plastic or steel washers (caps) already assembled to the nail, having a bright or galvanized finish, a ring, fluted or spiral shank, an actual length of 0.500″ to 8″, inclusive; and an actual shank diameter of 0.1015″ to 0.166″, inclusive; and an actual washer or cap diameter of 0.900″ to 1.10″, inclusive; (2) Non-collated (*i.e.,* hand-driven or bulk), steel nails having a bright or galvanized finish, a smooth, barbed or ringed shank, an actual length of 0.500″ to 4″, inclusive; an actual shank diameter of 0.1015″ to 0.166″, inclusive; and an actual head diameter of 0.3375″ to 0.500″, inclusive; (3) Wire collated steel nails, in coils, having a galvanized finish, a smooth, barbed or ringed shank, an actual length of 0.500″ to 1.75″, inclusive; an actual shank diameter of 0.116″ to 0.166″, inclusive; and an actual head diameter of 0.3375″ to 0.500″, inclusive; and (4) Non-collated (*i.e.,* hand-driven or bulk), steel nails having a convex head (commonly known as an umbrella head), a smooth or spiral shank, a galvanized finish, an actual length of 1.75″ to 3″, inclusive; an actual shank diameter of 0.131″ to 0.152″, inclusive; and an actual head diameter of 0.450″ to 0.813″, inclusive.

Also excluded from the scope of this order are corrugated nails. A corrugated nail is made of a small strip of corrugated steel with sharp points on one side. Also excluded from the scope of this order are fasteners suitable for use in powder-actuated hand tools, not threaded and threaded, which are currently classified under HTSUS 7317.00.20 and 7317.00.30. Also excluded from the scope of this order are thumb tacks, which are currently classified under HTSUS 7317.00.10.00.

Also excluded from the scope of this order are certain brads and finish nails that are equal to or less than 0.0720 inches in shank diameter, round or rectangular in cross section, between 0.375 inches and 2.5 inches in length, and that are collated with adhesive or polyester film tape backed with a heat seal adhesive. Also excluded from the scope of this order are fasteners having a case hardness greater than or equal to 50 HRC, a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Respondent Selection

Section 777A(c)(1) of the Tariff Act of 1930, as amended (''Act'') directs the Department to calculate individual dumping margins for each known exporter or producer of the subject merchandise.[9] However, section 777A(c)(2) of the Act gives the Department discretion to limit its examination to a reasonable number of exporters or producers, if the number of companies involved is so large that it is not practicable to individually examine all exporters or producers for which the review is initiated.

On October 7, 2011, the Department released CBP data for entries of the subject merchandise during the POR under administrative protective order (''APO'') to all interested parties having access to materials released under APO and invited comments regarding the CBP data and respondent selection.[10] The Department received comments from Petitioner, Stanley, and Itochu Building Products Co., Inc. (''Itochu'') regarding respondent selection between October 24, 2011 and October 25, 2011. On October 31, Stanley submitted rebuttal comments regarding respondent selection.

On November 28, 2011, the Department issued its respondent selection memorandum.[11] The Department determined that with 383 companies involved, it would be impracticable to individually review each company. After determining that the number of companies (*i.e.,* 383) was too large a number for individual reviews, the Department determined that it could reasonably examine the exporters accounting for the largest volume of entries subject to this review. Pursuant to section 777A(c)(2)(B) of the Act, the Department selected Stanley and JISCO as mandatory respondents.[12] On November 29, 2011, the Department issued an antidumping duty questionnaire to these two mandatory respondents. On February 6, 2012, after receiving timely requests for withdrawal of review from JISCO and Petitioner, the Department selected Hongli as a mandatory respondent in place of JISCO.[13] On February 6, 2012, the Department issued an antidumping duty questionnaire to Hongli.

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if a party that requested the review withdraws the request within 90 days of the date of publication of the initiation notice of the requested review. Besides the requests for review submitted by Petitioner as discussed above, several companies requested review of themselves.[14] On December 22, 2011, JISCO timely withdrew its request for an administrative review of itself and its affiliates. On January 3, 2012, the Department received a timely letter from Petitioner withdrawing its requests for review of 316 of the 383 companies that were originally under review.

[9] *See also* 19 CFR 351.204(c) regarding respondent selection, in general.

[10] *See* Memorandum to the File from Alexis Polovina regarding Certain Steel Nails from the People's Republic of China: U.S. Customs and Border Protection Data, dated October 7, 2011.

[11] *See* Memorandum to James Doyle through Matthew Renkey from Jamie Blair-Walker regarding: Respondent Selection for the Third Antidumping Duty Administrative Review of Certain Steel Nails from the People's Republic of China, dated November 28, 2011 (''First Respondent Selection Memo'').

[12] *See id.*

[13] *See* Memorandum to James Doyle through Matthew Renkey from Jamie Blair-Walker regarding Respondent Selection for the Third Antidumping Duty Administrative Review of Certain Steel Nails from the People's Republic of China: Selection of an Additional Mandatory Respondent, dated February 6, 2012 (''Second Respondent Selection Memo'').

[14] *See* Appendix I.

For those companies named in the *Initiation Notice* for which all reviews requests have been withdrawn and who previously received separate rate status in prior segments of this case we are rescinding this administrative review, in accordance with 19 CFR 351.213(d)(1). These companies are: (1) Dezhou Hualude Hardware Products Co., Ltd.; (2) JISCO Corporation; (3) Koram Panagene Co., Ltd.; (4) Qingdao Koram Steel Co., Ltd.; (5) Romp (Tianjin) Hardware Co., Ltd.; (6) Shandong Oriental Cherry Hardware Group Co., Ltd.; (7) Shandong Oriental Cherry Hardware Import and Export Co., Ltd.; (8) Shanxi Pioneer Hardware Industrial Co., Ltd.; (9) Tianjin Lianda Group Co., Ltd.; (10) Tianjin Universal Machinery Import & Export Corporation; and (11) Xi'an Metals & Minerals Import & Export Co., Ltd. Petitioner's timely request for an administrative review included a request to conduct an administrative review of multiple companies that do not have separate rates. As described above, Petitioner withdrew its review request covering these companies. While the requests for review of those companies were timely withdrawn,[15] those withdrawn companies remain under review as part of the PRC-wide entity and the Department will make a determination with respect to the PRC-wide entity at these preliminary results and the final results.[16]

Preliminary Partial Rescission of Administrative Review

Twelve companies (collectively, ''No Shipment Respondents'') filed timely no-shipment certifications indicating that they had no shipments of subject merchandise to the United States during the POR.[17, 18] Subsequent to receiving no-shipment certifications, the Department examined entry statistics obtained from CBP. The Department also issued no-shipment inquiries to CBP, asking it to respond only if it had information that the above-companies may have shipped entries of subject merchandise during the POR. For nine companies, we did not receive any response from CBP, thus indicating that there were no entries of subject merchandise into the United States exported by these companies. CBP did indicate potential entries of nails during the POR for the three remaining companies and the Department requested CBP entry packages for these. On July 18, 2012, we placed these entry packets on the record and requested comments from interested parties.[19] In its response, CPI demonstrated that it was a third country reseller and as its Chinese vendors had knowledge the subject merchandise was destined for the United States, CPI was not the ''exporter.'' [20] China Staple stated that its entries were for non-subject merchandise and provided product descriptions demonstrating its merchandise was non-subject and noted the importer placed the post entry adjustment on the record.[21] Hengshui Mingyao explained that due to the Department's changed circumstances review, it entries are no longer subject and its importer has requested refund.[22] After reviewing the responses, the corrected entry documents, and the CBP information, pursuant to 19 CFR 351.213(d)(3), we preliminarily determine that these 12 No Shipment Respondents did not have any reviewable transactions during the POR and, as a result, we are preliminarily rescinding the administrative review for these companies.

Non-Market Economy Country Status

In accordance with section 771(18)(C)(i) of the Act, the designation of a country as a nonmarket economy (''NME'') country remains in effect until it is revoked by the Department. As such, we continue to treat the PRC as an NME in this proceeding. When the Department investigates imports from an NME country and available information does not permit the Department to determine NV, pursuant to section 773(a) of the Act, then, pursuant to section 773(c)(1) of the Act, the Department determines NV on the basis of the factors of production (''FOP'') utilized in producing the merchandise.

Surrogate Country

Section 773(c)(4) of the Act, directs the Department to value an NME producer's FOPs, to the extent possible, in one or more market-economy (''ME'') countries that (1) are at a level of economic development comparable to that of the NME country, and (2) are significant producers of comparable merchandise. From the countries that are both economically comparable and significant producers, the Department will select a primary surrogate country based upon whether the data for valuing FOPs are both available and reliable.[23] In this review, the Department determined that Colombia, Indonesia, the Philippines, Peru, South Africa, Thailand, and Ukraine are countries comparable to the PRC in terms of economic development.[24]

On December 12, 2011, the Department sent interested parties a letter inviting comments on surrogate country selection and information regarding valuing FOPs.[25] On March 26, 2011, interested parties submitted comments on the selection of a surrogate country.[26] Between April 30, 2012, and August 6, 2012, interested parties submitted surrogate value (''SV'') comments and rebuttal comments.[27]

Economic Comparability

As explained in our Surrogate Country List, the Department considers Colombia, Indonesia, the Philippines, Peru, South Africa, Thailand, and Ukraine all comparable to the PRC in terms of economic development.[28] In its surrogate country comments, Stanley argued that India should also be considered economically comparable to the PRC because a report by the World Bank identifies India, along with three

[15] *See* Appendix II.

[16] *See, e.g., Narrow Woven Ribbons With Woven Selvedge From the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review,* 77 FR 47363, 47363 (August 8, 2012).

[17] *See* Appendix III.

[18] As noted above, Hebei submitted an untimely certification, which the Department rejected. Therefore, Hebei is not included in the No Shipment Respondents.

[19] *See* Third Antidumping Duty Administrative Review of Certain Steel Nails from the People's Republic of China (''PRC''): No Shipment Supplemental Questionnaire Letters from the Department of Commerce, to CPI, China Staple, and Hengshui Mingyao, dated July 18, 2012.

[20] *See* CPI's No Shipment Supplemental Response, dated July 31, 2012.

[21] *See* China Staple's No Shipment Supplemental Response, dated July 27, 2012; *see also,* SBD's Post Entry Adjustment, dated July 24, 2012. We are also confirming the post entry documents with CBP.

[22] *See* Hengshui Mingyao's No Shipment Supplemental Response, dated July 31, 2012.

[23] *See* Import Administration Policy Bulletin 04.1: Non-Market Economy Surrogate Country Selection Process (March 1, 2004) (''*Policy Bulletin 04.1*''), available on the Department's Web site at *http://ia.ita.doc.gov/policy/index.html*.

[24] *See* Memorandum to Matthew Renkey, Acting Program Manager, AD/CVD Operations, Office 9, Import Administration, from Carole Showers, Director, Office of Policy, Import Administration re: Request for a List of Surrogate Countries for an Administrative Review of the Antidumping Duty Order on Certain Steel Nails from the People's Republic of China (''PRC''), dated December 8, 2011.

[25] *See* the Department's Letter to All Interested Parties; Third Administrative Review of Certain Steel Nails from the People's Republic of China (''PRC''): Deadlines for Surrogate Country and Surrogate Value Comments, dated December 12, 2011 (''Surrogate Country List'').

[26] *See* Letters from Stanley, GDLSK Respondents (Counsel to Hongli), and Petitioner, regarding Surrogate Country Comments dated March 26, 2011.

[27] *See* Surrogate Value Submissions from GDLSK Respondents (Counsel to Hongli) and Petitioner, dated April 30, 2012; Surrogate Value Rebuttal Comments, dated May 7, 2012; *see also* Pre-Preliminary Results Comments from Stanley, dated August 6, 2012.

[28] *See* Surrogate Country List.

of the countries identified by Policy as ''low middle income countries.'' [29] We note that in *Steel Wheels* [30] the Department stated:

> {U}nless we find that all of the countries determined to be equally economically comparable are not significant producers of comparable merchandise, do not provide a reliable source of publicly available surrogate data or are unsuitable for use for other reasons, we will rely on data from one of these countries.

Therefore, because the Department finds that at least one of the countries included in the Surrogate Country List meet the selection criteria as explained below, the Department is not considering India as the primary surrogate country.

Significant Producers of Comparable Merchandise

Section 773(c)(4)(B) of the Act requires the Department to value FOPs in a surrogate country that is a significant producer of comparable merchandise. Neither the statute nor the Department's regulations provide further guidance on what may be considered comparable merchandise. Given the absence of any definition in the statute or regulations, the Department looks to other sources such as the *Policy Bulletin 04.1* for guidance on defining comparable merchandise. The *Policy Bulletin 04.1* states that ''{t}he terms 'comparable level of economic development,' 'comparable merchandise,' and 'significant producer' are not defined in the statute.'' [31] The *Policy Bulletin 04.1* further states that ''{i}n all cases, if identical merchandise is produced, the country qualifies as a producer of comparable merchandise.'' [32] Conversely, if identical merchandise is not produced, then a country producing comparable merchandise is sufficient in selecting a surrogate country.[33] Further, when selecting a surrogate country, the statute requires the Department to consider the comparability of the merchandise, not the comparability of the industry.[34] ''In cases where the identical merchandise is not produced, the team must determine if other merchandise that is comparable is produced. How the team does this depends on the subject merchandise.'' [35] In this regard, the Department recognizes that any analysis of comparable merchandise must be done on a case-by-case basis:

> In other cases, however, where there are major inputs, *i.e.,* inputs that are specialized or dedicated or used intensively, in the production of the subject merchandise, *e.g.,* processed agricultural, aquatic and mineral products, comparable merchandise should be identified narrowly, on the basis of a comparison of the major inputs, including energy, where appropriate.[36]

Further, the statute grants the Department discretion to examine various data sources for determining the best available information.[37]

In this case, because production data of identical or comparable merchandise was not available, we analyzed which of the seven countries are exporters of comparable merchandise, as a proxy for production data. We obtained export data using the Global Trade Atlas (''GTA'') for Harmonized Tariff Schedule (''HTS'') 7317.00: ''Nails, tacks drawing pins, staples (other than in strips), and similar articles of iron or steel excluding such articles with heads of copper.'' The Department found that all seven of these countries had exports of comparable merchandise during the POR at the following levels: Colombia 3,339,661 kilograms (''kg''); Indonesia 842,759 kg; the Philippines 27,759 kg; Peru 1,319,276 kg; South Africa 912,572 kg; Thailand 8,784,527 kg; and Ukraine 18,571,880 kg.[38] As these levels suggest domestic production in these countries, we considered them as having met this prong of the surrogate country selection criteria because each exported comparable merchandise at volumes from which we can reasonably infer domestic production.

Data Availability

When evaluating SV data, the Department considers several factors including whether the SV is publicly available, contemporaneous with the POR, represents a broad-market average, from an approved surrogate country, tax and duty-exclusive, and specific to the input.[39] There is no hierarchy among these criteria.[40] It is the Department's practice to carefully consider the available evidence in light of the particular facts of each industry when undertaking its analysis.[41]

Parties placed significant SV data on the record for both Thailand and Ukraine.[42] Similar to the circumstances in *Fish Fillets AR6* and *AR7,* the record does not contain any SV data for the remaining countries: Colombia, Indonesia, the Philippines, Peru, and South Africa; thus, these countries will not be considered for primary surrogate country purposes at this time.[43] Much of the Thai and Ukrainian data placed on the record are import statistics from GTA, and therefore, satisfy the publicly available, contemporaneous with the POR, broad-market average, from an approved surrogate country, and tax and duty-exclusive, criteria. As such, we will examine specificity of data available for the relevant the inputs.

In this case, the wire rod is a significant input because most steel nails made by the respondents are made largely from wire rod. Therefore, we must consider the availability and reliability of the SVs for wire rod on the record. The record contains equally specific Thai and Ukraine HTSs for imports of bars and rods under 14 millimeters (''mm'') in size and of varying carbon contents from GTA.[44] Additionally, the record contains monthly price data during the POR for 6.5–8 mm wire rod for Ukraine from Metal Expert, an independent provider of analysis of world steel markets.[45] Because respondents consumed wire rod measuring 6.5 mm in diameter, we

[29] *See* Letter from Stanley regarding Surrogate Country Comments at 2, dated March 26, 2011.

[30] *See Certain Steel Wheels From the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value, Partial Affirmative Preliminary Determination of Critical Circumstances, and Postponement of Final Determination,* 76 FR 677703 (November 2, 2011) (''*Steel Wheels*'').

[31] *See Policy Bulletin 04.1.*

[32] *See id.*

[33] The *Policy Bulletin 04.1* also states that ''{i}f considering a producer of identical merchandise leads to data difficulties, the operations team may consider countries that produce a broader category of reasonably comparable merchandise.'' *See id.,* at n. 6.

[34] *See Sebacic Acid from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 62 FR 65674 (December 15, 1997), and accompanying Issues and Decision Memorandum at Comment 1 (''to impose a requirement that merchandise must be produced by the same process and share the same end uses to be considered comparable would be contrary to the intent of the statute'').

[35] *See Policy Bulletin 04.1.*

[36] *See id.*

[37] *See* section 773(c)(1) of the Act; *Nation Ford Chem. Co.* v. *United States,* 166 F.3d 1373, 1377 (Fed. Cir. 1999).

[38] *See* Memorandum to the File, from Alexis Polovina regarding Surrogate Country Exports, dated August 30, 2012.

[39] *See id; see also* section 773(c)(1) of the Act.

[40] *See Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Results and Partial Rescission of the Seventh Antidumping Duty Administrative Review,* 76 FR 15941 (March 14, 2012), and accompanying Issues and Decision Memorandum (''*Fish Fillets AR7*'') at Comment II.

[41] *See id.*

[42] *See* Surrogate Value Submissions from Hongli and Petitioner, dated April 30, 2012.

[43] *See Fish Fillets AR7* at Comment I*; see also Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Results of the Sixth Antidumping Duty Administrative Review and Sixth New Shipper Review,* 76 FR 15941 (March 22, 2011), and accompanying Issues and Decision Memorandum (''*Fish Fillets AR6*'') at Comment I.

[44] *See* Surrogate Value Submissions from Hongli and Petitioner, dated April 30, 2012.

[45] *See id.*

consider Metal Expert data a more specific match.

Financial ratios are also an important component of the antidumping duty calculation. The record contains one set of contemporaneous financial statements from both Thailand and Ukraine. However, the financial statements from Thailand are for the year ending 2010, while the Ukrainian financial statements are for the year ending 2011, making them more contemporaneous with the POR (seven months of 2011 overlap with the POR compared to five months of 2010).

Both Thailand and Ukraine are economically comparable to the PRC, significant producers of comparable merchandise, and have viable data options. However, Ukraine offers a more specific option for valuing the main input, wire rod, and a more contemporaneous set of financial statements. Therefore, for the preliminary results we have selected Ukraine as the surrogate country because it represents the best available information.

Separate Rates

In proceedings involving NME countries, it is the Department's practice to begin with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assessed a single antidumping duty rate.[46] In the *Initiation Notice,* the Department notified parties of the application process by which exporters may obtain separate rate status in NME reviews.[47] It is the Department's policy to assign all exporters of merchandise subject to investigation in an NME country this single rate unless an exporter can affirmatively demonstrate that it is sufficiently independent from government control so as to be entitled to a separate rate.[48] Exporters can demonstrate this independence through the absence of both *de jure* and *de facto* government control over export activities.[49] The Department analyzes each entity's export independence under a test first articulated in *Sparklers* and as further developed in *Silicon Carbide.*[50] However, if the Department determines that a company is wholly foreign-owned or located in an ME, then a separate rate analysis is not necessary to determine whether it is independent from government control.[51]

In addition to the two mandatory respondents, Stanley and Hongli, the Department received separate rate applications (''SRAs'') from 3 companies[52] and separate rate certifications (''SRCs'') from 15 companies,[53, 54], (collectively, the ''Separate Rate Respondents'').

Separate Rate Respondents

1. Wholly Foreign-Owned

Stanley reported that it is wholly-owned by a company located in an ME country.[55] Therefore, there is no PRC ownership of Stanley and, because the Department has no evidence indicating that Stanley is under the control of the PRC, a separate rates analysis is not necessary.[56] Additionally, seven other exporters under review not selected for individual review demonstrated in their SRAs or SRCs that they are wholly foreign owned by companies located in ME countries.[57] Accordingly, the Department has preliminarily granted separate rate status to Stanley and the other wholly owned companies.

2. Joint Ventures Between Chinese and Foreign Companies or Wholly Chinese-Owned Companies

Hongli[58] and 11 other Separate Rate Respondents[59] stated that they are either joint ventures between Chinese and foreign companies or are wholly Chinese-owned companies. In accordance with our practice, the Department has analyzed whether these Separate Rate Respondents have demonstrated the absence of *de jure* and *de facto* governmental control over their respective export activities.

a. Absence of De Jure Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies.[60] The evidence provided by Hongli[61] and the Separate Rate Respondents[62] supports a preliminary finding of *de jure* absence of government control based on the following: (1) An absence of restrictive stipulations associated

[46] *See, e.g., Small Diameter Graphite Electrodes From the People's Republic of China: Final Results of the Antidumping Duty Administrative Review,* 77 FR 40854, 40855 (July 11, 2011); *see also Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China,* 71 FR 53079, 53080 (September 8, 2006).

[47] *See Initiation Notice,* 76 FR at 61076–77.

[48] *See id.*

[49] *See id.*

[50] *See Final Determination of Sales at Less Than Fair Value: Sparklers From the People's Republic of China,* 56 FR 20588 (May 6, 1991) (''*Sparklers*''); *see also Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China,* 59 FR 22585 (May 2, 1994) (''*Silicon Carbide*'').

[51] *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles from the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

[52] These companies include: 1) Cana (Tianjin) Hardware Industrial Co., Ltd.; 2) Shanghai Curvet Hardware Products Co., Ltd.; and 3) Huanghua Jinhai Hardware Products Co., Ltd.

[53] The 15 other companies include: (1) Shanxi Tianli Industries Co., Ltd.; (2) Shanghai Jade Shuttle Hardware Tools Co., Ltd.; (3) Shandong Dinglong Import & Export Co., Ltd.; (4) Tianjin Jinchi Metal Products Co., Ltd.; (5) Huanghua Xionghua Hardware Products Co., Ltd.; (6) Tianjin Zonglian Metals Ware Co., Ltd.; (7) Shanghai Yueda Nails Industry Co., Ltd.; (8) Hebei Cangzhou New Century Foreign Trade Co., Ltd.; (9) Zhaoqing Harvest Nails Co., Ltd.; (10) Nanjing Yuechang Hardware Co., Ltd.; (11) S-Mart (Tianjin) Technology Development Co. Ltd.; (12) SDC International Australia Pty., Ltd.; (13) Shanxi Hairui Trade Co., Ltd.; (14) Guangdong Foreign Trade Import & Export Corporation; and (15) Qingdao D&L Group Ltd., collectively (''Separate Rate Respondents'').

[54] One additional company applied for a separate rate, Mingguang Abundant Hardware Products Co., Ltd., however, as explained below we are not considering it as a Separate Rate Respondent at this time.

[55] *See* Stanley's Section A Questionnaire Response, dated December 20, 2011, at 2.

[56] *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles From the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007); *Brake Rotors From the People's Republic of China: Preliminary Results and Partial Rescission of the Fourth New Shipper Review and Rescission of the Third Antidumping Duty Administrative Review,* 66 FR 1303, 1306 (January 8, 2001), unchanged in *Brake Rotors From the People's Republic of China: Final Results and Partial Rescission of Fourth New Shipper Review and Rescission of Third Antidumping Duty Administrative Review,* 66 FR 27063 (May 16, 2001); *Notice of Final Determination of Sales at Less Than Fair Value: Creatine Monohydrate From the People's Republic of China,* 64 FR 71104 (December 20, 1999).

[57] These companies are: (1) Cana (Tianjin) Hardware Industrial Co., Ltd.; (2) Shanghai Curvet Hardware Products Co., Ltd.; (3) Shanghai Jade Shuttle Hardware Tools Co., Ltd.; (4) Huanghua Xionghua Hardware Products Co., Ltd.; (5) Zhaoqing Harvest Nails Co., Ltd.; (6) S-Mart Tianjing Technology Development Co., Ltd.; and (7) SDC International Australia Pty., Ltd.

[58] *See* Hongli's Section A Questionnaire Response, dated March 8, 2012, at 1–13.

[59] These companies are: (1) Huanghua Jinhai Hardware Products Co., Ltd.; (2) Shanxi Tianli Industries Co., Ltd.; (3) Shandong Dinglong Import & Export Co., Ltd.; (4) Tianjin Jinchi Metal Products Co., Ltd.; (5) Tianjin Zhonglian Metals Ware Co., Ltd.; (6) Shanghai Yueda Nails Industry Co., Ltd.; (7) Hebei Cangzhou New Century Foreign Trade Co., Ltd.; (8) Nanjing Yuechang Hardware Co., Ltd.; (9) Guangdong Foreign Trade Import & Export Corporation; (10) Shanxi Hairui Trade Co., Ltd.; and (11) Qingdao D&L Group Ltd.

[60] *See Sparklers,* 56 FR at 20589.

[61] *See, e.g.,* Hongli's Section A Questionnaire Response, dated March 8, 2012, at 4 and Exhibit A–2.

[62] *See* Separate Rate Respondents' SRAs and SRCs, dated between October 11 and December 5, 2011.

with the individual exporter's business and export licenses; (2) there are applicable legislative enactments decentralizing control of the companies; and (3) there are formal measures by the government decentralizing control of companies.

b. Absence of De Facto Control

Typically the Department considers four factors in evaluating whether each respondent is subject to *de facto* government control of its export functions: (1) Whether the export prices are set by or are subject to the approval of a government agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses.[63] The Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates. The evidence provided by Hongli[64] and the Separate Rate Respondents[65] supports a preliminary finding of *de facto* absence of government control based on the following: (1) The companies set their own export prices independent of the government and without the approval of a government authority; (2) the companies have authority to negotiate and sign contracts and other agreements; (3) the companies have autonomy from the government in making decisions regarding the selection of management; and (4) there is no restriction on any of the companies' use of export revenue. Therefore, the Department preliminarily finds that Stanley, Hongli, and Separate Rate Respondents have established that they qualify for a separate rate under the criteria established by *Silicon Carbide* and *Sparklers.*

We note that for Mingguang Abundant Hardware Co., Ltd., (''Mingguang Abundant''), we are not granting a separate rate. Although it applied for a separate rate, the CBP data do not contain evidence of an entry during the POR. We issued a supplemental requesting Mingguang Abundant demonstrate it had an entry of subject merchandise during the POR. Mingguang Abundant was only able to provide the invoice, shipping list, and proof of payment.[66] Because Mingguang Abundant was unable to provide the CBP 7501 demonstrating the date the merchandise entered the United States, we intend to rescind the review for Mingguang Abundant unless Mingguang Abundant can demonstrate it had POR entries of subject merchandise within 20 days after the date of publication of these preliminary results.

Calculation of Margin for Separate Rate Companies

The statute and the Department's regulations do not address the establishment of a rate to be applied to individual companies not selected for examination where the Department limited its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, we have looked to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents we did not examine in an administrative review. Section 735(c)(5)(A) of the Act instructs that we are not to calculate an all-others rate using any zero or *de minimis* margins or any margins based entirely on facts available. Accordingly, the Department's practice in this regard, in reviews involving limited respondent selection based on exporters accounting for the largest volume of trade, has been to average the rates for the selected companies, excluding zero and *de minimis* rates and rates based entirely on facts available.[67] Section 735(c)(5)(B) of the Act also provides that, where all margins are zero, *de minimis,* or based entirely on facts available, we may use ''any reasonable method'' for assigning the rate to non-selected respondents, including ''averaging the estimated weighted average dumping margins determined for the exporters and producers individually investigated.'' In this instance, consistent with our practice, we have preliminarily established a margin for the Separate Rate Respondents based on the rate we calculated for the mandatory respondents whose rates were not zero, *de minimis,* or based entirely on facts available.[68]

PRC-Wide Entity

As discussed above, in this administrative review we limited the selection of respondents using CBP import data.[69] In this case, we made available to the companies who were not selected, the SRA and SRC, which were put on the Department's Web site.[70] Because certain parties for which a review was requested did not apply for separate rate status, they did not demonstrate eligibility for a separate rate and effectively became part of the PRC-wide entity, which is considered to be part of this review.[71] We continue to use the PRC-wide rate determined in the original investigation, the highest rate identified in the petition of 118.04 percent.[72] Certain companies did not apply for separate rates and are thus considered to be part of the PRC-wide entity.[73]

Date of Sale

The date of sale is generally the date on which the parties agree upon all substantive terms of the sale, which normally includes the price, quantity, delivery terms and payment terms.[74] 19 CFR 351.401(i) states that, ''{i}n identifying the date of sale of the merchandise under consideration or foreign like product, the Secretary normally will use the date of invoice, as

[63] *See Silicon Carbide,* 59 FR at 22586–87; *see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995).

[64] *See* Hongli's Section A Questionnaire Response, dated March 8, 2012, at 8–9.

[65] *See* Separate Rate Respondents' SRAs and SRCs, dated between October 11 and December 5, 2011.

[66] *See* Mingguang Abundant's Separate Rate Certification Supplemental Response, dated July 23, 2012.

[67] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 73 FR 52273, 52275 (September 9, 2008), and accompanying Issues and Decision Memorandum at Comment 6.

[68] *See, e.g., Fourth Administrative Review of Certain Frozen Warmwater Shrimp From the People's Republic of China: Preliminary Results, Preliminary Partial Rescission of Antidumping Duty Administrative Review and Intent Not To Revoke, In Part,* 75 FR 11855, 11859 (March 12, 2010).

[69] *See* First and Second Respondent Selection Memos.

[70] *See Initiation Notice.*

[71] *See, e.g., Honey From the People's Republic of China: Preliminary Results of Review,* 77 FR 46699, 46700 (August 6, 2012); *Certain Preserved Mushrooms From the People's Republic of China; Preliminary Results of Antidumping Duty Administrative Review,* 71 FR 64930, 64933 (November 6, 2006).

[72] *See Certain Steel Nails From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances and Postponement of Final Determination,* 73 FR 3928, 3934–35 (January 23, 2008) (unchanged in the final results).

[73] *See* Appendix IV.

[74] *See Carbon and Alloy Steel Wire Rod from Trinidad and Tobago: Final Results of Antidumping Duty Administrative Review,* 72 FR 62824 (November 7, 2007), and accompanying Issues and Decision Memorandum at Comment 1; *see also Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Flat-Rolled Carbon Quality Steel Products from Turkey,* 65 FR 15123 (March 21, 2000), and accompanying Issues and Decision Memorandum at Comment 2.

recorded in the exporter or producer's records kept in the normal course of business. The Secretary may use a date other than the date of invoice if the Secretary is satisfied that a different date better reflects the date on which the exporter or producer establishes the material terms of sale.'' [75] However, as noted by the Court of International Trade (''CIT'') in *Allied Tube,* a party seeking to establish a date of sale other than invoice date bears the burden of establishing that ''a different date better reflects the date on which the exporter or producer establishes the material terms of sale.'' [76]

As in the last administrative review, Stanley explained that because of alterations or cancellations, the earlier of invoice date or shipment date is the appropriate date of sale because it reflects the date on which the material terms no longer change.[77] Consistent with the regulatory presumption for invoice date and because the Department found no evidence on the record contrary to Stanley's claims, for these preliminary results, the Department used the invoice date as the date of sale. Consistent with the Department's practice, for those sales where shipment date preceded invoice date, the Department used the shipment date as the date of sale, as Stanley provided evidence that the material terms of sale were set on that date.[78]

Hongli reported that the PRC Export Declaration is the appropriate date of sale.[79] As explained above, the Department will not use a date other than the date of invoice unless a party provides sufficient evidence that a different date better reflects the date on which the material terms of sale were established.[80] Hongli did not provide such evidence. Instead, Hongli merely asserted that the PRC Export Declaration date is the correct date of sale without any discussion or factual support of when the material terms of sale such as price and quantity were established for their sales.[81] Therefore, given its failure to demonstrate that a date other than invoice date better reflects the date on which the material terms of sale were established, the Department is following the presumption established in its regulation and using the invoice date as the date of sale.

Fair Value Comparisons

To determine whether sales of certain steel nails to the United States by Stanley and Hongli were made at less than NV, the Department compared export price (''EP'') and constructed export price (''CEP'') to NV, as described in the ''U.S. Price,'' and ''Normal Value'' sections below.[82]

U.S. Price

Export Price

For Hongli, in accordance with section 772(a) of the Act, we based the U.S. price for sales on EP because the first sale to an unaffiliated purchaser in the United States was made prior to importation, and the use of CEP was not otherwise warranted. In accordance with section 772(c) of the Act, we calculated EP by deducting the applicable movement expenses and adjustments from the gross unit price. We based these movement expenses on SVs where a PRC company provided the service and was paid in Renminbi (''RMB''). *See* ''Factors of Production'' section below for further discussion. For details regarding our EP calculations, *see* Memorandum regarding: Antidumping Duty Administrative Review of Certain Steel Nails from the People's Republic of China: Tianjin Jinghai County Hongli Industry and Business Co., Ltd.,'' dated concurrently with this notice.

Constructed Export Price

In accordance with section 772(b) of the Act, we based the U.S. price for Stanley's sales on CEP because the first sale to an unaffiliated customer was made by Stanley's U.S. affiliate. In accordance with section 772(c)(2)(A) of the Act, we calculated CEP by deducting the applicable expenses from the gross unit price charged to the first unaffiliated customer in the United States. Further, in accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), where appropriate, we deducted from the starting price the applicable selling expenses associated with economic activities occurring in the United States. In addition, pursuant to section 772(d)(3) of the Act, we made an adjustment to the starting price for CEP profit. We based movement expenses on either SVs or actual expenses, where appropriate. For details regarding our CEP calculations, and for a complete discussion of the calculation of the U.S. price for Stanley, *see* Memorandum regarding: Antidumping Duty Administrative Review of Certain Steel Nails from the People's Republic of China: Stanley,'' dated concurrently with this notice.

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine the NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. The Department bases NV on the FOPs because the presence of government controls on various aspects of NMEs renders price comparisons and the calculation of production costs invalid under the Department's normal methodologies.

In accordance with 19 CFR 351.408(c)(1), the Department will normally use publicly available information to value the FOPs, but when a producer sources an input from an ME country and pays for it in an ME currency, the Department may value the factor using the actual price paid for the input. During the POR, Stanley reported that it purchased certain inputs from an ME supplier, which were produced in an ME country, and paid for the inputs in an ME currency.[83] The Department has a rebuttable presumption that ME input prices are the best available information for valuing an input when the total volume of the input purchased from all ME sources during the period of investigation or review exceeds 33 percent of the total volume of the input purchased from all sources during the period.[84]

[75] *See* 19 CFR 351.401(i); *see also Allied Tube & Conduit Corp. v. United States,* 132 F. Supp. 2d 1087, 1090–1092 (CIT 2001) (''*Allied Tube*'').

[76] *See Allied Tube,* 132 F. Supp. 2d at 1090 (quoting 19 CFR 351.401(i)).

[77] *See* Stanley's section A questionnaire response at 25, dated December 20, 2011; *see also* Stanley's Supplemental A Response at 3–6, dated April 4, 2012.

[78] *See* 19 CFR 351.401(i); *see also Certain Steel Nails From the People's Republic of China: Preliminary Results and Preliminary Rescission, in Part, of the Antidumping Duty Administrative Review and Preliminary Intent To Rescind New Shipper Review,* 76 FR 56147, 56151 (September 12, 2011) (unchanged in the final results).

[79] *See* Hongli's Section A questionnaire response at 16, dated March 8, 2012, and Hongli's supplemental A questionnaire response at 4–6, dated May 15, 2012.

[80] *See* 19 CFR 351.401(i).

[81] *See* Hongli's Supplemental Section A Questionnaire Response at 6, dated May 15, 2012; *see also* Hongli's Sections C & D Questionnaire Response at 8, dated April 4, 2012.

[82] In these preliminary results, the Department applied the weighted-average dumping margin calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012) (''*Final Modification for Reviews*''). In particular, the Department compared monthly weighted-average EPs (or CEPs) with monthly weighted-average NVs and granted offsets for non-dumped comparisons in the calculation of the weighted average dumping margin.

[83] *See* Stanley's Section D Response at 7–8, dated January 19, 2012; and Stanley's Supplemental C Response at Exhibit SC–3(a), dated April 25, 2012.

[84] *See Antidumping Methodologies: Market Economy Inputs, Expected Non-Market Economy*

Continued

In this case, unless case-specific facts provide adequate grounds to rebut the Department's presumption, the Department will use the weighted-average ME purchase price to value the input. Alternatively, when the volume of an NME firm's purchases of an input from ME suppliers during the period is below 33 percent of its total volume of purchases of the input during the period, but where these purchases are otherwise valid and there is no reason to disregard the prices, the Department will weight-average the ME purchase price with an appropriate SV according to their respective shares of the total volume of purchases, unless case-specific facts provide adequate grounds to rebut the presumption.[85] When a firm has made ME input purchases that may have been dumped or subsidized, are not *bona fide,* or are otherwise not acceptable for use in a dumping calculation, the Department will exclude them from the numerator of the ratio to ensure a fair determination of whether valid ME purchases meet the 33 percent threshold.[86]

In accordance with section 773(c) of the Act, we calculated NV based on FOP data reported by the respondents. To calculate NV, we multiplied the reported per-unit factor-consumption rates by publicly available SVs. In selecting SVs, the Department is tasked with using the best available information on the record.[87] To satisfy this statutory requirement, we compared the quality, specificity, and contemporaneity of the potential SV data.[88] The Department's practice is to select, to the extent practicable, SVs which are: publicly available; representative of non-export, broad market average values; contemporaneous with the POR; product-specific; and exclusive of taxes and import duties.[89] As appropriate, we adjusted input prices by including freight costs to make them delivered prices. Specifically, we added to Ukrainian SVs a surrogate freight cost using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory where appropriate. This adjustment is in accordance with the Court of Appeals for the Federal Circuit's decision in *Sigma Corp.* v. *United States,* 117 F.3d 1401, 1407–08 (Fed. Cir. 1997). For a detailed description of all SVs selected in these preliminary results, *see* Memorandum regarding: Antidumping Duty Administrative Review of Certain Steel Nails from the People's Republic of China: Surrogate Values for the Preliminary Results, dated concurrently with this notice (''Preliminary Surrogate Value Memo'').

For these preliminary results, we concluded that publicly available Ukrainian sources constitute the best available information on the record for the SVs for the respondents' raw materials, packing, by-products, and the surrogate financial ratios. The record shows that data from these sources, are contemporaneous with the POR, product-specific, tax-exclusive, and represent a broad market average.[90]

The Department has disregarded statistics from NMEs, countries with generally available export subsidies, and countries listed as ''unidentified'' [91] in GTA in calculating the average value.[92] In accordance with the *Omnibus Trade and Competitiveness Act of 1988* legislative history, the Department continues to apply its long-standing practice of disregarding SVs if it has a reason to believe or suspect the source data may be subsidized.[93] In this regard, the Department has previously found that it is appropriate to disregard such prices from *e.g.,* India, Indonesia, South Korea and Thailand, because we have determined that these countries maintain broadly available, non-industry specific export subsidies.[94] Based on the existence of these subsidy programs that were generally available to all exporters and producers in these countries at the time of the POR, the Department finds that it is reasonable to infer that all exporters from India, Indonesia, South Korea and Thailand may have benefitted from these subsidies.

Lastly, to value factory overhead, selling, general, and administrative expenses, and profit, the Department used the 2011 audited financial statements of Dneprometiz Co., a Ukrainian producer of nails and other comparable merchandise. Although Petitioner argued that the financial statements of Dneprometiz Co. were not publicly available,[95] through our own research, the Department found Dneprometiz Co.'s financial statements available online for a fee.[96] In similar situations, we have considered this ''publicly available.'' [97]

Currency Conversion

Where appropriate, the Department made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank.

Preliminary Results of Review

The Department preliminarily determines that the following weighted-average dumping margins exist:

Wages, Duty Drawback; and Request for Comments, 71 FR 61716, 61717–18 (October 19, 2006) (''*Antidumping Methodologies*'').

[85] *See Antidumping Methodologies,* 71 FR at 61717–18.

[86] *See Antidumping Methodologies,* 71 FR at 61717–18.

[87] *See* section 773(c) of the Act.

[88] *See, e.g., Fresh Garlic From the People's Republic of China: Final Results of Antidumping Duty New Shipper Review,* 67 FR 72139 (December 4, 2002), and accompanying Issues and Decision Memorandum at Comment 6; *Final Results of First New Shipper Review and First Antidumping Duty Administrative Review: Certain Preserved Mushrooms From the People's Republic of China,* 66 FR 31204 (June 11, 2001), and accompanying Issues and Decision Memorandum at Comment 5.

[89] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value, Negative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp From the Socialist Republic of Vietnam,* 69 FR 42672, 42682 (July 16, 2004), unchanged in *Final Determination of Sales at Less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp from the Socialist Republic of Vietnam,* 69 FR 71005 (December 8, 2004).

[90] *See* Preliminary Surrogate Value Memo.

[91] We excluded imports labeled as originating from an ''unspecified'' country from the average value because we could not be certain that they were not from either an NME country or a country with generally available export subsidies.

[92] *See Certain Non-Frozen Apple Juice Concentrate from the People's Republic of China: Notice of Preliminary Results of the New Shipper Review,* 75 FR 47270, 47273 (August 5, 2010); *see also Drill Pipe From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Affirmative Determination of Critical Circumstances, and Postponement of Final Determination,* 75 FR 51004, 51006 (August 18, 2010).

[93] Omnibus Trade and Competitiveness Act of 1988, Conf. Report to Accompany H.R. 3, H.R. Rep. No. 576, 100th Cong., 2nd Sess. (1988) at 590.

[94] *See, e.g., Expedited Sunset Review of the Countervailing Duty Order on Carbazole Violet Pigment 23 from India,* 75 FR 13257 (March 19, 2010), and accompanying Issues and Decision Memorandum at 4–5; *Expedited Sunset Review of the Countervailing Duty Order on Certain Cut-to-Length Carbon Quality Steel Plate from Indonesia,* 70 FR 45692 (August 8, 2005), and accompanying Issues and Decision Memorandum at 4; *see Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea: Final Results of Countervailing Duty Administrative Review,* 74 FR 2512 (January 15, 2009), and accompanying Issues and Decision Memorandum at 17, 19–20; *see Certain Hot-Rolled Carbon Steel Flat Products from Thailand: Final Results of Countervailing Duty Determination,* 66 FR 50410 (October 3, 2001), and accompanying Issues and Decision Memorandum at 23.

[95] *See* Petitioner's Response to GDLSK Respondents' First Surrogate Value Submission, dated May 7, 2012.

[96] *See* Memorandum to the File, from Alexis Polovina, Third Antidumping Duty Administrative Review of Certain Steel Nails From the People's Republic of China: Placing Additional Data on the Record, dated August 30, 2012.

[97] *See Certain Preserved Mushrooms From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Rescission in Part,* 76 FR 56732, 56734 (September 14, 2011) (''*Mushrooms from the PRC*'').

Exporter	Weighted average margin (percent)
(1) The Stanley Works (Langfang) Fastening Systems Co., Ltd. and Stanley Black & Decker	0.00
(2) Tianjin Jinghai County Hongli Industry and Business Co., Ltd	22.07
(3) Cana (Tianjin) Hardware Industrial Co., Ltd	22.07
(4) Shanghai Curvet Hardware Products Co., Ltd	22.07
(5) Huanghua Jinhai Hardware Products Co., Ltd	22.07
(6) Shanxi Tianli Industries Co., Ltd	22.07
(7) Shanghai Jade Shuttle Hardware Tools Co., Ltd	22.07
(8) Shandong Dinglong Import & Export Co., Ltd	22.07
(9) Tianjin Jinchi Metal Products Co., Ltd	22.07
(10) Huanghua Xionghua Hardware Products Co., Ltd	22.07
(11) Tainjin Zhonglian Metals Ware Co., Ltd	22.07
(12) Shanghai Yueda Nails Industry Co., Ltd	22.07
(13) Hebie Cangzhou New Century Foreign Trade Co., Ltd	22.07
(14) Zhaoqing Harvest Nails Co., Ltd	22.07
(15) Nanjing Yuechang Hardware Co., Ltd	22.07
(16) S-Mart (Tianjin) Technology Development Co., Ltd	22.07
(17) SDC International Australia Pty., Ltd	22.07
(18) Shanxi Hairui Trade Co., Ltd	22.07
(19) Guangdong Foreign Trade Import & Export Corporation	22.07
(20) Qingdao D&L Group Ltd	22.07
PRC-Wide Rate	118.04

Disclosure and Public Comment

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice.[98] Interested parties may submit case briefs and/or written comments no later than 30 days after the date of publication of these preliminary results of review.[99] Rebuttal briefs and rebuttals to written comments, limited to issues raised in such briefs or comments, may be filed no later than five days after the deadline for filing case briefs.[100] Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[101] Written comments and rebuttal comments should be submitted via the Department's Import Administration Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS'').[102] An electronically filed document must be received successfully in its entirety by 5 p.m. Eastern Time (ET) on the day it is due.

In accordance with 19 CFR 351.301(c)(3)(ii), for the final results of this administrative review, interested parties may submit publicly available information to value FOPs within 20 days after the date of publication of these preliminary results. Interested parties must provide the Department with supporting documentation for the publicly available information to value each FOP. Additionally, in accordance with 19 CFR 351.301(c)(1), for the final results of this administrative review, interested parties may submit factual information to rebut, clarify, or correct factual information submitted by an interested party less than 10 days before, on, or after, the applicable deadline for submission of such factual information. However, the Department notes that 19 CFR 351.301(c)(1) permits new information only insofar as it rebuts, clarifies, or corrects information recently placed on the record. The Department generally cannot accept ''the submission of additional, previously absent-from-the-record alternative surrogate value or financial ratio information'' pursuant to 19 CFR 351.301(c)(1).[103] Additionally, for each piece of factual information submitted with SV rebuttal comments, the interested party must provide a written explanation of what information that is already on the record of the ongoing proceeding that the factual information is rebutting, clarifying, or correcting.

Additionally, pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, within 30 days of the date of publication of this notice and file the request via IA ACCESS.[104] Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. The Department will issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act unless the deadline is extended.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. In accordance with 19 CFR 351.212(b)(1), we are calculating importer- (or customer-) specific assessment rates for the merchandise subject to this review. In these preliminary results, the Department applied the assessment rate calculation method adopted in *Final Modification for Reviews, i.e.,* on the basis of monthly average-to-average comparisons using only the transactions associated with that importer with offsets being provided for non-dumped

[98] *See* 19 CFR 351.224(b).

[99] *See* 19 CFR 351.309(c)(1)(ii).

[100] *See* 19 CRR 351.309(d).

[101] *See* 19 CFR 351.309(c), (d).

[102] *See, generally,* 19 CFR 351.303.

[103] *See Glycine From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007), and accompanying Issues and Decision Memorandum at Comment 2.

[104] *See* 19 CFR 351.310(c).

comparisons.[105] Where the respondent has reported reliable entered values, we calculate importer- (or customer-) specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer). Where an importer- (or customer-) specific *ad valorem* rate is greater than *de minimis,* we will apply the assessment rate to the entered value of the importers'/customers' entries during the POR, pursuant to 19 CFR 351.212(b)(1).

Where we do not have entered values for all U.S. sales to a particular importer/customer, we calculate a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to that importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).[106] To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer- (or customer-) specific *ad valorem* ratios based on the estimated entered value. Where an importer- (or customer-) specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[107]

For the companies receiving a separate rate that were not selected for individual review, we will assign an assessment rate based on the rate we calculated for the mandatory respondent whose rate was not *de minimis,* as discussed above. We intend to instruct CBP to liquidate entries containing subject merchandise exported by the PRC-wide entity at the PRC-wide rate. Finally, for those companies for which this review has been preliminarily rescinded, the Department intends to assess antidumping duties at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(2), if the review is rescinded for these companies.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be established in the final results of this review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, no cash deposit will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 118.04 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: August 28, 2012.

Paul Piquado

Assistant Secretary for Import Administration.

Appendix I

Companies that requested an administrative review of themselves:

Cana (Tianjin) Hardware Ind., Co., Ltd.;
Certified Products International Inc.;
ECO System Corporation;
Guangdong Foreign Trade Import & Export Corporation;
Heibei Minmentals Co., Ltd.;
Huanghua Jinhai Hardware Products Co., Ltd.;
Huanghua Xionghua Hardware Products Co., Ltd.;
JISCO Corporation;
Mingguang Abundant Hardware Products Co., Ltd.;
Qingdao D&L Group Ltd.;
Qingdao Jisco Co., Ltd.;
SDC International Australia Pty., Ltd.;
Shandong Dinglong Import & Export Co., Ltd.;
Shanghai Curvet Hardware Products Co., Ltd.;
Shanghai Jade Shuttle Hardware Tools Co., Ltd.;
Shanghai Yueda Nails Industry Co., Ltd.;
Shanxi Hairui Trade Co., Ltd.;
Shanxi Tianli Industries Co., Ltd.;
S-mart (Tianjin) Technology Development Co., Ltd.;
Suzhou Xingya Nail Co., Ltd.;
Stanley Black & Decker, Inc.;
The Stanley Works (Langfang) Fastening Systems Co., Ltd.;
Tianjin Jinchi Metal Products Co., Ltd.;
Tianjin Jinghai County Hongli Industry & Business Co., Ltd.;
Tianjin Zhonglian Metals Ware Co., Ltd.;
Tradex Group, Inc.;
Zhaoqing Harvest Nails Co., Ltd.

Appendix II

Companies that are part of the PRC-wide entity for which Petitioner has withdrawn its review request:

ABF Freight System, Inc.;
Agritech Products Ltd.;
Aihua Holding Group Co., Ltd.;
Anping County Anning Wire Mesh Co.;
Anping Fuhua Wire Mesh Making Co.;
APM Global Logistics O/B Hasbro Toy;
Beijing Daruixing Global Trading Co., Ltd.;
Beijing Daruising Nail Products Co., Ltd.;
Beijing Jinheuang Co., Ltd.;
Beijing Kang Jie Kong Cargo Agent;
Beijing KJK Intl Cargo Agent Co., Ltd.;
Beijing Long Time Rich Tech Develop;
Beijing Tri-Metal Co., Ltd.;
Beijing Yonghongsheng Metal Products Co., Ltd.;
Brighten International, Inc.;
Century Shenzhen Xiamin Branch;
Changzhou MC I/E Co., Ltd.;
Changzhou Quyan Machinery Co., Ltd.;
Changzhou Refine Flag & Crafts Co., Ltd.;
Chao Jinqiao Welding Material Co.;
Chaohu Bridge Nail Industry Co., Ltd.;
Chaohu Jinqiao Welding Material Co.;
Chewink Corp.;
China Container Line (Shanghai) Ltd.;
China Silk Trading & Logistics Co., Ltd.;
Chongqing Hybest Nailery Co., Ltd.;
Chongqing Hybest Tools Group Co., Ltd.;
Cintee Steel Products Co., Ltd.;
Cyber Express Corporation;
Damco Shenzhen;
Daxing Niantan Industrial;
Delix International Co., Ltd.;
Dingzhou Derunda Material and Trade Co., Ltd.;
Dingzhou Ruili Nail Production Co., Ltd.;
Dong'e Fuqiang Metal Products Co., Ltd.;
Dongguan Five Stone Machinery Products Trading Co., Ltd.;
Elite International Logistics Co.;
Elite Master International Ltd.;
England Rich Group (China) Ltd.;
Entech Manufacturing (Shenzhen) Ltd.;
Expeditors China Tianjin Branch;
Fedex International Freight Forward Agency Services (Shanghai) Co., Ltd.;
Feiyin Co., Ltd.; Fension International Trade Co., Ltd.;

[105] *See Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8103 (February 14, 2012) ("*Final Modifications for Reviews*").

[106] *See* 19 CFR 351.212(b)(1).

[107] *See* 19 CFR 351.106(c)(2).

Foreign Economic Relations & Trade; Fujiansmarness Imp. & Exp. Co., Ltd.;
Fuzhou Builddirect Ltd.;
Goal Well Stone Co., Ltd.;
Gold Union Group Ltd.;
Goldever International Logistics Co.;
Goldmax United Ltd.;
Grace News Inc.;
Guangzhou Qiwei Imports and Exports Co., Ltd.;
Guoxin Group Wang Shun I/E Co., Ltd.;
GWP Industries (Tianjin) Co., Ltd.;
Haierce Industry Co., Ltd.;
Haixing Hongda Hardware Production Co., Ltd.;
Haixing Linhai Hardware Products Factory;
Haiyan Fefine Import and Export Co.;
Handuk Industrial Co., Ltd.;
Hangzhou Kelong Electrical Appliance & Tools Co. Ltd;
Hangzhou New Line Co., Ltd.;
Hangzhould Zhongding Imp. & Exp. Co., Ltd.;
Hebei Development Metals Co., Ltd.;
Hebei Jinsidun (JSD) Co., Ltd.;
Hebei Machinery Import and Export Co., Ltd.;
Hebei My Foreign Trade Co., Ltd.;
Hebei Super Star Pneumatic Nails Co., Ltd.;
Henan Pengu Hardware Manufacturing Co., Ltd.;
Heretops (Hong Kong) Internaitonal Ltd.;
Hilti (China) Limited;
HK Villatao Sourcing Co., Ltd.;
Hong Kong Hailiang Metal Trading Ltd.;
Huadu Jin Chuan Manufactory Co Ltd,;
Huanghua Honly Industry Corp.;
Huanghua Huarong Hardware Products Co., Ltd.;
Hubei Boshilong Technology Co., Ltd.;
Huiyuan Int'l commerce Exhibition Co., Ltd.;
Jiashan Superpower Tools Co., Ltd.;
Jiaxing Yaoliang Import & Export Co., Ltd.;
Jinding Metal Products Ltd.;
Jinhua Kaixin Imp & Exp Ltd.;
Joto Enterprise Co., Ltd.;
K.E. Kingstone;
Karius Custom Metal Parts Mfg. Ltd.;
Kasy Logistics (Tianjin) Co., Ltd.;
Kuehne & Nagel Ltd.;
Kum Kang Trading Co., Ltd.;
Kyung Dong Corp.;
Le Group Industries Corp. Ltd.;
Leang Wey Int. Business Co., Ltd.;
Liang's Industrial Corp.;
Lijiang Liantai Trading Co., Ltd.;
Limhai Chicheng Arts & Crafts Co., Ltd.;
Lins Corp.;
Linyi Flying Arrow Imp & Exp Co., Ltd.;
Maanshan Cintee Steel Products Co., Ltd.;
Maanshan Leader Metal Products Co. Ltd.;
Maanshan Longer Nail Product Co., Ltd.;
Manufacutersinchina (HK) Company Ltd.;
Marsh Trading Ltd.;
Master International Co., Ltd.;
Montana (Taiwan) Int'l Co., Ltd.;
Nanjing Dayu Pneumatic Gun Nails Co., Ltd.;
Nantong Corporation for Internation;
Ningbo Bolun Electric Co, Ltd.;
Ningbo Dollar King Industrial Co., Ltd.;
Ningbo Endless Energy Electronic Co., Ltd.;
Ningbo Fension International Trade Center;
Ningbo Fortune Garden Tools and Equipment Inc.;
Ningbo Haixin Railroad Material Co.;
Ningbo Huamao Imp &Exp. Co., Ltd.;
Ningbo Hyderon Hardware Co., Ltd.;
Ningbo JF Tools Industrial Co., Ltd.;
Ningbo KCN electric Co., Ltd.;
Ningbo Meizhi Tools Co., Ltd.;
Ningbo Ordam Import & Export Co., Ltd.;
OEC Logistics (Qingdao) Co. Ltd.;
Omega Products International;
OOCL Logistics O B OF Winston Marketing Group;
Orisun Electronics HK Co., Ltd.;
Pacole International Ltd.;
Panagene Inc.;
Pavilion Investment Ltd.;
Perfect Seller Co., Ltd.;
Prominence Cargo Service, Inc.;
Qianshan Huafeng Trading Co., Ltd.;
Qingdao Bestworld Industry Trading;
Qingdao Denarius Manufacture Co. Limited;
Qingdao Golden Sunshine ELE–EAQ Co., Ltd.;
Qingdao International Fastening Systems Inc.;
Qingdao Lutai Industrial Products Manufacturing Co., Ltd.;
Qingdao Meijia Metal Products Co.;
Qingdao Rohuida International Trading Co., Ltd.;
Qingdao Sino-Sun International Trading Company Limited;
Qingdao Super United Metals & Wood Prods. Co. Ltd.;
Qingdao Tiger Hardware Co., Ltd.;
Qingfu Metal Craft Manufacturing Ltd.;
Qinghai Wutong (Group) Industry Co.;
Qingyuan County Hongyi Hardware Products Factory;
Qingyun Hongyi Hardware Factory;
Qinhuandao Kaizheng Industry and Trade Co. Ltd.;
Q-Yield Outdoor Great Ltd.;
Region International Co., Ltd.;
Richard Hung Ent. Co. Ltd.;
River Display Ltd.;
Rizhao Changxing Nail-Making Co., Ltd.;
Rizhao Handuk Fasteners Co., Ltd.;
Rizhao Qingdong Electric Appliance Co., Ltd.;
Saikelong Electric Appliances (Suzhou) Co., Ltd.; Se Jung (China) Shipping Co., Ltd.;
Senco Products, Inc.;
Shandex Co., Ltd;
Shandex Industrial Inc.;
Shandong Minmetals Co., Ltd.;
Shanghai Chengkai Hardware Product Co., Ltd.;
Shanghai Colour Nail Co., Ltd.;
Shanghai Ding Ying Printing & Dyeing CLO;
Shanghai GBR Group International Co.;
Shanghai Holiday Import & Export Co., Ltd.;
Shanghai Jian Jie International TRA;
Shanghai March Import & Export Company Ltd.;
Shanghai Mizhu Imp & Exp Corporation;
Shanghai Nanhui Jinjun Hardware Factory;
Shanghai Pioneer Speakers Co., Ltd.;
Shanghai Pudong Int'l Transportation Booking Dep't;
Shanghai Shengxiang Hardware Co.;
Shanghai Suyu Railway Fastener Co.;
Shanghai Tengyu Hardware Products Co., Ltd.;
Shanghai Tymex International Trade Co., Ltd.;
Shanghai Yuet Commercial Consulting Co., Ltd.;
Shanxi Yuci Wire Material Factory;
Shaoguang International Trade Co.;
Shenyang Yulin International;
Shenzhen Changxinghongye Imp.;
Shenzhen Erisson Technology Co., Ltd.;
Shenzhen Meiyuda Trade Co., Ltd.;
Shenzhen Pacific-Net Logistics Inc.;
Shenzhen Shangqi Imports-Exports TR;
Shijiazhuang Anao Imp & Export Co. Ltd.;
Shijiazhuang Fangyu Import & Export Corp.;
Shijiazhuang Fitex Trading Co., Ltd.;
Shijiazhuang Glory Way Trading Co.;
Shijiazhuang Shuangjian Tools Co., Ltd.;
Shitong Int'l Holding Limited;
Sinochem Tianjin Imp & Exp Shenzhen Corp.;
Sirius Global Logistics Co., Ltd.;
Sunfield Enterprise Corporation;
Sunlife Enterprises (Yangjiang) Ltd.;
Sunworld International Logistics;
Superior International Australia Pty Ltd.;
Suzhou Guoxin Group Wangshun I/E Co. Imp. Exp. Co., Ltd.;
Telex Hong Kong Industry Co., Ltd.;
The Everest Corp.;
Thermwell Products;
Tian Jin Sundy Co., Ltdl (a/k/a/Tianjin Sunny Co., Ltd.);
Tianjin Baisheng Metal Products Co., Ltd.;
Tianjin Bosai Hardware Tools Co., Ltd.;
Tianjin Certified Products Inc.;
Tianjin Chengyi International Trading Co., Ltd.;
Tianjin City Dagang Area Jinding Metal Products Factory;
Tianjin City Daman Port Area Jinding Metal Products Factory;
Tianjin City Jinchi Metal Products Co., Ltd.;
Tianjin Dagang Dongfu Metallic Products Co., Ltd.;
Tianjin Dagang Hewang Nail Factory;
Tianjin Dagang Hewang Nails Manufacture Plant;
Tianjin Dagang Huasheng Nailery Co., Ltd.;
Tianjin Dagang Jingang Nail Factory;
Tianjin Dagang Jingang Nails Manufacture Plant;
Tianjin Dagang Linda Metallic Products Co., Ltd.;
Tianjin Dagang Longhua Metal Products Plant;
Tianjin Dagang Shenda Metal Products Co., Ltd.;
Tianjin Dagang Yate Nail Co., Ltd.;
Tianjin Dagang Yate Nail Co., Ltd.;
Tianjin Dery Import and Export Co., Ltd.;
Tianjin Everwin Metal Products Co., Ltd.;
Tianjin Foreign Trade (Group) Textile & Garment Co., Ltd.;
Tianjin Hewang Nail Making Factory;
Tianjin Huachang Metal Products Co., Ltd.;
Tianjin Huapeng Metal Company;
Tianjin Huasheng Nails Production Co., Ltd.;
Tianjin jetcom Manufacturing Co., Ltd.;
Tianjin Jieli Hengyuan Metallic Products Co.; Ltd.;
Tianjin Jietong Hardware Products Co., Ltd.;
Tianjin Jietong Metal Products Co., Ltd;
Tianjin Jin Gang metal Products Co., Ltd.;
Tianjin Jinjin Pharmaceutical Factory Co., Ltd.;
Tianjin Jishili Hardware Co., Ltd.;
Tianjin JLHY Metal Products Co., Ltd.;
Tianjin Jurum Metal Products Co., Ltd.;
Tianjin Kunxin Hardware Co., Ltd.;
Tianjin Kunxin Metal Products Co., Ltd.;
Tianjin Linda Metal Company;
Tianjin Longxing (Group) Huanyu Imp. & Exp. Co., Ltd.;

Tianjin Master Fastener Co., Ltd. (a/k/a Master Fastener Co., Ltd.);
Tianjin Mei Jia Hua Trade Co., Ltd.;
Tianjin Metals and Minerals;
Tianjin Port Free Trade Zone Xiangtong Intl. Industry & Trade Corp.;
Tianjin Products & Energy Resources dev. Co., Ltd.;
Tianjin Qichuan Metal Products Co., Ltd.;
Tianjin Ruiji Metal Products Co., Ltd.;
Tianjin Senbohengtong International;
Tianjin Senmiao Import and Export Co., Ltd.;
Tianjin Shenyuan Steel Producting Group Co., Ltd.;
Tianjin Shishun Metal Product Co., Ltd.;
Tianjin Shishun Metallic Products Co., Ltd.;
Tianjin Xiantong Fucheng Gun Nail Manufacture Co., Ltd.;
Tianjin Xiantong Juxiang Metal MFG Co., Ltd.;
Tianjin Xinyuansheng Metal Products Co., Ltd.;
Tianjin Yihao Metallic Products Co., Ltd.;
Tianjin Yongchang Metal Product Co., Ltd.;
Tianjin Yongxu Metal Products Co., Ltd.;
Tianjin Yongye Furniture;
Tianjin Yongyi Standard Parts Production Co., Ltd.;
Tianjin Zhong Jian Wanli Stone Co., Ltd.;
Tianjin Zhongsheng Garment Co., Ltd.;
Tianwoo Logistics Developing Co., Ltd.;
Topocean Consolidation Service (CHA) Ltd.;
Traser Mexicana, S.A. De C.V.;
Treasure Way International Dev. Ltd.;
True Value Company (HK) Ltd.;
Unicatch Industrial Co. Ltd.;
Unigain Trading Co., Ltd.;
Vinin Industries Limited;
Wenzhou KLF Medical Plastics Co., Lt.;
Wenzhou Ouxin Foreign Trade Co., Ltd.;
Wenzhou Yuwei Foreign Trade Co., Ltd.;
Winsmart International Shipping Ltd., O/B Zhaoqing Harvest Nails Co., Ltd.;
Worldwide Logistics Co., Ltd., (Tianjin Branch);
Wuhan Xinxin Native Produce & Animal By-Products Mfg. Co. Ltd.;
Wuhu Sheng Zhi Industrial Co., Ltd.;
Wuqiao County Huifeng Hardware Products Factory;
Wuqiao County Sinchuang Hardware Products Factory;
Wuqiao County Huifeng Hardware Production Co., Ltd.;
Wuxi Baolin Nail Enterprises;
Wuxi Baolin Nail-Making Machinery Co., Ltd.;
Wuxi Colour Nail Co., Ltd.;
Wuxi Jinde Assets Management Co., Ltd.;
Wuxi Moresky Developing Co., Ltd.;
Wuxi Qiangye Metal work Production Co., Ltd.;
Xi'an Steel; Xiamen New Kunlun Trade Co., Ltd.;
XL Metal Works Co., Ltd.; XM International, Inc.;
Yeswin Corporation;
Yiwu Dongshun Toys Manufacture;
Yiwu Excellent Import & Export Co., Ltd.;
Yiwu Jiehang Import & Export Co., Ltd.;
Yiwu Qiaoli Import & Export Co., Ltd.;
Yiwu Richway Imp & Exp Co., Ltd.;
Yiwu Zhongai Toys Co., Ltd.;
Yongcheng Foreign Trade Corp.;
Yu Chi Hardware Co., Ltd.;
Yue Sang Plastic Factory;
Yuhuan Yazheng Importing;
Zhangjiagang Lianfeng Metals Products Co., Ltd.;
Zhangjiagang Longxiang Packing Materials Co., Ltd.;
Zhejiang Hungyan Xingzhou Industria;
Zhejiang Jinhua Nail Factory;
Zhejiang Minmetals Sanhe Imp & Exp Co.;
Zhejiang Qifeng Hardware Make Co., Ltd.;
Zhejiang Taizhou Eagle Machinery Co.;
Zhejiang Yiwu Huishun Import/Export Co., Ltd.;
Zhongshan Junlong Nail Manufactures Co., Ltd.;
ZJG Lianfeng Metals Product Ltd.

Appendix III

Companies that filed no-shipment certifications, collectively (''No Shipment Respondents''):

(1) Jining Huarong Hardware Products Co., Ltd.;
(2) Chiieh Yung Metal Ind. Corp.;
(3) CYM (Nanjing) Nail Manufacture Co., Ltd.;
(4) Qidong Liang Chyuan Metal Industry Co., Ltd.;
(5) Certified Products International Inc. (''CPI'');
(6) Besco Machinery Industry (Zhejiang) Co., Ltd.;
(7) China Staple Enterprise (Tianjin) Co., Ltd.;
(8) Zhejiang Gem-Chun Hardware Accessory Co., Ltd.;
(9) PT Enterprise Inc.;
(10) Shanxi Yuci Broad Wire Products Co., Ltd.;
(11) Hengshui Mingyao Hardware & Mesh Products Co., Ltd. (''Hengshui Mingyao'');
(12) Union Enterprise (Kunshan) Co., Ltd.

Appendix IV

Companies that did not apply for separate rates and are considered to be part of the PRC-wide entity:

Aironware (Shanghai) Co., Ltd.;
Beijing Hong Sheng Metal Products Co., Ltd.;
Beijing Hongsheng Metal Products Co., Ltd.;
Dagang Zhitong Metal Products Co., Ltd.;
Faithful Engineering Products Co., Ltd.;
Hebei Minmetals Co., Ltd.;[108]
Hong Kong Yu Xi Co., Ltd.;
Huanghua Shenghua Hardware Manufactory Factory;
Huanghua Xinda Nail Production Co., Ltd.;
Huanghua Yuftai Hardware Products Co., Ltd.;
Senco-Xingya Metal Products (Taicang) Co., Ltd.;
Shanghai Seti Enterprise International Co., Ltd.;
Shanghai Tengyu Hardware Tools Co., Ltd.;
Shanxi Tianli Enterprise Co., Ltd.;
Shaoxing Chengye Metal Producting Co., Ltd.;
Shouguang Meiqing Nail Industry Co., Ltd.;
Suntec Industries Co., Ltd.;
Suzhou Xingya Nail Co., Ltd.;
Suzhou Yaotian Metal Products Co., Ltd.;
Shandex Industrial Inc.;
Tianjin Chentai International Trading Co., Ltd.;
Tianjin Jurun Metal Products Co., Ltd.;
Tianjin Xiantong Material & Trade Co., Ltd.;
Tradex Group, Inc.;
Wintime Import & Export Corporation Limited of Zhongshan;
Wuhu Shijie Hardware Co., Ltd.;
Wuhu Sin Lan De Industrial Co., Ltd.;
Wuxi Chengye Metal Products Co., Ltd.;
Xuzhou CIP International Group Co., Ltd.;
Yitian Nanjing Hardware Co., Ltd.

[108] Hebei, submitted an untimely no shipment certification that the Department has rejected (*see* page 2). Therefore, this company is now considered to be part of the PRC-wide entity.

[FR Doc. 2012–21708 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–893]

Administrative Review of Certain Frozen Warmwater Shrimp From the People's Republic of China: Final Results, Partial Rescission of Sixth Antidumping Duty Administrative Review and Determination Not To Revoke in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On March 2, 2012, the Department of Commerce (''Department'') published in the **Federal Register** the *Preliminary Results* of the sixth administrative review (''AR'') of the antidumping duty order on certain frozen warmwater shrimp from the People's Republic of China (''PRC'').[1] We gave interested parties an opportunity to comment on the *Preliminary Results.* Based upon our analysis of the comments and information received, we have determined that the application of total adverse facts available (''AFA'') to Hilltop,[2] as part of the PRC-wide entity, is appropriate in this review. Additionally, we continue to find that Zhanjiang Regal Integrated Marine Resources Co., Ltd. (''Regal'') has not sold subject merchandise at less than normal value (''NV'') during the period of review (''POR''), February 1, 2010, through January 31, 2011.

DATES: *Effective Date:* September 4, 2012.

FOR FURTHER INFORMATION CONTACT: Bob Palmer and Kabir Archuletta, AD/CVD

[1] *See Certain Frozen Warmwater Shrimp From the People's Republic of China: Preliminary Results, Partial Rescission, Extension of Time Limits for the Final Results, and Intent to Revoke, in Part, of the Sixth Antidumping Duty Administrative Review,* 77 FR 12801 (March 2, 2012) (''*Preliminary Results*'').

[2] Hilltop International, Yangjiang City Yelin Hoitat Quick Frozen Seafood Co., Ltd., Fuqing Yihua Aquatic Food Co., Ltd., Ocean Duke Corporation and Kingston Foods Corporation (collectively, ''Hilltop'').

Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–9068 and (202) 482–2593, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 31, 2011, the Department initiated an administrative review of 84 producers/exporters of subject merchandise from the PRC.[3] In the *Preliminary Results,* the Department preliminarily rescinded the review with respect to Shantou Yuexing Enterprise Company which submitted a no shipment certification and for which we have not found any information to contradict this claim.[4]

As noted above, on March 2, 2012, the Department published the *Preliminary Results* of this administrative review and extended the deadline for the final results by 60 days. On April 26, 2012, the Petitioner,[5] Domestic Processors,[6] and Hilltop submitted additional surrogate value information. On May 7, 2012, Domestic Processors and Hilltop submitted rebuttal surrogate value information.

On June 19, 2012, the Department issued a letter to all interested parties establishing June 26, 2012, and July 2, 2012, as the case and rebuttal brief deadlines, respectively, for all issues except those concerning Hilltop's U.S. sales and request for company-specific revocation.[7] On June 26, 2012, Petitioner, Domestic Processors and Hilltop filed case briefs. On July 2, 2012, Petitioner, Domestic Processors, and Hilltop filed rebuttal briefs.

On July 6, 2012, the Department issued a letter to all interested parties establishing July 17, 2012, and July 23, 2012, as the case and rebuttal brief deadlines, respectively, for issues pertaining to Hilltop's U.S. sales and revocation request.[8] On July 17, 2012, Petitioner, Domestic Processors and Hilltop filed case briefs with respect to the Hilltop issues. On July 23, 2012, Petitioner, Domestic Processors and Hilltop filed rebuttal briefs with respect to the Hilltop issues.

Background Regarding Hilltop

On March 12, 2012, Petitioner submitted information concerning recent criminal convictions of entities/persons affiliated with Hilltop and allegations of a transshipment scheme of shrimp through the Kingdom of Cambodia (''Cambodia'') during the first and second administrative reviews of this proceeding. The involved parties included Hilltop, Hilltop's U.S. affiliate Ocean Duke Corporation (''Ocean Duke''), and Ocean King (Cambodia) Co., Ltd. (''Ocean King''), a Cambodian company.[9] Between March 29 and May 16, 2012, interested parties submitted comments regarding these allegations. Between March 16 and May 16, 2012, interested parties met with Department officials to discuss their submissions.[10]

On May 17, 2012, the Department placed U.S. Customs and Border Protection (''CBP'') data on the record of this review for entries of shrimp to the United States imported under Harmonized Tariff Schedule of the United States (''HTSUS'') numbers included in the scope of the Order with a country-of-origin designation of Cambodia during the period January 1, 2003, through May 2, 2012.[11] Between May 24, 2012, and May 31, 2012, interested parties submitted comments regarding the Cambodian CBP data.

On June 1, 2012, the Department sent Hilltop a supplemental questionnaire addressing a number of the allegations regarding Hilltop and potentially undisclosed affiliations, as well as other issues brought to light in Petitioner's March 12 Submission.[12] On June 15, 2012, Hilltop submitted its response, which largely consisted of a ''Preliminary Statement,'' in which Hilltop provided an analysis that detailed why Hilltop believes the allegations of misconduct prior to AR4 are irrelevant to the Department's revocation analysis, argued that it is improper for the Department to investigate allegations of transshipment in a review proceeding, and stated its refusal to answer any questions regarding it activities prior to AR4.[13] Hilltop also stated that it already disclosed all affiliations to the Department and that it had no undisclosed Cambodian affiliate during this period of review or the two previous review periods (*i.e.* the revocation period).

On June 19, 2012, the Department placed on the record of this review public registration documentation listing To Kam Keung, the General Manager[14] of Hilltop, as an owner and director of Ocean King from September 2005 through September 2010, *i.e.* during AR3–AR5 and through the first half of AR6.[15] On June 19, 2012, the Department also issued to Hilltop a supplemental questionnaire requesting that Hilltop respond to those questions which it previously refused to address and provide additional information related to the public registration documentation for Ocean King.[16] On June 26, 2012, Hilltop submitted its response to the Seventh Supplemental Questionnaire and again refused to answer those questions it deemed irrelevant; however Hilltop admitted that an affiliation with Ocean King did exist from September 2005 until September 28, 2010.[17]

On July 6, 2012, the Department placed on the record CBP data for U.S. imports of subject merchandise from the PRC for the period February 1, 2007 through January 31, 2008, which is the period corresponding with the third

[3] *See Initiation of Antidumping Duty Administrative Reviews, Requests for Revocation in Part, and Deferral of Administrative Review,* 76 FR 17825 (March 31, 2011) (''*Initiation*'') for a list of these companies.

[4] *See Preliminary Results* at 12803.

[5] The Ad Hoc Shrimp Trade Action Committee (hereinafter referred to as ''Petitioner'').

[6] These domestic parties are the American Shrimp Processors Association (hereinafter referred to as ''Domestic Processors'').

[7] *See* Letter from the Department to All Interested Parties, dated June 19, 2012.

[8] *See* Letter from the Department to All Interested Parties, dated July 6, 2012.

[9] *See* Letter from Petitioner to the Secretary of Commerce ''Certain Frozen Warmwater Shrimp from China: Comments On the Department's Preliminary Determination to Grant Hilltop's Request for Company-Specific Revocation Pursuant to 19 C.F.R. § 351.222(b)(2) and Comments in Anticipation of Hilltop's Forthcoming Verification'' (March 12, 2012) (''Petitioner's March 12 Submission'').

[10] *See* Memo to the File from Kabir Archuletta, International Trade Analyst, Office 9, ''Meeting with Counsel for Petitioner'' (March 16, 2012); Memo to the File from Kabir Archuletta, International Trade Analyst, Office 9, ''Certain Frozen Warmwater Shrimp from the People's Republic of China: *Ex Parte* Meeting with Counsel for Hilltop International'' (April 16, 2012); Memo to the File from Kabir Archuletta, International Trade Analyst, Office 9, ''Certain Frozen Warmwater Shrimp from the People's Republic of China: *Ex Parte* Meeting with Counsel for Petitioner'' (May 16, 2012).

[11] *See* Memo to the File from Kabir Archuletta, International Trade Analyst, Office 9, ''Customs Data of U.S. Imports of Certain Frozen Warmwater Shrimp from Cambodia'' (May 17, 2012).

[12] *See* Letter from the Catherine Bertrand, Program Manager, Office 9, regarding the Sixth Supplemental Questionnaire (June 1, 2012) (''Hilltop Sixth Supplemental Questionnaire'').

[13] *See* Letter from Hilltop to the Secretary of Commerce ''Hilltop's Response to June 1, 2012 Supplemental Questionnaire'' (June 15, 2012) (''Hilltop Sixth Supplemental Response'').

[14] *See* Letter from Hilltop to the Secretary of Commerce ''Section A Response for Hilltop International in the Sixth Administrative Review of Certain Frozen Warmwater Shrimp from the People's Republic of China'' (June 15, 2011) at Exhibit 2.

[15] *See* Memo to the File from Kabir Archuletta, International Trade Analyst, Office 9, ''Public Registration Documents for Ocean King (Cambodia) Co., Ltd.'' (June 19, 2012).

[16] *See* Letter from Catherine Bertrand, Program Manager, Office 9, to Hilltop ''Seventh Supplemental Questionnaire'' (July 19, 2012) (''Seventh Supplemental Questionnaire'').

[17] *See* Letter from Hilltop to the Secretary of Commerce ''Hilltop's Response to June 1, 2012 Supplemental Questionnaire'' (June 26, 2012) at pg. 1 (''Hilltop Seventh Supplemental Response'').

administrative review of this proceeding. On July 11, 2012, Petitioner submitted comments on the AR3 CBP data.[18]

Scope of the Order

The scope of the order includes certain frozen warmwater shrimp and prawns, whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off,[19] deveined or not deveined, cooked or raw, or otherwise processed in frozen form.

The frozen warmwater shrimp and prawn products included in the scope of the order, regardless of definitions in the Harmonized Tariff Schedule of the United States (''HTS''), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the *Penaeidae* family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, white-leg shrimp (*Penaeus vannemei*), banana prawn (*Penaeus merguiensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn (*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope of the order. In addition, food preparations, which are not ''prepared meals,'' that contain more than 20 percent by weight of shrimp or prawn are also included in the scope of the order.

Excluded from the scope are: (1) Breaded shrimp and prawns (HTS subheading 1605.20.1020); (2) shrimp and prawns generally classified in the *Pandalidae* family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTS subheadings 0306.23.0020 and 0306.23.0040); (4) shrimp and prawns in prepared meals (HTS subheading 1605.20.0510); (5) dried shrimp and prawns; (6) Lee Kum Kee's shrimp sauce; (7) canned warmwater shrimp and prawns (HTS subheading 1605.20.1040); (8) certain dusted shrimp;[20] and (9) certain battered shrimp. Dusted shrimp is a shrimp-based product: (1) That is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a ''dusting'' layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the non-shrimp content of the end product constituting between four and 10 percent of the product's total weight after being dusted, but prior to being frozen; and (5) that is subjected to individually quick frozen (''IQF'') freezing immediately after application of the dusting layer. Battered shrimp is a shrimp-based product that, when dusted in accordance with the definition of dusting above, is coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the order are currently classified under the following HTS subheadings: 0306.13.0003, 0306.13.0006, 0306.13.0009, 0306.13.0012, 0306.13.0015, 0306.13.0018, 0306.13.0021, 0306.13.0024, 0306.13.0027, 0306.13.0040, 0306.17.0003, 0306.17.0006, 0306.17.0009, 0306.17.0012, 0306.17.0015, 0306.17.0018, 0306.17.0021, 0306.17.0024, 0306.17.0027, 0306.17.0040, 1605.20.1010, 1605.20.1030, 1605.21.1030, and 1605.29.1010. These HTS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope of the order is dispositive.

Final Partial Rescission

In the *Preliminary Results,* the Department preliminarily rescinded this review with respect to Shantou Yuexing Enterprise Company. The Department determined that it had no shipments of subject merchandise to the United States during the POR.[21] Subsequent to the *Preliminary Results,* no information was submitted on the record indicating that it made sales to the United States of subject merchandise during the POR and no party provided written arguments regarding this issue. Thus, in accordance with 19 CFR 351.213(d)(3), and consistent with our practice, we are rescinding this review with respect to Shantou Yuexing Enterprise Company.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this review are addressed in the ''Sixth Administrative Review of Frozen Warmwater Shrimp from the People's Republic of China: Issues and Decision Memorandum for the Final Results,'' which is dated concurrently with this notice (''I&D Memo''). A list of the issues that parties raised and to which we respond in the I&D Memo is attached to this notice as Appendix I. The I&D Memo is a public document and is on file in the Central Records Unit (''CRU''), Main Commerce Building, Room 7046, and is accessible on the Department's Web site at *http://www.trade.gov/ia.* The paper copy and electronic version of the memorandum are identical in content.

Changes Since the Preliminary Results

Based on a review of the record as well as comments received from parties regarding our *Preliminary Results,* we made three revisions to Regal's margin calculation for the final results. First, we have corrected an inadvertent error in the calculation of the ice surrogate value used in the *Preliminary Results.* For further information *see* I&D Memo at Comment 14; *see also* Final SV Memo.[22] Additionally, we have included Kongphop Frozen Foods Company Ltd. (''Kongphop'') and Sea Bonanza Frozen Foods Company Limited (''Sea Bonanza'') financial statements to calculate the surrogate financial ratios,

[18] *See* Letter from Petitioner to the Secretary of Commerce.

[19] ''Tails'' in this context means the tail fan, which includes the telson and the uropods.

[20] On April 26, 2011, the Department amended the antidumping duty order to include dusted shrimp, pursuant to the U.S. Court of International Trade (''CIT''') decision in *Ad Hoc Shrimp Trade Action Committee* v. *United States,* 703 F. Supp. 2d 1330 (CIT 2010) and the U.S. International Trade Commission (''ITC''') determination, which found the domestic like product to include dusted shrimp. Because the amendment of the antidumping duty order occurred after this POR, dusted shrimp continue to be excluded in this review. *See Certain Frozen Warmwater Shrimp from Brazil, India, the People's Republic of China, Thailand, and the Socialist Republic of Vietnam: Amended Antidumping Duty Orders in Accordance with Final Court Decision,* 76 FR 23277 (April 26, 2011); *see also Ad Hoc Shrimp Trade Action Committee* v. *United States,* 703 F. Supp. 2d 1330 (CIT 2010) and *Frozen Warmwater Shrimp from Brazil, China, India, Thailand, and Vietnam* (Investigation Nos. 731–TA–1063, 1064, 1066–1068 (Review), USITC Publication 4221, March 2011. However, we note that this review only covers suspended entries that did not include dusted shrimp, but cash deposits going forward will apply to dusted shrimp.

[21] *See Preliminary Results* at 12801, 12803.

[22] *See* Memorandum to the File through Catherine Bertrand, Program Manager, Office 9 from Bob Palmer, Case Analyst, Office 9; Sixth Administrative Review of Certain Frozen Warmwater Shrimp from the People's Republic of China: Surrogate Factor Valuations for the Final Results, (''Final SV Memo'') dated concurrently with this notice.

because they are processors of frozen shrimp and their financial statements are contemporaneous and complete and indicate that they are unsubsidized. For further information *see* I&D Memo at Comment 12; *see also* Final SV Memo. We have also corrected various errors related to the calculation of the surrogate financial ratios using the financial statements of Kiang Huat Sea Gull Trading Frozen Food Public Co. Ltd. (''Kiang Huat''). For further information *see* I&D Memo at Comment 13; *see also* Final SV Memo. The Department's determination to find Hilltop to be part of the PRC-wide entity and deny its company-specific revocation request from the *Order* are discussed below.

Separate Rates

In our *Preliminary Results,* we preliminarily determined that Regal met the criteria for the application of a separate rate.[23] We have not received any information since the issuance of the *Preliminary Results* that provides a basis for the reconsideration of this determination. Therefore, the Department continues to find that Regal meets the criteria for a separate rate.

Further, while we preliminarily determined that Hilltop had satisfied the criteria for the application of a separate rate in the *Preliminary Results,* based on information subsequently placed on the record, for these final results we find that Hilltop's separate rate information is no longer reliable or usable and Hilltop has failed to demonstrate its eligibility for a separate rate. In *PRC Shrimp AR5,* we found Hilltop to be part of a single entity, which included affiliates in a third country that had extensive production facilities in the PRC.[24] In the *Preliminary Results,* we stated that because Hilltop had presented no additional evidence to demonstrate that it is not a part of this single entity, we continued to find that Hilltop and its affiliates were part of a single entity in this review.[25] While we note that Hilltop is located in Hong Kong, its affiliated producers are located in the PRC. As we cannot rely on any of the information provided in Hilltop's section A questionnaire responses, we cannot determine that this single entity of affiliated companies, of which Hilltop is a part, has met the criteria for a separate rate. Therefore, we are not granting a separate rate to Hilltop and its affiliates and we find Hilltop to be part of the PRC-wide entity.

Facts Otherwise Available

Sections 776(a)(1) and 776(a)(2) of the Act provide that if necessary information is not available on the record, or if an interested party (A) withholds information that has been requested by the Department; (B) fails to provide such information in a timely manner or in the form or manner requested subject to sections 782(c)(1) and (e) of the Act; (C) significantly impedes a proceeding under the antidumping statute; or (D) provides such information but the information cannot be verified, then the Department shall, subject to subsection 782(d) of the Act, use facts otherwise available in reaching the applicable determination.

Section 782(d) of the Act provides that, if the Department determines that a response to a request for information does not comply with the request, the Department will inform the person submitting the response of the nature of the deficiency and shall, to the extent practicable, provide that person the opportunity to remedy or explain the deficiency. If that person submits further information that continues to be unsatisfactory, or this information is not submitted within the applicable time limits, then the Department may, subject to section 782(e) of the Act, disregard all or part of the original and subsequent responses, as appropriate.

Section 782(e) of the Act states that the Department shall not decline to consider information deemed ''deficient'' under section 782(d) if (1) the information is submitted by the established deadline; (2) the information can be verified; (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the applicable determination; (4) the interested party has demonstrated that it acted to the best of its ability in providing the information and meeting the requirements established by the Department; and (5) the information can be used without undue difficulties.

Hilltop/PRC-Wide Entity

As explained further in Comment 1 of the I&D Memo, the Department finds that the information to calculate an accurate and otherwise reliable margin is not available on the record with respect to Hilltop. Because the Department finds that necessary information is not on the record, and that Hilltop withheld information that has been requested, failed to submit information in a timely manner, significantly impeded this proceeding, and provided information that could not be verified,[26] pursuant to sections 776(a)(1) and (2)(A), (B), (C) and (D) of the Tariff Act of 1930, the Department is using the facts otherwise available. For a more detailed discussion of the Department's determination, *see* I&D Memo at Comment 1 and Hilltop AFA Memo.[27] Further, because we determine that the entirety of Hilltop's data are unusable, we also find that Hilltop has failed to demonstrate that it is eligible for a separate rate and is therefore part of the PRC-wide entity. Accordingly, we are assigning facts available to the PRC-wide entity, of which Hilltop is a part.

Adverse Facts Available

When relying on facts otherwise available, the Department may apply an adverse inference. Section 776(b) of the Act states that if the Department ''finds that an interested party has failed to cooperate by not acting to the best of its ability to comply with a request for information from the administering authority * * * {the Department} * * * may use an inference that is adverse to the interests of the party in selecting from among the facts otherwise available.'' [28] Adverse inferences are appropriate to ''ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.'' [29] In selecting an adverse inference, the Department may rely on information derived from the petition, the final determination in the investigation, any previous review, or any other information placed on the record.[30]

Based on record evidence, the Department determines that the PRC-wide entity, which includes Hilltop, has failed to cooperate to the best of its ability in providing the requested information. Accordingly, pursuant to

[23] *See Preliminary Results* at 12801, 12804.

[24] *See Certain Frozen Warmwater Shrimp From the People's Republic of China: Preliminary Results and Preliminary Partial Rescission of Fifth Antidumping Duty Administrative Review,* 76 FR 8338, 8339 (February 14, 2011), unchanged in *Administrative Review of Certain Frozen Warmwater Shrimp From the People's Republic of China: Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 76 FR 51940 (August 19, 2011) (''PRC Shrimp AR5'').

[25] *See Preliminary Results* at 12801, 12803.

[26] *See e.g., Certain Lined Paper Products from the People's Republic of China: Notice of Final Results of the Second Administrative Review of the Antidumping Order,* 74 FR 63387 (December 3, 2009), affirmed in *The Watanabe Group v. United States,* 2010 Ct. Int. Trade LEXIS 144, Slip. Op. 2010–139 (2010).

[27] *See* Memorandum to the File through Catherine Bertrand, Program Manager, Office 9, from Kabir Archuletta, Analyst, Office 9, re: ''Administrative Review of Certain Frozen Warmwater Shrimp from the People's Republic of China: Application of Adverse Facts Available to Hilltop International,'' dated concurrently with this notice (''Hilltop AFA Memo'').

[28] *See also* Statement of Administrative Action accompanying the Uruguay Round Agreements Act, H.R. Rep. No., 103–316 at 870 (1994) (''SAA'').

[29] *See id.*

[30] *See* section 776(b) of the Act.

sections 776(a)(2)(A), (B), (C), and (D), and section 776(b) of the Act, we find it appropriate to apply a margin to the PRC-wide entity based entirely on facts available with an adverse inference.[31] By doing so, we ensure that the PRC-wide entity, which includes Hilltop, will not obtain a more favorable result by failing to cooperate than had it cooperated fully in this review. *See* I&D Memo at Comment 1 and Hilltop AFA Memo.

The Department's practice is to select an AFA rate that is sufficiently adverse as to effectuate the purpose of the facts available rule to induce respondents to provide the Department with complete and accurate information in a timely manner and that ensures that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.[32] In choosing the appropriate balance between providing respondents with an incentive to respond accurately and imposing a rate that is reasonably related to the respondent's prior commercial activity, selecting the highest prior margin ''reflects a common sense inference that the highest prior margin is the most probative evidence of current margins, because, if it were not so, the importer, knowing of the rule, would have produced current information showing the margin to be less.'' [33] Specifically, the Department's practice in reviews, when selecting a rate as total AFA, is to use the highest rate on the record of the proceeding which, to the extent practicable, can be corroborated.[34] The CIT and U.S. Court of Appeals for the Federal Circuit (''Federal Circuit'') have affirmed Commerce's practice of selecting the highest margin on the record for any segment of the proceeding as the AFA rate.[35] Therefore, we are assigning as AFA to the PRC-wide entity, which includes Hilltop, a rate of 112.81%, which is the highest rate on the record of this proceeding and which was the rate assigned to the PRC-wide entity in the less than fair value investigation (''LTFV'') of this proceeding.[36]

Corroboration of PRC-Wide Entity Rate

Section 776(c) of the Act requires that when relying on secondary information, the Department must corroborate, to the extent practicable, the rate which it applies as AFA. To be considered corroborated, the Department must find the information has probative value, meaning that the information must be found to be both reliable and relevant.[37] As noted above, we are applying as AFA the highest rate from any segment of this proceeding, which is the rate currently applicable to all exporters subject to the PRC-wide rate. Although Hilltop has questioned the reliability of the PRC-wide rate because it was based on normal values calculated using Indian surrogate values,[38] the Department sees no reason to deviate from its standard practice of using petition rates as the rates for applying adverse facts available.[39] The Department's practice is not to recalculate margins provided in petitions, but rather to corroborate the applicable petition rate when applying that rate as AFA.[40] The AFA rate in the current review (*i.e.,* the PRC-wide rate of 112.81 percent) represents the highest rate from the petition in the LTFV investigation and was corroborated in the LTFV investigation.[41]

With respect to the relevance aspect of corroboration, the Department will consider information reasonably at its disposal to determine whether a margin continues to have relevance. Where circumstances indicate that the selected margin is not appropriate as AFA, the Department will disregard the margin and determine an appropriate margin. For example, in *Fresh Cut Flowers from Mexico,*[42] the Department disregarded the highest margin on the record as not being the best information available (the predecessor to adverse facts available) because the margin was based on another company's uncharacteristic business expense resulting in an unusually high margin. The information used in calculating this margin was based on sales and production data submitted by the petitioner in the LTFV investigation, together with the most appropriate surrogate value information available to the Department chosen from submissions by the parties in the LTFV investigation.[43] Furthermore, the calculation of this margin was subject to comment from interested parties during the investigation after it was selected as the rate for the PRC-wide entity in the preliminary results.[44] This has been the rate applicable to the PRC-wide entity since the investigation. As there is no information on the record of this review that demonstrates that this rate is not appropriate for use as AFA, we determine that this rate continues to be relevant. Further, the CIT has held that where a respondent is found to be part of the country-wide entity based on adverse inferences, the Department need not corroborate the country-wide rate

[31] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Preliminary Results of the First Administrative Review,* 72 FR 10689, 10692 (March 9, 2007) (decision to apply total AFA to the NME-wide entity), unchanged in *Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results of the First Administrative Review and First New Shipper Review,* 72 FR 52052 (September 12, 2007).

[32] *See Notice of Final Determination of Sales at Less than Fair Value: Static Random Access Memory Semiconductors From Taiwan,* 63 FR 8909, 8911 (February 23, 1998); *see also Brake Rotors From the People's Republic of China: Final Results and Partial Rescission of the Seventh Administrative Review; Final Results of the Eleventh New Shipper Review,* 70 FR 69937, 69939 (November 18, 2005), and SAA at 870.

[33] *See Rhone Poulenc, Inc.* v. *United States,* 899 F.2d 1185, 1190 (Fed. Cir. 1990).

[34] *See Glycine from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review,* 74 FR 15930, 15934 (April 8, 2009), unchanged in *Glycine From the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 74 FR 41121 (August 14, 2009); *see also Fujian Lianfu Forestry Co., Ltd.* v. *United States*, 638 F. Supp. 2d 1325, 1336 (CIT August 10, 2009) (''Commerce may, of course, begin its total AFA selection process by defaulting to the highest rate in any segment of the proceeding, but that selection must then be corroborated, to the extent practicable.'').

[35] *See, e.g., KYD, Inc.* v *United States,* 607 F.3d 760, 766–767 (CAFC 2010) (''*KYD*''); *see also NSK Ltd.* v. *United States,* 346 F. Supp. 2d 1312, 1335 (CIT 2004) (affirming a 73.55 percent total AFA rate, the highest available dumping margin calculated for a different respondent in the investigation).

[36] *See Notice of Preliminary Determination of Sales at Less Than Fair Value, Partial Affirmative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp From the People's Republic of China,* 69 FR 42654, 42662 (July 16, 2004) (''*PRC Shrimp Prelim LTFV*''), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp From the People's Republic of China*, 69 FR 70997, 71002 (December 8, 2004) (''*PRC Shrimp Final LTFV*'').

[37] *See* SAA at 870; *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished From Japan, and Tapered Roller Bearings Four Inches or Less in Outside Diameter and Components Thereof, From Japan; Preliminary Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews,* 61 FR 57391, 57392 (November 6, 1996) unchanged in *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished From Japan, and Tapered Roller Bearings Four Inches or Less in Outside Diameter and Components Thereof, From Japan; Final Results of Antidumping Duty Administrative Reviews and Termination in Part,* 62 FR 11825 (March 13, 1997).

[38] *See* Letter from Hilltop to the Secretary of Commerce, ''Hilltop-Specific Issues Rebuttal Brief for Hilltop International'' (July 23, 2012) at 26.

[39] *See, e.g., Certain Steel Grating From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 75 FR 32366 (June 8, 2010) and accompanying Issues and Decision Memorandum at Comment 2.

[40] *See Narrow Woven Ribbons With Woven Selvedge From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 75 FR 41808 (July 19, 2010) and accompanying Issues and Decision Memorandum at Comment 1.

[41] *See PRC Shrimp Prelim LTFV,* unchanged in *PRC Shrimp Final LTFV.*

[42] *See Fresh Cut Flowers from Mexico; Final Results of Antidumping Administrative Review*, 61 FR 6812, 6814 (February 22, 1996) (''*Fresh Cut Flowers From Mexico*'').

[43] *See PRC Shrimp Prelim LTFV* at 42654, 42662.

[44] *See id.*

with respect to information specific to that respondent because there is ''no requirement that the country-wide entity rate based on Adverse Facts Available relate specifically to the individual company.'' [45]

Because the 112.81 percent rate is both reliable and relevant, we determine that it has probative value and is corroborated to the extent practicable, in accordance with section 776(c) of the Act. Therefore, we have assigned this AFA rate to exports of the subject merchandise by the PRC-wide entity, which includes Hilltop.

Request for Revocation

In the *Preliminary Results,* we determined that ''pursuant to section 751(d) of the Act and 19 CFR 351.222(b)(2) * * * the application of the antidumping duty order with respect to Hilltop is no longer warranted for the following reasons: (1) The company had a zero or *de minimis* margin for a period of at least three consecutive years; (2) the company has agreed to immediate reinstatement of the order if the Department finds that it has resumed making sales at less than NV; and, (3) the continued application of the order is not otherwise necessary to offset dumping.'' [46] After thorough analysis of the record evidence submitted after the *Preliminary Results* in this review, we find that Hilltop, even it were considered to be eligible for a separate rate and received a calculated zero or *de minimis* margin in this review, has failed to demonstrate that the ''continued application of the order is not otherwise necessary to offset dumping.'' Rather, we find that the deficiencies on the record of this review, which also implicate prior reviews, preclude the Department from granting Hilltop's revocation request, in part due to Hilltop's material misrepresentations in this review and its refusal to provide information regarding activities relevant to the proceeding. *See* I&D Memo at Comment 2; *see also* Hilltop AFA Memo. Furthermore, because Hilltop (even if it were eligible for a separate rate) receives an AFA rate in these final results, it does not satisfy the threshold requirement for revocation that a company must have three consecutive periods of sales at or above normal value. Thus we find that the criteria for revocation have not been satisfied, and we are not revoking the *Order* with regard to Hilltop.

Final Results of Review

The weighted-average dumping margins for the POR are as follows:

Exporter	Weighted-average margin (percent)
Zhanjiang Regal Integrated Marine Resources Co., Ltd	0.00
PRC-Wide Entity [47]	112.81

Assessment

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. For assessment purposes, we calculated importer (or customer)-specific assessment rates for merchandise subject to this review. Where appropriate, we calculated an *ad valorem* rate for each importer (or customer) by dividing the total dumping margins for reviewed sales to that party by the total entered values associated with those transactions. For duty-assessment rates calculated on this basis, we will direct CBP to assess the resulting *ad valorem* rate against the entered customs values for the subject merchandise. Where appropriate, we calculated a per-unit rate for each importer (or customer) by dividing the total dumping margins for reviewed sales to that party by the total sales quantity associated with those transactions. For duty-assessment rates calculated on this basis, we will direct CBP to assess the resulting per-unit rate against the entered quantity of the subject merchandise. Where an importer (or customer)-specific assessment rate is *de minimis* (*i.e.,* less than 0.50 percent), the Department will instruct CBP to assess that importer (or customer's) entries of subject merchandise without regard to antidumping duties, in accordance with 19 CFR 351.106(c)(2). The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

Cash Deposit Requirements

The following cash-deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate established in the final results of this review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, no cash deposit will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 112.81 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO

[45] *See Watanabe Group* v. *United States,* 2010 Ct. Int. Trade LEXIS 144, Slip. Op. 2010–139 (2010); quoting *Peer Bearing Co.-Changshan* v. *United States,* 587 F. Supp. 2d 1319, 1327 (CIT 2008); *Shandong Mach. Imp. & Exp. Co.* v. *United States,* Slip Op. 09–64, 2009 Ct. Intl. Trade LEXIS 76, 2009 WL 2017042, at *8 (CIT June 24, 2009) (''Commerce has no obligation to corroborate the PRC-wide rate as to an individual party where that party has failed to qualify for a separate rate'').

[46] *See Preliminary Results* at 12803.

[47] *See* Appendix II—PRC-Wide Entity Companies.

materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: August 27, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix I—Issues & Decision Memorandum

Comment 1: Whether the Department Should Apply Facts Available With an Adverse Inference to Hilltop
Comment 2: Whether Hilltop's Revocation Request Should Be Denied
Comment 3: Whether the Record Suggests a Violation of 18 U.S.C. § 1001
Comment 4: Whether the Department Should Initiate Changed Circumstances Reviews
Comment 5: Whether the Department Should Reject Petitioner's Untimely Submission of Factual Evidence
Comment 6: Whether the Department Should Formally Cancel Verification of Hilltop
Comment 7: Whether To Apply AFA to Regal
Comment 8: Respondent Selection Methodology
Comment 9: Shrimp Larvae
Comment 10: Shrimp Feed
Comment 11: Labor Surrogate Value
Comment 12: Surrogate Financial Statement Selection
Comment 13: Surrogate Financial Ratio Adjustment
Comment 14: Surrogate Value Calculation for Ice

Appendix II—PRC-Wide Entity Companies

The PRC-wide entity includes Hilltop and the 81 companies currently under review that have not established their entitlement to a separate rate. Those 81 companies are:

Allied Pacific Aquatic Products Zhanjiang Co Ltd.
Allied Pacific Food (Dalian) Co., Ltd.
Asian Seafoods (Zhanjiang) Co., Ltd.
Beihai Evergreen Aquatic Product Science And Technology Co Ltd.
Beihai Qinguo Frozen Foods Co., Ltd.
Capital Prospect
Dalian Hualian Foods Co., Ltd.
Dalian Shanhai Seafood Co., Ltd.
Dalian Z&H Seafood Co., Ltd.
Ever Hope International Co., Ltd.
Everflow Ind. Supply
Flags Wins Trading Co., Ltd.
Fuchang Aquatic Products Freezing
Fujian Chaohui International Trading
Fuqing Minhua Trade Co., Ltd.
Fuqing Yihua Aquatic Food Co., Ltd.
Fuqing Yiyuan Trading Co., Ltd.
Gallant Ocean (Nanhai), Ltd.
Guangdong Jiahuang Foods
Guangdong Jinhang Foods Co., Ltd.
Guangdong Wanya Foods Fty. Co., Ltd.
Hai Li Aquatic Co., Ltd.
Hainan Brich Aquatic Products Co., Ltd.
Hainan Golden Spring Foods Co., Ltd.
Hainan Hailisheng Food Co., Ltd.
Hainan Seaberry Seafoods Corporation
Hainan Xiangtai Fishery Co., Ltd.
Haizhou Aquatic Products Co., Ltd.
Hua Yang (Dalian) International
Jet Power International Ltd.
Jin Cheng Food Co., Ltd.
Leizhou Yunyuan Aquatic Products Co., Ltd.
Maple Leaf Foods International
North Seafood Group Co.
Panasonic Mfg. Xiamen CoPhoenix Intl.
Rizhao Smart Foods
Rui'an Huasheng Aquatic Products Processing Factory
Savvy Seafood Inc.
Sea Trade International Inc.
Shanghai Linghai Fisheries Trading Co. Ltd.
Shanghai Smiling Food Co., Ltd.
Shanghai Zhoulian Foods Co., Ltd.
Shantou Jiazhou Foods Industry
Shantou Jin Cheng Food Co., Ltd.
Shantou Longfeng Foodstuff Co., Ltd.
Shantou Longsheng Aquatic Product Foodstuff Co., Ltd.
Shantou Ruiyuan Industry Company Ltd.
Shantou Wanya Foods Fty. Co., Ltd.
Shantou Xinwanya Aquatic Product Ltd. Company
Shantou Yue Xiang Commercial Trading Co., Ltd.
Shengsi Huali Aquatic Co., Ltd.
SLK Hardware
Thai Royal Frozen Food Zhanjiang Co., Ltd.
Tongwei Hainan Aquatic Products Co. Ltd.
Top One Intl.
Xiamen Granda Import & Export Co., Ltd.
Xinjiang Top Agricultural Products Co., Ltd.
Xinxing Aquatic Products Processing Factory
Yancheng Hi-king Agriculture Developing Co., Ltd.
Yangjiang Wanshida Seafood Co., Ltd.
Yelin Enterprise Co., Ltd.
Zhangzhou Xinwanya Aquatic Product
Zhanjiang East Sea Kelon Aquatic Products Co. Ltd
Zhanjiang Fuchang Aquatic Products Co., Ltd.
Zhanjiang Go Harvest Aquatic Products Co., Ltd.
Zhanjiang Haizhou Aquatic Product Co. Ltd.
Zhanjiang Jinguo Marine Foods Co., Ltd.
Zhanjiang Longwei Aquatic Products Industry Co., Ltd.
Zhanjiang Universal Seafood Corp.
Zhejiang Daishan Baofa Aquatic Products Co., Ltd.
Zhejiang Industrial Group Co., Ltd.
Zhejiang Shaoxing Green Vegetable Instant Freezing Co., Ltd.
Zhejiang Zhoufu Food Co., Ltd.
Zhongshan Foodstuffs & Aquatic Imp. & Exp. Group Co. Ltd. of Guangdong
Zhoushan City Shengtai Aquatic Co.
Zhoushan Junwei Aquatic Product Co.
Zhoushan Lianghong Aquatic Foods Co. Ltd.
Zhoushan Mingyu Aquatic Product Co. Ltd.
Zhoushan Putuo Huafa Sea Products Co., Ltd.

[FR Doc. 2012–21734 Filed 8–31–12; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

Background

Every five years, pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') and the International Trade Commission automatically initiate and conduct a review to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for October 2012

The following Sunset Reviews are scheduled for initiation in October 2012 and will appear in that month's Notice of Initiation of Five-Year Sunset Review.

	Department contact
Antidumping Duty Proceedings	
Folding Metal Tables and Chairs from China (A–570–868) (2nd Review)	Jennifer Moats (202) 482–5047
Welded Large Diameter Line Pipe from Japan (A–588–857) (2nd Review)	Dana Mermelstein (202) 482–1391
Silicomanganese from India (A–533–823) (2nd Review)	Dana Mermelstein (202) 482–1391
Silicomanganese from Kazakhstan (A–834–807) (2nd Review)	Dana Mermelstein (202) 482–1391
Silicomanganese from Venezuela (A–307–820) (2nd Review)	Dana Mermelstein (202) 482–1391

Countervailing Duty Proceedings

No Sunset Review of Countervailing duty orders is scheduled for initiation in October 2012.

Suspended Investigations

No Sunset Review of suspended investigations is scheduled for initiation in October 2012.

The Department's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in the Department's Policy Bulletin 98.3—*Policies Regarding the Conduct of Five-year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin,* 63 FR 18871 (April 16, 1998). The Notice of Initiation of Five-Year (''Sunset'') Reviews provides further information regarding what is required of all parties to participate in Sunset Reviews.

Pursuant to 19 CFR 351.103(c), the Department will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing within 10 days of the publication of the Notice of Initiation.

Please note that if the Department receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue. Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation.

This notice is not required by statute but is published as a service to the international trading community.

Dated: August 10, 2012.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–21728 Filed 8–31–12; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Waters, Office of AD/CVD Operations, Customs Unit, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (''the Act''), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (''the Department'') conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, the Department intends to select respondents based on U.S. Customs and Border Protection (''CBP'') data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (''APO'') to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department has found that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that, with regard to reviews requested on the basis of anniversary months on or after September 2012, the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance has prevented it from submitting a timely withdrawal request. Determinations by the Department to

extend the 90-day deadline will be made on a case-by-case basis.

The Department is providing this notice on its Web site, as well as in its ''Opportunity to Request Administrative Review'' notices, so that interested parties will be aware of the manner in which the Department intends to exercise its discretion in the future.

Opportunity To Request a Review: Not later than the last day of September 2012,[1] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in September for the following periods:

	Period of review
Antidumping Duty Proceedings	
Belarus: Steel Concrete Reinforcing Bars, A–822–804	9/1/11—8/31/12
India: Certain Lined Paper Products, A–533–843	9/1/11—8/31/12
Indonesia:	
Certain Lined Paper Products, A–560–818	9/1/11—8/31/12
Steel Concrete Reinforcing Bars, A–560–811	9/1/11—8/31/12
Italy: Stainless Steel Wire Rod, A–475–820	9/1/11—8/31/12
Japan: Stainless Steel Wire Rod, A–588–843	9/1/11—8/31/12
Latvia: Steel Concrete Reinforcing Bars, A–449–804	9/1/11—8/31/12
Mexico: Certain Magnesia Carbon Bricks, A–201–837	9/1/11—8/31/12
Moldova: Steel Concrete Reinforcing Bars, A–841–804	9/1/11—8/31/12
Poland: Steel Concrete Reinforcing Bars, A–455–803	9/1/11—8/31/12
Republic of Korea: Stainless Steel Wire Rod, A–580–829	9/1/11—8/31/12
Spain: Stainless Steel Wire Rod, A–469–807	9/1/11—8/31/12
Taiwan:	
Narrow Woven Ribbons With Woven Selvedge, A–583–844	9/1/11—8/31/12
Raw Flexible Magnets, A583–842	9/1/11—8/31/12
Stainless Steel Wire Rod, A–583–828	9/1/11—8/31/12
The People's Republic of China:	
Certain Lined Paper Products, A–570–901	9/1/11—8/31/12
Certain Magnesia Carbon Bricks, A–570–954	9/1/11—8/31/12
Foundry Coke, A–570–862	9/1/11—8/31/12
Freshwater Crawfish Tailmeat, A–570–848	9/1/11—8/31/12
Kitchen Appliance Shelving and Racks, A–570–941	9/1/11—8/31/12
Narrow Woven Ribbons With Woven Selvedge, A–570–952	9/1/11—8/31/12
New Pneumatic Off-The-Road Tires, A–570–912	9/1/11—8/31/12
Raw Flexible Magnets, A–570–922	9/1/11—8/31/12
Steel Concrete Reinforcing Bars, A–570–860	9/1/11—8/31/12
Ukraine:	
Silicomanganese,[2]A–823–805	9/1/11—8/31/12
Solid Agricultural Grade Ammonium Nitrate, A–823–810	9/1/11—8/31/12
Steel Concrete Reinforcing Bars, A–823–809	9/1/11—8/31/12
Countervailing Duty Proceedings	
India: Certain Lined Paper Products, C–533–844	1/1/11—12/31/11
Indonesia: Certain Lined Paper Products, C–560–819	1/1/11—12/31/11
The People's Republic of China:	
Certain Magnesia Carbon Bricks, C–570–955	1/1/11—12/31/11
Kitchen Appliance Shelving and Racks, C–570–942	1/1/11—12/31/11
Narrow Woven Ribbons With Woven Selvedge, C–570–953	1/1/11—12/31/11
New Pneumatic Off-The-Road Tires, C–570–913	1/1/11—12/31/11
Raw Flexible Magnets, C–570–923	1/1/11—12/31/11
Suspension Agreements	
Argentina: Lemon Juice, A–357–818	9/1/11—8/31/12
Mexico: Lemon Juice, A–201–835	9/1/11—8/31/12

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters.[3] If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin and each country of

[1] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when the Department is closed.

[2] This antidumping duty order was published on August 21, 2001. *See* 63 FR 43838. Pursuant to 19 CFR 351.102(b), 19 CFR 351.213(b) and Diamond Sawblades and Parts Thereof From the People's Republic of China and the Republic of Korea: Notice of Anniversary Month and First Opportunity To Request an Administrative Review, 75 FR 969, January 7, 2010, August is the correct anniversary month. We included this order in the August opportunity notice. *See* 77 FR 45580. Because we have previously treated this order as an order with an anniversary date in September, we are also including it in this year's September opportunity notice so as not to disadvantage any parties. In the future, however, we intend to include this order in the August opportunity notice.

[3] If the review request involves a non-market economy and the parties subject to the review request do not qualify for separate rates, all other exporters of subject merchandise from the non-market economy country who do not have a separate rate will be covered by the review as part of the single entity of which the named firms are a part.

origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Please note that, for any party the Department was unable to locate in prior segments, the Department will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), the Department has clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders. *See also* the Import Administration Web site at *http://ia.ita.doc.gov.*

All requests must be filed electronically in Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS'') on the IA ACCESS Web site at *http://iaaccess.trade.gov. See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011). Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

The Department will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of September 2012. If the Department does not receive, by the last day of September 2012, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period, of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: August 10, 2012.

Gary Taverman,

Senior Advisor for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–21733 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 12–00004]

Export Trade Certificate of Review

ACTION: Notice of issuance of an Export Trade Certificate of Review to Colombia Poultry Export Quota, Inc. (''COLOM–PEQ'') (Application #12–00004).

SUMMARY: On August 14, 2012, the U.S. Department of Commerce issued an Export Trade Certificate of Review to Colombia Poultry Export Quota, Inc. (''COLOM–PEQ''). This notice summarizes the conduct for which certification has been granted.

FOR FURTHER INFORMATION CONTACT: Joseph E. Flynn, Director, Office of Competition and Economic Analysis, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR part 325 (2010). The U.S. Department of Commerce, International Trade Administration, Office of Competition and Economic Analysis (''OCEA'') is issuing this notice pursuant to 15 CFR § 325.6(b), which requires the Secretary of Commerce to publish a summary of the issuance in the **Federal Register**. Under Section 305(a) of the Export Trading Company Act (15 U.S.C. 4012(b)(1)) and 15 CFR § 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Members (Within the Meaning of 15 CFR 325.2(1)

COLOM–PEQ's members under this certificate are the USA Poultry and Egg Export Council (USAPEEC) and Federacion Nacional de Avicultores, the Sector Representative Association (''*sector gremial representativo*'') for poultry in the Republic of Colombia.

Description of Certified Conduct

COLOM–PEQ is certified to engage in the Export Trade Activities and Methods of Operation described below in the following Export Trade and Export Markets.

Export Trade

COLOM–PEQ plans to export poultry products as described in the Agricultural Tariff Schedule of the Republic of Colombia, as appended to the TPA, and including the following Colombian HTS Codes: 0207.1300.A—leg quarters [fresh or chilled] curators traseros [frescos o refrigerados]); 0207.1400A—leg quarters [frozen] (curators traseros [congelados]); 1602.3200.A—leg quarters, seasoned and frozen (curators traseros, sazonados y congelados).

Export Markets

Poultry products for which awards will be made will be exported to the Republic of Colombia.

Export Trade Activities and Methods of Operation

With respect to the conduct of Export Trade in the Export Markets, COLOM–PEQ may, subject to the terms and conditions set forth below, engage in the following Export Trade Activities and Methods of Operation:

1. *Purpose:* COLOM–PEQ will manage on an open tender basis the tariff-rate quotas (TRQs) for poultry products granted by the Republic of Colombia to the United States under the terms of the TPA or any amended or successor agreement providing for Colombian TRQs for poultry from the United States of America.

Specifically, the TRQs for poultry products are set forth at Paragraph 6 of Appendix I of the General Notes of Colombia, Annex 2.3 to the TPA. COLOM PEQ also will provide for

distributions of the proceeds received from the tender process based on exports of poultry products (''the TRQ System'') to support the operation and administration of COLOM–PEQ and for the benefit of the poultry industry of the United States and the Republic of Colombia.

2. *Administrator.* COLOM–PEQ shall contract with a neutral third party Administrator who shall bear responsibility for administering the TRQ System, subject to general supervision and oversight by the Board of Directors of COLOM–PEQ.

3. *Open Tender Process.* COLOM–PEQ shall offer TRQ Certificates for duty-free shipments of chicken leg quarters to the Republic of Colombia solely and exclusively through an open tender process with certificates awarded to the highest bidders (''TRQ Certificates''). COLOM–PEQ shall hold tenders in accordance with tranches at least four times each year. The award of TRQ Certificates under the open tender process shall be determined solely and independently by the Administrator in accordance with Section I without any participation by the members of COLOM–PEQ or the COLOM–PEQ Board of Directors.

4. *Persons or Entities Eligible to Bid.* Any person or entity incorporated or with a legal address in the United States of America shall be eligible to bid in the open tender process.

5. *Notice.* The Administrator shall publish notice (''Notice'') of each open tender process to be held to award TRQ Certificates in the *Journal of Commerce* and, at the discretion of the Administrator, in other publications of general circulation within the U.S. poultry industry or in the Republic of Colombia. The Notice will invite independent bids and will specify (i) the total amount (in metric tons) that will be allocated pursuant to the applicable tender; (ii) the shipment period for which the TRQ Certificates will be valid; (iii) the date and time by which all bids must be received by the Administrator in order to be considered (the ''Bid Date''); and (iv) a minimum bid amount per ton, as established by the Board of Directors, to ensure the costs of administering the auction are recovered. The Notice normally will be published not later than 30 days prior to the first day of the auction process and will specify a Bid Date. The Notice will specify the format for bid submissions. Bids must be received by the Administrator not later than 5:00 p.m. EST on the Bid Date.

6. *Contents of Bid.* The bid shall be in a format established by the Administrator and shall state (i) the name, address, telephone and facsimile numbers, and email address of the bidder; (ii) the quantity of poultry products bid, in an amount stated in metric tons or fractions thereof; (iii) the bid price in U.S. dollars per metric ton; and (iv) the total value of the bid. The bid form shall contain a provision that must be signed by the bidder, agreeing that (i) any dispute that may arise relating to the bidding process or to the award of TRQ Certificates shall be settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules; and (ii) judgment on any award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

7. *Performance Security.* The bidder shall submit with each bid a performance bond, irrevocable letter of credit drawn on a U.S. bank, cashier's check, wire transfer or equivalent security, in a form approved and for the benefit of an account designated by the Administrator, in the amount of $50,000 or the total value of the bid, whichever is less. The bidder shall forfeit such performance security if the bidder fails to pay for any TRQ Certificates awarded within five (5) business days. The bidder may chose to apply the performance security to the price of any successful bid, or to retain the performance security for a subsequent open tender process. Promptly after the close of the open tender process, the Administrator shall return any unused or non-forfeited security to the bidder.

8. *Award of TRQ Certificates.* The Administrator shall award TRQ Certificates for the available tonnage to the bidders who have submitted the highest price conforming bids. If two or more bidders have submitted bids with identical prices, the Administrator shall divide the remaining available tonnage in proportion to the quantities of their bids, and offer each TRQ Certificates in the resulting tonnages. If any bidder declines all or part of the tonnage offered, the Administrator shall offer that tonnage first to the other tying bidders, and then to the next highest bidder.

9. *Payment for TRQ Certificates.* Promptly after being notified of a TRQ award and within the time specified in the Notice, the bidder shall pay the full amount of the bid, either by wire transfer or by certified check, to an account designated by the Administrator. If the bidder fails to make payment within five (5) days, the Administrator shall revoke the award and award the tonnage to the next highest bidder(s).

10. *Delivery of TRQ Certificates.* The Administrator shall establish an account for each successful bidder in the amount of tonnage available for TRQ Certificates. Upon request, the Administrator will issue TRQ Certificates in the tonnage designated by the bidder, consistent with the balance in that account. The TRQ Certificate shall state the delivery period for which it is valid.

11. *Transferability.* TRQ Certificates shall be freely transferable except that (i) any TRQ Certificate holder who intends to sell, transfer or assign any rights under that Certificate shall publish such intention on a Web site maintained by the Administrator at least three (3) business days prior to any sale, transfer or assignment; and (ii) any TRQ holder who sells, transfers or assigns its rights under a TRQ Certificate shall provide the Administrator with notice and a copy of the sale, transfer or assignment within three (3) business days.

12. *Deposit of Proceeds:* The Administrator shall cause all proceeds of the open tender process to be deposited in an interest-bearing account in a financial institution approved by the COLOM–PEQ Board of Directors.

13. *Disposition of Proceeds.* The proceeds of the open tender process shall be applied and distributed as follows:

A. The Administrator shall pay from tender proceeds, as they become available, all operating expenses of COLOM–PEQ, including legal, accounting and administrative costs of establishing and operating the TRQ System, as authorized by the Board of Directors.

B. Of the proceeds remaining at the end of each year of operations after all costs described in (A) above have been paid—

(a) Fifty percent (50%) shall be distributed to fund market access, market promotion, educational, scientific and technical projects to benefit the United States poultry industry. COLOM–PEQ shall accept proposals for the funding of projects approved by resolution of the Board of Directors of USAPEEC.

(b) Fifty percent (50%) shall be distributed by the Administrator to FENAVI to fund market access, market promotion, educational, capacity-building, competitiveness, scientific and technical projects to benefit the poultry industry of the Republic of Colombia. COLOM–PEQ shall accept proposals for the funding of projects approved by resolution of the Board of Directors of FENAVI.

14. *Arbitration of Disputes.* Any dispute, controversy or claim arising out of or relating to the TRQ System or the breach thereof, including inter alia, a Member's qualification for distribution, interpretation of documents, or of the distribution itself, shall be settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

15. *Confidential Information.* The Administrator shall maintain as confidential all export documentation or other business sensitive information submitted in connection with application for COLOM–PEQ membership, bidding in the open tender process, or requests for distribution of proceeds, where such documents or information has been marked ''Confidential'' by the person making the submission. The Administrator shall disclose such information only to another neutral third party or authorized government official of the United States or of the Republic of Colombia and only as necessary to ensure the effective operation of the TRQ System or where required by law (including appropriate disclosure in connection with the arbitration of a dispute)

16. *Annual Reports.* COLOM–PEQ shall publish an annual report including a statement of its operating expenses and data on the distribution of proceeds, as reflected in the audited financial statement of the COLOM–PEQ TRQ System.

Terms and Conditions

In engaging in Export Trade Activities and Methods of Operation,

1. Except as authorized in Paragraph 15 of the Export Trade Activities and Methods of Operation, neither COLOM–PEQ, the Administrator, any Member, nor any neutral third party shall intentionally disclose, directly or indirectly, to any Member (including parent companies, subsidiaries, or other entities related to any Member) any information regarding any other Member's or bidder's costs, production, capacity, inventories, domestic prices, domestic sales, or U.S. business plans, strategies, or methods, unless such information is already generally available to the trade or public.

2. COLOM–PEQ will comply with requests made by the Secretary of Commerce on behalf of the Secretary or the Attorney General for information or documents relevant to conduct under the Certificate. The Secretary of Commerce will request such information or documents when either the Attorney General or the Secretary of Commerce believes that the information or documents are required to determine that the Export Trade, Export Trade Activities and Methods of Operation of a person protected by this Certificate of Review continue to comply with the standards of section 303(a) of the Act.

3. COLOM–PEQ will ensure that the Administrator holds the auctions in accordance with tranches established in the relevant regulations of the Republic of Colombia, or in the absence of such, at least once by February 15 of each year. Failure to so hold auctions may result in revocation of the Certificate.

Definitions

''Neutral third party'', as used in this Certificate of Review, means a party not otherwise associated with COLOM–PEQ or any Member and who is not engaged in the production, sale, distribution or export of poultry or poultry products.

''TRQ System'', as used in this Certificate of Review, refers to distributions of the proceeds received from the tender process.

Dated: August 28, 2012.

Joseph E. Flynn,

Director, Office of Competition and Economic Analysis.

[FR Doc. 2012–21735 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (''Sunset'') Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') is automatically initiating five-year reviews (''Sunset Reviews'') of the antidumping duty orders listed below. The International Trade Commission (''the Commission'') is publishing concurrently with this notice its notice of *Institution of Five-Year Review* which covers the same orders.

DATES: *Effective Date:* September 1, 2012.

FOR FURTHER INFORMATION CONTACT: The Department official identified in the *Initiation of Review* section below at AD/CVD Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230. For information from the Commission contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

The Department's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in the Department's Policy Bulletin 98.3—*Policies Regarding the Conduct of Five-Year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders: Policy Bulletin,* 63 FR 18871 (April 16, 1998), and in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

Initiation of Review

In accordance with 19 CFR 351.218(c), we are initiating Sunset Reviews of the following antidumping duty orders:

DOC case No.	ITC case No.	Country	Product	Department contact
A–475–818	731–TA–734	Italy	Certain Pasta (3rd Review)	David Goldberger, (202) 482–4136.
C–475–819	701–TA–365	Italy	Certain Pasta (3rd Review)	David Goldberger, (202) 482–4136.
A–489–805	731–TA–735	Turkey	Certain Pasta (3rd Review)	David Goldberger, (202) 482–4136.
C–489–806	701–TA–366	Turkey	Certain Pasta (3rd Review)	David Goldberger, (202) 482–4136.

Filing Information

As a courtesy, we are making information related to Sunset proceedings, including copies of the pertinent statue and Department's regulations, the Department schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on the Department's Internet Web site at the following address: ''*http://ia.ita.doc.gov/sunset/.*'' All submissions in these Sunset Reviews must be filed in accordance with the Department's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''), can be found at 19 CFR 351.303. *See also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

This notice serves as a reminder that any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information. *See* section 782(b) of the Act. Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives in all AD/CVD investigations or proceedings initiated on or after March 14, 2011. *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings: Interim Final Rule,* 76 FR 7491 (February 10, 2011) (''*Interim Final Rule*'') amending 19 CFR 351.303(g)(1) and (2) and supplemented by *Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings: Supplemental Interim Final Rule,* 76 FR 54697 (September 2, 2011). The formats for the revised certifications are provided at the end of the *Interim Final Rule.* The Department intends to reject factual submissions if the submitting party does not comply with the revised certification requirements.

Pursuant to 19 CFR 351.103(d), the Department will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing within 10 days of the publication of the Notice of Initiation.

Because deadlines in Sunset Reviews can be very short, we urge interested parties to apply for access to proprietary information under administrative protective order (''APO'') immediately following publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The Department's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306.

Information Required From Interested Parties

Domestic interested parties defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b) wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with the Department's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, the Department will automatically revoke the order without further review. *See* 19 CFR 351.218(d)(1)(iii).

If we receive an order-specific notice of intent to participate from a domestic interested party, the Department's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that the Department's information requirements are distinct from the Commission's information requirements. Please consult the Department's regulations for information regarding the Department's conduct of Sunset Reviews.[1] Please consult the Department's regulations at 19 CFR Part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at the Department.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: August 10, 2012.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–21732 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–DS–P

[1] In comments made on the interim final sunset regulations, a number of parties stated that the proposed five-day period for rebuttals to substantive responses to a notice of initiation was insufficient. This requirement was retained in the final sunset regulations at 19 CFR 351.218(d)(4). As provided in 19 CFR 351.302(b), however, the Department will consider individual requests to extend that five-day deadline based upon a showing of good cause.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC212

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council's (Council) Groundfish Committee will meet to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Wednesday, September 19, 2012 at 9 a.m.

ADDRESSES: The meeting will be held at the Fairfield Inn & Suites, 185 MacArthur Drive, New Bedford, MA 02740; telephone: (774) 634–2000; fax: (774) 634–2001.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The items of discussion in the committee's agenda are as follows:

The Groundfish Oversight Committee will discuss possible adjustments to sector management measures and issues related to setting Acceptable Biological Catches (ABCs), Annual Catch Limits (ACLs), and Accountability Measures (AMs). They will continue to develop options to improve sector monitoring, including both at-sea and dockside monitoring. They may discuss appropriate monitoring coverage levels and full retention of allocated groundfish species. The Committee will develop measures that may help mitigate expected low catch levels in fishing year 2013. These measures could

include modifications to groundfish closed areas (including habitat areas). The Committee will further review a motion passed at its last meeting that would provide increased access to most groundfish closed areas, and may consider modifications to that motion that will be forwarded to the Council. They may consider other modifications to the sector program, such as creating areas for fishing on Georges Bank (GB) that are not subject to the GB yellowtail flounder ACE limits. With respect to ABCs/ACLs/AMs, the Committee will consider options for addressing catches of groundfish stocks (primarily SNE/MAB windowpane flounder) by other fisheries (such as the fluke, scup and squid fisheries), and may either develop options for additional sub-ACLs or may propose changes to accountability measures to control those catches. The Committee may also discuss other issues that may be incorporated into the framework. Options identified by the Committee will be included in a future management action (Framework Adjustment 48) that will be considered by the Council in the fall of 2012. The Committee is also expected to receive a preliminary report on catch advice developed for Eastern Georges Bank cod and haddock, and Georges Bank yellowtail flounder that will be developed by the Transboundary Management Guidance Committee. The Committee may provide comments for consideration by the Council when it considers these Fishing Year 2013 quotas. The Committee may discuss scallop/groundfish management issues, such as yellowtail flounder allocations and the timing of scallop vessel access to groundfish closed areas. Other business may be discussed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

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

Dated: August 29, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–21687 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC213

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council's (Council) Herring Committee will meet jointly with the Atlantic States Marine Fishery Council's (ASMFC) Section to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Thursday, September 20, 2012 at 9:30 a.m.

ADDRESSES: The meeting will be held at the Comfort Inn, 1940 Post Road, Warwick, RI 02886; telephone: (401) 732–0470; fax: (401) 732–6872.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The items of discussion in the committee's agenda are as follows:

The Herring Committee and the ASMFC Section will meet to develop Atlantic herring fishery specifications for the upcoming fishing years (2013–15); discussion may include specifications related to the overfishing limit (OFL), acceptable biological catch (ABC), management uncertainty and a stockwide annual catch limit (ACL), domestic annual harvesting (DAH), domestic annual processing (DAP), border transfer (BT), sub-ACLs for the four herring management areas, and set-asides for research and the fixed gear fishery. They will discuss the recent court decision regarding Amendment 4 to the Atlantic Herring Fishery Management Plan (FMP), related correspondence, and possible upcoming Council actions, including a possible action to maintain the 2012 specifications through 2013 and develop a comprehensive specifications package for 2014–16 to address some elements of the Amendment 4 court order. Also on the agenda will be the review and discussion of the recent benchmark stock assessment for Atlantic Herring (SAW/SARC 54). The Committees will also review and discuss recommendations of the Council's Scientific and Statistical Committee (SSC) regarding scientific uncertainty and the specification of ABC. They will review and discuss issues related to management uncertainty and develop recommendation for specification of management uncertainty and a stockwide ACL.

Additionally, the Committees will discuss other elements of herring fishery specifications and possible options for management area sub-ACLs. They will address other business as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

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

Dated: August 29, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–21688 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC214

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 31 Gulf of Mexico Red Snapper Post-Data Workshop Webinar.

SUMMARY: The SEDAR 31 assessment of the Gulf of Mexico Red Snapper fishery will consist of a series of workshops and supplemental webinars. This notice is for a webinar associated with the Data Workshop of the SEDAR process. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 31 Post-Data Workshop Webinar will be held on September 20, 2012, from 1 p.m. to 5 p.m. EDT. The established time may be adjusted as necessary to accommodate the timely completion of discussion relevant to the stock assessment process. Such adjustments may result in the meeting being extended from, or completed prior to the times established by this notice.

ADDRESSES: The webinar will be held via a GoToMeeting Webinar Conference. The webinar is open to members of the public. Those interested in participating should contact Ryan Rindone at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request meeting information at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Ryan Rindone, SEDAR Coordinator, 2203 N. Lois Ave., Suite 1100, Tampa FL 33607; telephone: (813) 348–1630; email: *ryan.rindone@gulfcouncil.org*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico Fishery Management Council, in conjunction with NOAA Fisheries, has implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop, (2) Assessment Process including a workshop and webinars, (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting Panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico Fishery Management Council, NOAA Fisheries Southeast Regional Office, and NOAA Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGOs; International experts; and staff of Councils, Commissions, and state and federal agencies.

SEDAR 31 Post-Data Workshop Webinar

Panelists will continue deliberations and discussions regarding data evaluation methodologies for the Gulf of Mexico Red Snapper prior to the completion of the Data Workshop Report.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **FOR FURTHER INFORMATION CONTACT**) at least 10 business days prior to the meeting.

Dated: August 29, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–21689 Filed 8–31–12; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Availability of a Legal Entity Identifier Meeting the Requirements of the Regulations of the Commodity Futures Trading Commission and Designation of Provider of Legal Entity Identifiers To Be Used in the Recordkeeping and Swap Data Reporting

AGENCY: Commodity Futures Trading Commission.

ACTION: Order.

SUMMARY: On July 23, 2012, the Commodity Futures Trading Commission issued an order designating DTCC–SWIFT as the provider of the legal entity identifiers (LEIs) which will be used by registered entities and swap counterparties in complying with the CFTC's swap data reporting regulations. These identifiers will be known as CFTC Interim Compliant Identifiers (CICIs) until establishment of a global LEI system, and will transition into the global LEI system when it is established. The order included findings of fact by the Commission that the CICI provided by DTCC–SWIFT is the only available identifier that satisfies all requirements of the Commission's swap data reporting rules, and can be provided to market participants sufficiently in advance of the initial compliance date for swap data reporting to enable compliance with the rules. The designation is made for a limited term of two years, and is subject to four conditions specified in the order.

FOR FURTHER INFORMATION CONTACT: David Taylor, Associate Director, Division of Market Oversight, 202–418–5488, *dtaylor@cftc.gov;* or Srini Bangarbale, Chief Data Officer, Office of Data and Technology, 202–418–5315, *sbangarbale@cftc.gov;* Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20851.

SUPPLEMENTARY INFORMATION: Section 21(b) of the Commodity Exchange Act, (''CEA''), added to the CEA by Section 728 of the Dodd-Frank Act, directs the Commission to prescribe standards that specify the data elements for each swap that shall be reported to, and collected and maintained by, swap data repositories. Pursuant to this authority, part 45 of the Commission's regulations establishes recordkeeping and data reporting requirements for swaps subject to the jurisdiction of the Commission.[1] Section 45.6, *Legal entity identifiers,* includes a legal entity identifier (''LEI'') for each swap counterparty among the data elements required to be reported for each swap. That section provides that:

> Each counterparty to any swap subject to the jurisdiction of the Commission shall be identified in all recordkeeping and all swap data reporting pursuant to this part by means of a single legal entity identifier as specified in this section.[2]

As noted in part 45, and stated in the CPSS–IOSCO *Report on OTC Derivatives Data Reporting and Aggregation Requirements,* ''a standard system of LEIs is an essential tool for aggregation of OTC derivatives data.''[3]

In order to enable compliance with this requirement by registered entities and swap counterparties subject to the Commission's jurisdiction, part 45 provides that:

> The Commission shall determine, as provided in paragraphs (e)(1)(i) through (iii) of this section, whether a legal entity identifier system that satisfies the requirements set forth in this section is

[1] 17 CFR part 45, Swap Data Recordkeeping and Reporting Requirements, 77 FR 2136 (Jan. 13, 2012), *http://www.cftc.gov/ucm/groups/public/@lrfederalregister/documents/file/2011-33199a.pdf.*

[2] § 45.6.

[3] Committee on Payment and Settlement Systems and Technical Committee of the International Organization of Securities Commissions, *Report on OTC Derivatives Data Reporting and Aggregation Requirements* (Dec. 2011).

available to provide legal entity identifiers for registered entities and swap counterparties required to comply with this part.[4]

Section 45.6(e)(1)(i) specifies five factors that the Commission shall consider in making this determination.

Section 45.6 emphasizes that making this determination and having LEIs available for identification of swap counterparties when swap data reporting commences as of the compliance dates set forth in part 45 is highly important to achieving the systemic risk mitigation, transparency, and market abuse prevention purposes of the Dodd-Frank Act. For this reason, § 45.6(e)(1)(ii) provides that:

In making this determination, the Commission shall consider all candidates meeting the criteria set forth in paragraph (e)(1)(i) of this section, but shall not consider any candidate that does not demonstrate that it in fact can provide LEIs for identification of swap counterparties in swap data reporting commencing as of the compliance dates set forth in this part.

In addition, § 45.6(e)(1)(iii) provides that:

The Commission shall make this determination at a time it believes is sufficiently prior to the compliance dates set forth in this part to enable issuance of LEIs far enough in advance of those compliance dates to enable compliance with this part.

If the Commission determines that a provider whose LEI system provides LEIs meeting the requirements of part 45 is available, the rule calls for the Commission to inform registered entities and swap counterparties subject to the Commission's jurisdiction of where they can obtain the LEIs needed for compliance with part 45, by issuing an order designating the provider of the LEIs to be used for that purpose. Section 45.6(e)(2) provides that:

If the Commission determines pursuant to paragraph (e)(1) of this section that such a legal entity identifier system is available, the Commission shall designate the legal entity identifier system as the provider of legal entity identifiers to be used in recordkeeping and swap data reporting pursuant to this part, by means of a Commission order that is published in the **Federal Register** and on the Web site of the Commission, as soon as practicable after such determination is made. The order shall include notice of this designation, the contact information of the LEI utility, and information concerning the procedure and requirements for obtaining legal entity identifiers.

Once the Commission has determined that an LEI meeting the requirements of part 45 is available, and has designated its provider as set forth in § 45.6(e)(2), registered entities and swap counterparties subject to the Commission's jurisdiction are required to use the LEIs furnished by that provider in recordkeeping and swap data reporting. Section 45.6(f)(1) provides that:

When a legal entity identifier system has been designated by the Commission pursuant to paragraph (e) of this section, each registered entity and swap counterparty shall use the legal entity identifier provided by that system in all recordkeeping and swap data reporting pursuant to this part.

II. Determination and Designation Process

A. Request for Submissions

Pursuant to these provisions of part 45, on March 9, 2012, the Commission issued a public request for submissions from industry participants that wished to be considered for designation by the Commission as the provider of LEIs to be used in complying with the rule.[5]

The Commission's request for submissions included provisions relating to international aspects of LEIs. It reiterated that part 45 calls for issuance of the identifier used in recordkeeping and swap data reporting under CFTC jurisdiction, and for any utility formed to issue such identifiers, to be subject to international supervision by a governance structure that includes the Commission and other financial regulators in any jurisdiction requiring use of the legal entity identifier pursuant to applicable law. It noted the Commission's ongoing participation in an international process, coordinated by the Financial Stability Board (''FSB''), to establish governance principles and reference data requirements for a global legal entity identifier, to be contained in recommendations by an international regulatory LEI Expert Group (including the Commission) for consideration by the FSB in May 2012. In light of that process, and as requested by other international financial regulators, the request for submissions stated that the Commission would refer to the identifier to be used in reporting under part 45 as the CFTC Interim Compliant Identifier (''CICI'') until after the FSB Plenary meeting in May 2012, and would defer its designation of the provider of CICIs until after that meeting. The request also reiterated that, as provided in part 45, the Commission plans to adopt the governance principles and LEI reference data requirements endorsed by the FSB, making them applicable to identification of swap counterparties under CFTC jurisdiction. The request further stated that, once these steps are completed, the Commission anticipates that the identifier then called the CICI will transition into the global LEI, and be referred to as the LEI.

In its request for submissions, the Commission stated that submitters must be prepared to demonstrate that they meet all of the requirements set forth in part 45. It further notified submitters that: (1) The Commission's determination and designation process would include an on-site, live demonstration for Commission staff of the process to be used for issuance of CICIs; (2) the Commission's designation will be for a limited term of two years, and be terminable on six months' notice if a different central utility for the global LEI is chosen later through the FSB process and becomes operational; and (3) subject to applicable confidentiality laws, the Commission's designation will require that the designated LEI utility must make public all CICI data, operations, identity validation processes and audit trail, and to pass to any successor LEI utility, free of charge, all CICI data and all CICI intellectual property rights.

B. Requirements for Designation as the LEI Utility

Four parties expressed an interest in becoming the LEI provider. To assess their suitability, the Commission required the submitters to provide both (1) a written demonstration of their ability to meet the Commission's part 45 requirements, and (2) an on-site, live demonstration of their process for issuing CICIs.

1. Written Demonstration of Ability To Meet Commission Requirements

Detailed requirements for the written demonstration were provided to each submitter. The requirements document stated that, as provided in § 45.6(e)(1)(i) of the Commission's regulations, in determining whether a CICI meeting the requirements of part 45 is available, and if so designating its provider as the utility that will provide the CICI, the Commission would consider, without limitation, the following five factors:

- Whether the CICI provided by the utility is issued under, and conforms to, ISO Standard 17442, Legal Entity Identifier (LEI).
- Whether the CICI provided by the utility complies with all of the technical principles set forth in part 45.

[4] § 45.6(e)(1).

[5] Commodity Futures Trading Commission Press Release, *CFTC announces process to designate the provider of CFTC Interim Compliant Identifiers,* March 9, 2012.

• Whether the CICI utility complies with all of the governance principles set forth in part 45.

• Whether the CICI utility has demonstrated that it in fact can provide CICIs for identification of swap counterparties in swap data reporting commencing as of the compliance dates set forth in part 45.

• The acceptability of the CICI utility to industry participants required to use the LEI in complying with part 45.

The requirements document also described the functions to be performed by the CICI system, including, but not limited to, the following:

• Utility Administration (*e.g.,* accounting; audit; CICI fee collection; billing and payment; communications, human resources; and legal department).

• Data Management (*e.g.,* receive registrant data; establish and maintain registrant data record; apply validation and data quality assurance processes to registrant data; issue unique CICI; transmit CICI to registrant; maintain and update data record history; maintain and update required metadata; maintain complete audit trail of all records, data, and messages; and maintain appropriate system safeguards).

• Verification of Entity Identification (*e.g.,* cleanse and validate identification data submitted through both self-registration and third-party registration; connect to and communicate with national business registers in jurisdictions world-wide; provide identification data challenge services; verify uniqueness of submitted identification information; provide local verification in countries world-wide; visit provided addresses to verify entity presence; process entity messages regarding identification data, for example concerning corporate actions; perform periodic re-verification; and identify the verification level at which each record has been verified).

• Public Database (*e.g.,* establish and maintain free public database of all CICIs; provide 24/7 internet query facility; provide near-real time response to queries; provide complete, current CICI directory; and provide help desk and assistance services for the public).

• CICI Registration Services (*e.g.,* provide local language services world-wide; respond to market participant queries; receive and process both electronic and paper registration requests; and provide timely processing of CICI requests and timely assignment of CICIs).

• Compliance (*e.g.,* monitor and ensure adherence to technical and governance principles, to operational and technical standards and protocols, to regulatory policies concerning access to hierarchical data; and to applicable laws; regulatory oversight reporting; compliance with directives of international Regulatory Oversight Committee, when established; and maintain capability to transfer all CICI data to international central utility when established).

In addition, the requirements document provided that each submitter was required to provide detailed information concerning its relevant background and experience. This information was required to include details of the submitter's corporate and organization background and ownership and legal structure; its financial status; and its plan for financing establishment and operation of the CICI utility on a non-profit, cost-recovery basis, without charging market participants any fees that could reasonably be construed to constitute a barrier to participation in financial markets. Each submitter was also required to include a detailed description of its experience in assigning, maintaining, and managing validated corporate or legal entity identifiers, and its experience with gathering, cleansing, maintaining, and using reference data associated with identifying corporate or legal entities.

Each submitter provided a document to the Commission in response to the requirement for a written demonstration, as set forth above.

2. On-site, Live Demonstration of Complete CICI Issuance Process

Each submitter was also required to provide an on-site, live demonstration of its systems, operations, and processes for obtaining, cleansing, and using reference data to validate the identity of a legal entity and for issuing a CICI to such an entity. Submitters were asked to provide examples of preliminary identifiers and test files or test identifiers already prepared for or provided to swap counterparties for use in automated system preparation and testing in preparation for swap data reporting beginning on the applicable compliance date established in part 45. The demonstration was required to include live presentation of the submitter's web portal, file transmission facilities, and test processes that would be available to registered entities and swap counterparties for use in the CICI issuance process. The demonstration was also required to include live presentation of the submitter's procedures and staffing for obtaining entity reference data, entity challenge with respect to reference data, de-duplication of preliminary identifiers, and assignment of unique identifiers to all swap counterparties subject to the Commission's jurisdiction.

All four submitters provided some form of on-site, live demonstration to Commission staff.

D. Evaluation Criteria

The requirements document set forth criteria the Commission would use in evaluating the submitters and the CICIs they provide, for the purpose of determining whether a CICI meeting the requirements of part 45 is available, and if so, designating its provider as the source of CICIs to be used in compliance with part 45. Among other things, the four submissions were evaluated based on the following criteria:

1. Evidence that the submitter can in fact provide all CICIs required by market participants for the purpose of complying with part 45 of the Commission's regulations, and can do so sufficiently in advance of July 16, 2012, to enable market participants to be ready to comply as of that date. As provided in § 45.6 of the Commission's regulations, submitters that do not demonstrate this will not be considered further.

2. Whether the written demonstration completely and satisfactorily addresses all of the Commission's requirements addressed in the requirements document. Incomplete submissions will not be considered further.

3. Evidence of the submitter's satisfactory understanding of the Commission's requirements with respect to the CICI utility, as set forth in the requirements document.

4. Evidence satisfying the Commission that the submitter has commenced setting up, will fully set up before June 1, 2012, and can satisfactorily manage and maintain, a CICI utility meeting all of the Commission's requirements, as set forth in the requirements document and in part 45 of the Commission's regulations. Submissions not providing such evidence will not be considered further.

5. A successful, onsite, live, complete demonstration for Commission staff of the submitter's systems, operations, and processes for obtaining, cleansing, and using level one reference data to validate the identity of a legal entity and issuing a CICI to such an entity. Submitters who do not provide such a successful demonstration will not be considered further.

6. The submitter's relevant experience, as described in the requirements document, in assigning, maintaining, and managing validated corporate or legal entity identifiers, and the submitter's experience with gathering, cleansing, maintaining, and

using reference data associated with identifying corporate or legal entities.

7. A workable plan for financing the non-profit, cost-recovery-based establishment and operation of the CICI utility, without charging market participants any fee reasonably deemed to constitute a barrier to market participation.

III. Findings and Order

Now, therefore, based on the statutory provisions and Commission regulations cited above, and on the written submissions and on-site, live demonstrations provided by the submitters, the Commission makes the following findings and rulings:

The Commission FINDS that:

1. An LEI is available that: satisfies the requirements set forth in § 45.6 of the Commission's regulations; is provided by a utility fully set up by June 1, 2012; and can be provided to market participants sufficiently in advance of the initial compliance date for swap data reporting to enable compliance with the Commission's regulations. That LEI is the LEI provided by DTCC–SWIFT. DTCC–SWIFT met all of the Commission's requirements and evaluation criteria set forth in part 45 of the Commission's regulations and the requirements document.

2. The LEI provided by DTCC–SWIFT is the only available LEI that: satisfies the requirements set forth in § 45.6 of the Commission's regulations; is provided by a utility fully set up by June 1, 2012; and can be provided to market participants sufficiently in advance of the initial compliance date for swap data reporting to enable compliance with the Commission's regulations.

Therefore:

It is hereby ordered that:

1. DTCC–SWIFT is designated as the provider of legal entity identifiers (''LEIs''), to be known as CFTC Compliant Interim Identifiers (''CICIs'') until establishment of the global LEI system or further action by the Commission, to be used in recordkeeping and swap data reporting pursuant to parts 45 and 46 of the Commission's regulations.

a. This designation is conditioned on modification of the DTCC–SWIFT Web site and other facilities and documents used to provide identifiers for use in complying with parts 45 and 46, to refer to the CICI and not to refer to the LEI, the preliminary LEI, or other similar terms including the term LEI. This shall include, without limitation, references to the CICI rather than the LEI on the utility logo, documentation, instructions and field labels used by DTCC–SWIFT.

b. This designation is conditioned on DTCC–SWIFT's continuing compliance, for as long as it is authorized to provide LEIs (to be known as CICIs until establishment of the global LEI system), by this order or any future order of the Commission, with all of the legal entity identifier requirements of Part 45 of the Commission's regulations, and any related requirements as set forth in this order or in the requirements document provided to DTCC–SWIFT during the determination and designation process; including, without limitation, the requirement to be subject to supervision by a governance structure that includes the Commission and other financial regulators in any jurisdiction requiring use of legal entity identifiers pursuant to applicable law, for the purpose of ensuring that issuance and maintenance of CICIs and of associated reference data adheres on an ongoing basis to the Commission's requirements set forth in part 45.

c. This designation is further conditioned on the requirement that, subject to applicable confidentiality laws and other applicable law, (1) DTCC–SWIFT shall make public all CICI identifiers and associated reference data, utility operations, and identity validation processes, and (2) following establishment of the global LEI system by means of a charter acceded to by the Commission, or following designation by the Commission of a successor CICI utility, DTCC–SWIFT shall pass to any successor CICI utility, or to the global LEI system, free of charge, all CICI identifiers and associated reference data and all CICI intellectual property rights.

d. This designation is made for a limited term of two years from the date of this Order, and may be terminated by the Commission on six months' notice in connection with the establishment of a global LEI system. At the conclusion of the term of this designation, if the global LEI system is not yet operational, the Commission may consider the feasibility of having multiple CICI providers and the feasibility of coordination among them to avoid duplicative LEIs, and if it believes this is feasible, may consider submissions from DTCC–SWIFT as well as from other parties that seek to become CICI providers.

2. Registered entities and swap counterparties subject to the Commission's jurisdiction shall use CICIs provided by DTCC–SWIFT to comply with the legal entity identifier requirements of parts 45 and 46 of the Commission's regulations. For this purpose, registered entities and swap counterparties may contact DTCC–SWIFT at: The Depository Trust & Clearing Corporation, 55 Water Street, New York, NY 10041, 212–855–1000.

Issued in Washington, DC, this 23rd day of July, 2012.

By the Commission.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2012–21612 Filed 8–31–12; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2012–OS–0097]

Defense Transportation Regulation, Part IV

AGENCY: United States Transportation Command (USTRANSCOM), DoD.

ACTION: Notice.

SUMMARY: The Department of Defense has published draft Direct Procurement Method (DPM) business rules for the Defense Personal Property Program (DP3) in the Defense Transportation Regulation (DTR) Part IV (DTR 4500.9R). These business rules will encompass Transportation Service Providers (TSP) participation and procedures for Personal Property Shipping Offices (PPSO) as we transition to Phase III of the Defense Personal Property Program (DP3). The DPM business rules will replace the currently approved Domestic Small Shipment (dS2) business rules and will appear under DTR Part IV, Appendix V, to include operational business rules maintained on the Surface Deployment and Distribution Command (SCCD) Web site. The below listed draft business rules are available for review on the USTRANSCOM Web site at *http://www.transcom.mil/dtr/coord/coordpartiv.cfm.*

DATES: Comments must be received on or before October 4, 2012. Do not submit comments directly to the point of contact or mail your comments to any address other that what is shown below. Doing so will delay the posting of the submission. 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: Federal Docket Management System Office, 4800 Mark Center Drive, Suite 02G09, Alexandria VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for

comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Teague, United States Transportation Command, TCJ5/4–PI, 508 Scott Drive, Scott Air Force Base, IL 62225–5357; (618) 220–4803.

SUPPLEMENTARY INFORMATION: In furtherance of DoD's goal to develop and implement an efficient personal property program to facilitate quality movements of personal property for our military members and civilian employees, DPM business rules were developed in concert with the Military Services and SDDC. The following business rules are available for review and comment:

DPM Tender of Service (TOS)
Attachment V.E.1—Customer Satisfaction Survey
Attachment V.F.1—Best Value Score
Attachment V.F.2—Shipment Management
Attachment V.F.3—TSP Qualifications
Attachment V.F.4—Rate Filing
Attachment V.F.5—DPM CONUS Freight TSP
Attachment V.Q.2—Quality Assurance

Any subsequent modification(s) to the business rules will be published in the **Federal Register** and incorporated into the Defense Transportation Regulation (DTR) Part IV (DTR 4500.9R). These program requirements do not impose a legal requirement, obligation, sanction or penalty on the public sector, and will not have an economic impact of $100 million or more.

Additional Information: A complete version of the DTR is available via the Internet on the USTRANSCOM homepage at *http://www.transcom.mil/dtr/part-iv/.*

Dated: August 29, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–21696 Filed 8–31–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

[FE Docket No. 12–76–LNG]

The Dow Chemical Company; Application for Blanket Authorization To Export Previously Imported Liquefied Natural Gas on a Short-Term Basis

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt of an application (Application), filed on July 13, 2012, by The Dow Chemical Company (Dow), requesting blanket authorization to export liquefied natural gas (LNG) that previously had been imported into the United States from foreign sources in an amount up to the equivalent of 390 billion cubic feet (Bcf) of natural gas on a short-term or spot market basis for a two-year period commencing on October 5, 2012.[1] Dow seeks authorization to export this LNG from existing facilities on Quintana Island, Texas, to any country with the capacity to import LNG via ocean-going carrier and with which trade is not prohibited by U.S. law or policy. Dow is requesting this authorization both on its own behalf and as agent for other parties who hold title to the LNG at the time of export. The Application was filed under section 3 of the Natural Gas Act (NGA). Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., eastern time, October 4, 2012.

ADDRESSES: U.S. Department of Energy (FE–34), Office of Oil and Gas Global Security and Supply, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Larine Moore or Beverly Howard, U.S. Department of Energy (FE–34), Office of Oil and Gas Global Security and Supply, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478; (202) 586–9387;

Edward Myers, U.S. Department of Energy, Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, Room 6B–256, 1000 Independence Ave. SW., Washington, DC 20585, (202) 586–3397.

SUPPLEMENTARY INFORMATION:

Background

Dow is a Delaware corporation with its principal place of business in Midland, Michigan. Dow is an international chemical and plastics manufacturing company with operations in a number of U.S. states. Dow owns and operates a large petrochemical manufacturing facility in Freeport, Texas, which is in close proximity to the LNG import/export terminal owned and operated by Freeport LNG Development, L.P. (FLNG) on Quintana Island, Texas. Dow contracted 0.5 Bcf per day of terminal capacity from FLNG for a twenty-year period beginning in July 2008. Dow's petrochemical facility in Freeport has the capability to receive regasified LNG from the FLNG terminal via several pipelines that extend directly to the facility.

On April 20, 2012, FE granted Dow blanket authorization to import and export natural gas from and to Canada and Mexico and to import LNG from various international sources for a two-year term beginning on June 1, 2012.[2] Under the terms of the blanket authorization, the LNG may be imported to any LNG receiving facility in the United States or its territories.

Current Application

In the instant Application, Dow requests blanket authorization to export previously imported LNG on a short-term or spot market basis in an amount up to the equivalent of 390 Bcf of natural gas. Dow further requests that such authorization extend to LNG supplies imported from foreign sources to which Dow holds title, as well as to LNG supplies imported from foreign sources that Dow may export on behalf of other entities who themselves hold title. .Dow requests authorization to export this LNG from the FLNG terminal to any country with the capacity to import LNG via ocean-going carrier and with which trade is not prohibited by U.S. law or policy over a two-year period, on a short-term or spot market basis Dow states that it does not seek authorization to export domestically-produced natural gas.

Dow states that its interest in renewing its blanket re-export authorization is driven by its desire to optimize the long-term LNG terminalling capacity for which it has contracted at the FLNG terminal and its need for flexibility to respond to periodic changes in domestic and world markets for natural gas and LNG. Dow desires the flexibility either to export the imported LNG to other world markets or to have LNG regasified for sale or use in domestic markets,

[1] The Dow Chemical Company, DOE/FE Order No. 2859 (October 5, 2010) extends through October 4, 2012.

[2] *The Dow Chemical Company,* DOE/FE Order No. 3083 (April 20, 2012).

including at Dow's petrochemical facility in Freeport, a decision that would be based on prevailing market conditions.

Public Interest Considerations

In support of its Application, Dow states that pursuant to section 3 of the NGA, FE is required to authorize natural gas exports to a foreign country unless there is a finding that such exports ''will not be consistent with the public interest.'' [3] Dow states that section 3 thus creates a statutory presumption in favor of a properly framed export application.[4] Dow states further that the public interest determination is guided by DOE Delegation Order No. 0204–111, which provides that the domestic need for natural gas is the principal factor to be considered when evaluating an export application.[5]

As detailed in the Application, Dow states the blanket export authorization requested by Dow satisfies the public interest standard for the following reasons. Dow states that the LNG that may be exported pursuant to the blanket authorization requested in the Application is not needed to meet domestic demand. Dow states that DOE/FE has issued a number of blanket authorizations to export previously-imported LNG, including the one issued to Dow in Order No. 2859, finding that such LNG is not needed to meet domestic demand for natural gas. In addition, Dow states that on July 19, 2011, in Order No. 2986, which renewed FLNG's authorization to export previously imported LNG from its terminal facilities on Quintana Island, Texas, DOE/FE concluded that ''the evidence of record indicates that Untied States consumers continue to have access to substantial quantities of natural gas sufficient to meet domestic demand from multiple other sources at competitive prices without drawing on the LNG which Freeport LNG seeks to export.''

Dow further states that granting the requested export authorization will facilitate the importation of LNG into the United States. Further details can be found in the Application.

Environmental Impact

Dow asserts that its requested export authorization does not raise any environmental concerns. Dow states that no new facilities or modifications to any existing facilities at FLNG's Quintana Island terminal would be required in order for Dow to export LNG from the terminal. Dow further states that the environmental impacts of permitting the exportation of LNG from FLNG's Quintana Island terminal were already reviewed by DOE/FE in Order No. 2644 [6] as well as the granting of authority to others exporting previously imported LNG from the FLNG terminal. Dow asserts that consequently, the same conclusion is applicable to this Application insofar as the blanket authorization requested by Dow is substantially identical to its current blanket authorization.

DOE/FE Evaluation

This export Application will be reviewed pursuant to section 3 of the NGA, as amended, and the authority contained in DOE Delegation Order No. 00–002.00L (April 29, 2011) and DOE Redelegation Order No. 00–002.04E (April 29, 2011). In reviewing this LNG export Application, DOE will consider domestic need for the gas, as well as any other issues determined to be appropriate, including whether the arrangement is consistent with DOE's policy of promoting competition in the marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Parties that may oppose this Application should comment in their responses on these issues.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable. Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention, as applicable. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) Emailing the filing to *fergas@hq.doe.gov,* with FE Docket No. 12–76–LNG in the title line; (2) mailing an original and three paper copies of the filing to the Office of Oil and Gas Global Security and Supply at the address listed in **ADDRESSES**; or (3) hand delivering an original and three paper copies of the filing to the Office of Oil and Gas Global Security and Supply at the address listed in **ADDRESSES**.

A decisional record on the Application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

The Application filed by Dow is available for inspection and copying in the Office of Natural Gas Regulatory Activities docket room, 3E–042, 1000 Independence Avenue SW., Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The Application and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE web address:

[3] 15 U.S.C. 717b.(a). Natural gas is defined to include LNG in 10 CFR Part 590.102(i).

[4] Phillips Alaska Natural Gas Corp. and Marathon Oil Co., DOE/FE Order No. 1473 (2 FE ¶ 70,317) at 13 (April 2, 1999), citing Panhandle Producers and Royalty Owners Association v. ERA, 822 F.2d 1105, 1111 (DC Cir. 1987).

[5] Id at 14.

[6] Freeport LNG Development, L.P., Order No. 2644, June 8, 2009 at p. 12.

http://www.fe.doe.gov/programs/gasregulation/index.html.

Issued in Washington, DC, on August 29, 2012.

John A. Anderson,

Manager, Natural Gas Regulatory Activities, Office of Oil and Gas Global Security and Supply, Office of Fossil Energy.

[FR Doc. 2012–21690 Filed 8–31–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Proposed Subsequent Arrangement

AGENCY: Office of Nonproliferation and International Security, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This notice is being issued under the authority of section 131a. of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement under the Agreement for Cooperation Concerning Civil Uses of Nuclear Energy Between the Government of the United States of America and the Government of Canada and the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the United States of America and the European Atomic Energy Community.

DATES: This subsequent arrangement will take effect no sooner than September 19, 2012.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Oehlbert, Office of Nonproliferation and International Security, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–3806 or email: *Sean.Oehlbert@nnsa.doe.gov*.

SUPPLEMENTARY INFORMATION: This subsequent arrangement concerns the retransfer of 2,959,580 kg of U.S.-origin natural uranium hexafluoride (UF6) (67.60% U), 2,000,000 kg of which is uranium, from Cameco Corporation (Cameco) in Saskatoon, Saskatchewan, Canada, to URENCO in Almelo, Netherlands. The material, which is currently located at Cameco, will be used for toll enrichment by URENCO at their facility in Almelo, Netherlands. The material was originally obtained by Cameco from the Feed Component Substitution Implementing Contract.

In accordance with section 131a. of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement concerning the retransfer of nuclear material of United States origin will not be inimical to the common defense and security.

Dated: August 13, 2012.

For the Department of Energy.

Anne M. Harrington,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2012–21684 Filed 8–31–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Proposed Subsequent Arrangement

AGENCY: Office of Nonproliferation and International Security, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This notice is being issued under the authority of section 131a. of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement under the Agreement for Cooperation Concerning Civil Uses of Nuclear Energy Between the Government of the United States of America and the Government of Canada and the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the United States of America and the European Atomic Energy Community.

DATE: This subsequent arrangement will take effect no sooner than September 19, 2012.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Oehlbert, Office of Nonproliferation and International Security, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–3806 or email: *Sean.Oehlbert@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: This subsequent arrangement concerns the retransfer of 2,959,580 kg of U.S.-origin natural uranium hexafluoride (UF6) (67.60% U), 2,000,000 kg of which is uranium, from Cameco Corporation (Cameco) in Saskatoon, Saskatchewan, Canada, to URENCO in Capenhurst, United Kingdom. The material, which is currently located at Cameco, will be used for toll enrichment by URENCO at their facility in Capenhurst, United Kingdom. The material was originally obtained by Cameco from the Feed Component Substitution Implementing Contract.

In accordance with section 131a. of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement concerning the retransfer of nuclear material of United States origin will not be inimical to the common defense and security.

Dated: August 13, 2012.

For the Department of Energy.

Anne M. Harrington,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2012–21685 Filed 8–31–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Proposed Subsequent Arrangement

AGENCY: Office of Nonproliferation and International Security, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This notice is being issued under the authority of section 131a. of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement under the Agreement for Cooperation Concerning Civil Uses of Nuclear Energy Between the Government of the United States of America and the Government of Canada and the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the United States of America and the European Atomic Energy Community.

DATES: This subsequent arrangement will take effect no sooner than September 19, 2012.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Oehlbert, Office of Nonproliferation and International Security, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–3806 or email: *Sean.Oehlbert@nnsa.doe.gov*.

SUPPLEMENTARY INFORMATION: This subsequent arrangement concerns the retransfer of 2,959,580 kg of U.S.-origin natural uranium hexafluoride (UF6) (67.60% U), 2,000,000 kg of which is uranium, from Cameco Corporation (Cameco) in Saskatoon, Saskatchewan, Canada, to URENCO in Gronau, Germany. The material, which is currently located at Cameco, will be used for toll enrichment by URENCO at their facility in Gronau, Germany. The material was originally obtained by Cameco from the Feed Component Substitution Implementing Contract. In accordance with section 131a. of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement concerning the retransfer of nuclear material of United States origin will not be inimical to the common defense and security.

Dated: August 13, 2012.

For the Department of Energy.

Anne M. Harrington,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2012–21686 Filed 8–31–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC12–16–000]

Commission Information Collection Activities (FERC–715); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, Annual Transmission Planning and Evaluation Report.

DATES: Comments on the collection of information are due November 5, 2012.

ADDRESSES: You may submit comments (identified by Docket No. IC12–16–000) by either of the following methods:

- *eFiling at Commission's Web Site: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov*, or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov*, telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–715: Annual Transmission Planning and Evaluation Report.

OMB Control No.: 1902–0171.

Type of Request: Three-year extension of the FERC–715 information collection requirements with no changes to the current reporting requirements.

Abstract: Acting under FPA Section 213,[1] FERC requires each transmitting utility that operates integrated transmission system facilities rated above 100 kilovolts (kV) to submit annually:

- Contact information for the FERC–715;
- Base case power flow data (if it does not participate in the development and use of regional power flow data);
- Transmission system maps and diagrams used by the respondent for transmission planning;
- A detailed description of the transmission planning reliability criteria used to evaluate system performance for time frames and planning horizons used in regional and corporate planning;
- A detailed description of the respondent's transmission planning assessment practices (including, but not limited to, how reliability criteria are applied and the steps taken in performing transmission planning studies); and
- A detailed evaluation of the respondent's anticipated system performance as measured against its stated reliability criteria using its stated assessment practices.

The FERC–715 enables the Commission to use the information as part of their regulatory oversight functions which includes:

- The review of rates and charges;
- The disposition of jurisdictional facilities;
- The consolidation and mergers;
- The adequacy of supply and;
- Reliability of nation's transmission grid.

The FERC–715 enables the Commission to facilitate and resolve transmission disputes. Additionally, the Office of Electric Reliability (OER) uses the FERC–715 data to help protect and improve the reliability and security of the nation's bulk power system. OER oversees the development and review of mandatory reliability and security standards and ensures compliance with the approved standards by the users, owners, and operators of the bulk power system. OER also monitors and addresses issues concerning the nation's bulk power system including assessments of resource adequacy and reliability.

Without the FERC–715 data, the Commission would be unable to evaluate planned projects or requests related to transmission.

Type of Respondents: Integrated transmission system facilities rated at or above 100 kilovolts (kV).

Estimate of Annual Burden[2]: The Commission estimates the total Public Reporting Burden for this information collection as:

FERC–715—(IC12–16–000)—ANNUAL TRANSMISSION PLANNING AND EVALUATION REPORT

Number of respondents (A)	Number of responses per respondent (B)	Total number of responses (A) × (B) = (C)	Average burden hours per response (D)	Estimated total annual burden (C) × (D)
110	1	110	160	17,600

The total estimated annual cost burden to respondents is $1,214,569.23 [17,600 hours ÷ 2080 hours per year = 8.46153 * $143,540/year = $1,214,569.23]

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection;

[1] 16 U.S.C. 824l.

[2] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: August 28, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21664 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC12–17–000]

Commission Information Collection Activities (FERC–714); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 USC 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, Annual Electric Balancing Authority Area and Planning Area Report.

DATES: Comments on the collection of information are due November 5, 2012.

ADDRESSES: You may submit comments (identified by Docket No. [IC12–17–000]) by either of the following methods:

- *eFiling at Commission's Web Site: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–714: Annual Electric Balancing Authority Area and Planning Area Report.

OMB Control No.: 1902–0140.

Type of Request: Three-year extension of the FERC–714 information collection requirements with no changes to the current reporting requirements.

Abstract: The Federal Power Act authorizes the Commission to collect information from electric utility balancing authorities and planning areas in the United States. 18 CFR 141.51 mandates the data collection.

The Commission uses the collected data to analyze power system operations along with its regulatory functions. These analyses estimate the effect of changes in power system operations resulting from the installation of a new generating unit or plant, transmission facilities, energy transfers between systems, and/or new points of interconnections. Also, these analyses serve to correlate rates and charges, assess reliability and other operating attributes in regulatory proceedings, monitor market trends and behaviors, and determine the competitive impacts of proposed mergers, acquisitions, and dispositions.

Type of Respondents: Electric utilities operating balancing authority areas and planning areas with annual peak demand over 200 MW.

Estimate of Annual Burden [1]: The Commission estimates the total Public Reporting Burden for this information collection as:

FERC—714 (IC12–17–000)—ANNUAL ELECTRIC BALANCING AUTHORITY AREA AND PLANNING AREA REPORT

Number of respondents (A)	Number of responses per respondent (B)	Total number of responses (A) × (B) = (C)	Average burden hours per response (D)	Estimated total annual burden (C) × (D)
219	1	219	87	19,053

The total estimated annual cost burden to respondents is $1,314,839.32 [19,053 hours ÷ 2080 hours/year [2] = 9.16009 * $143,540/year [3] = $1,314,839.32]

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: August 28, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21665 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14447–000]

L.S. Starrett Company; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Exemption from Licensing.

[1] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

[2] 2080 hours = 52 weeks * 40 hours per week (i.e. 1 year of full-time employment).

[3] Average salary plus benefits per full-time equivalent employee.

b. *Project No.:* P–14447–000.

c. *Date filed:* August 15, 2012.

d. *Applicant:* L.S. Starrett Company.

e. *Name of Project:* Crescent Street Dam Hydroelectric Project.

f. *Location:* On the Millers River, in the Town of Athol, Worcester County, Massachusetts. The project would not occupy any federal lands.

g. *Filed Pursuant to:* Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2705, 2708.

h. *Applicant Contact:* Steve Walsh, L.S. Starrett Company, 121 Crescent Street, Athol, MA 01331; (978) 249–3551 ext. 229.

i. *FERC Contact:* Tom Dean, (202) 502–6041 or *thomas.dean@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: October 15, 2012.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

m. The application is not ready for environmental analysis at this time.

n. The existing project consists of: (1) A 28-foot-high, 127-foot-long concrete and masonry dam with a 98-foot-long spillway topped with a 3-foot-high bascule gate; (2) a 4.5-acre impoundment with a normal water surface elevation of 541.3 feet National Geodetic Vertical Datum of 1929; (3) generation facilities on the right side of the dam that include: (a) An intake structure equipped with a 7-foot-high, 7-foot-wide head gate and a 14-foot-high, 17.5-feet-wide trashrack with 1.25-inch clear bar spacing; (b) a 25-foot-long, 7-foot-diameter penstock; (c) a 44-foot-long, 28-foot-wide powerhouse containing a 250 kilowatt (kW) turbine generating unit; (d) a 7-foot-diameter, 47-foot-long bypass outlet conduit equipped with a 7-foot-high, 7-foot-wide gate; (e) a 16-foot-wide, 4-foot-deep, 200-foot-long tailrace; and (f) three 180-foot-long, 600 volt transmission lines; (4) generation facilities on the left side of the dam that include: (a) An 18-foot-long weir equipped with a 6-foot-high, 6-foot-wide slide gate and a 12-foot-high, 13.5-foot-wide trashrack with ¾-inch clear bar spacing; (b) a 55-foot-long, 6-foot-diameter penstock; (c) a 37-foot-long, 37-foot-wide powerhouse containing a 198 kW turbine generating unit; (d) and a 14-foot-wide, 9-foot-deep, 100-foot-long tailrace (e) six 900-foot-long, 600 volt transmission lines; and (f) appurtenant facilities. The project would have an estimated annual generation of 1,729.2 megawatt-hours.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. With this notice, we are initiating consultation with the Massachusetts State Historic Preservation Officer (SHPO), as required by section 106 of the National Historic Preservation Act and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. With this notice, we are designating L.S. Starrett as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

r. *Procedural schedule:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate (e.g., if there are no deficiencies and/or scoping is waived, the schedule would be shortened).

Issue Deficiency Letter	October 2012.
Issue Notice of Acceptance	December 2012.
Issue Scoping Document	January 2013.
Issue Notice ready for environmental analysis	March 2013.
Issue Notice of the availability of the EA	July 2013.

Dated: August 27, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21657 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2195–079]

Portland General Electric Company; Notice of Application Accepted for Filing, Soliciting Motions To Intervene, Protests, and Comments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Amendment of License.

b. *Project No:* 2195–079.

c. *Date Filed:* August 3, 2012.

d. *Applicant:* Portland General Electric Company.

e. *Name of Project:* Clackamas River Hydroelectric Project.

f. *Location:* On the Oak Grove Fork of the Clackamas River and the mainstem of the Clackamas River in Clackamas County, Oregon. The project occupies federal lands within the Mt. Hood National Forest, under the jurisdiction of the U.S. Forest Service, and a reservation of the U.S. Department of Interior's Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791(a)–825(r).

h. *Applicant Contact:* Julie A. Keil, Director of Hydro Licensing and Water Rights, Portland General Electric Company, 121 SW Salmon Street, Portland, OR 97204, (503) 464–8864.

i. *FERC Contact:* Jeremy Jessup, (202) 502–6779, *Jeremy.Jessup@ferc.gov.*

j. Deadline for filing motions to intervene, protests, and comments is 30 days from the issuance date of this notice.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: The Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. 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.

Please include the project number (P–2195–079) on any motions, protests, or comments filed.

k. *Description of Application:* The licensee proposes to amend the license for the Clackamas River Hydroelectric Project to remove two transmission lines that are no longer primary transmission lines. The licensee is requesting to delete the 17-mile Faraday-McLoughlin double-circuit transmission line and the 2.7-mile River Mill-Faraday transmission line from the project. The license's application states that both of the transmission lines function as part of the licensee's transmission and distribution system and are not jurisdictional under Part 1 of the Federal Power Act. The proposed amendment will reduce the amount of lands of the United States that the project occupies by 1.4 acres.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call (866) 208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Motions To Intervene, Protests, and Comments:* Anyone may submit a motion to intervene, protest, or comments in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any motions to intervene, protests, or comments must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must: (1) Bear in all capital letters the title ''MOTION TO INTERVENE,'' ''PROTEST,'' or ''COMMENTS'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person intervening, protesting, or commenting; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All motions to intervene, protests, or comments must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All motions to intervene, protests, or comments should relate to project works which are the subject of the application. Agencies may obtain copies of the application directly from the applicant. A copy of any motion to intervene or protest must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: August 27, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21666 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC12–137–000.

Applicants: Constellation Power Source Generation LLC, Brandon Shores LLC, C.P. Crane LLC, H.A. Wagner LLC.

Description: Joint Application of Constellation Power Source Generation LLC, Brandon Shores LLC, H.A. Wagner LLC and C.P. Crane LLC under Section 203.

Filed Date: 8/23/12.

Accession Number: 20120823–5141.

Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: EC12–138–000.
Applicants: Minonk Wind, LLC, Algonquin Power Fund (America) Inc.
Description: Application for Authorization for Disposition of Jurisdictional Facilities of Minonk Wind, LLC and Algonquin Power Fund (America) Inc.
Filed Date: 8/24/12.
Accession Number: 20120824–5111.
Comments Due: 5 p.m. ET 9/14/12.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG12–102–000.
Applicants: Brandon Shores LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator of Brandon Shores LLC.
Filed Date: 8/23/12.
Accession Number: 20120823–5146.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: EG12–103–000.
Applicants: H.A. Wagner LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator of H.A. Wagner LLC.
Filed Date: 8/23/12.
Accession Number: 20120823–5147.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: EG12–104–000.
Applicants: C.P. Crane LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator of C.P. Crane LLC.
Filed Date: 8/23/12.
Accession Number: 20120823–5148.
Comments Due: 5 p.m. ET 9/13/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2985–005; *ER10–3049–006; ER10–3051–006.*
Applicants: Champion Energy Marketing LLC, Champion Energy Services, LLC, Champion Energy, LLC.
Description: Notice of Non-Material Change in Status of Champion Energy Marketing LLC, et al.
Filed Date: 8/23/12.
Accession Number: 20120823–5143.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–645–005.
Applicants: California Ridge Wind Energy LLC.
Description: Change in Status Notice of California Ridge Wind Energy LLC.
Filed Date: 8/24/12.
Accession Number: 20120824–5052.
Comments Due: 5 p.m. ET 9/14/12.

Docket Numbers: ER12–1204–002.
Applicants: PJM Interconnection, L.L.C.
Description: Errata to Compliance Filing in ER12–1204 re Order 755 to be effective 10/1/2012.
Filed Date: 8/23/12.
Accession Number: 20120823–5119.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–2055–001.
Applicants: San Gorgonio Farms, Inc.
Description: Supplement to its Market-Based Rate Application.
Filed Date: 8/23/12.
Accession Number: 20120823–5018.
Comments Due: 5 p.m. ET 9/4/12.

Docket Numbers: ER12–2505–000.
Applicants: Southwest Power Pool, Inc.
Description: 2460 Tulsa LFG, LLC GIA to be effective 7/20/2012.
Filed Date: 8/20/12.
Accession Number: 20120820–5187.
Comments Due: 5 p.m. ET 9/10/12.

Docket Numbers: ER12–2506–000.
Applicants: Southern California Edison Company.
Description: SGIA with TA-Acacia, LLC, TA-Acacia Project to be effective 8/24/2012.
Filed Date: 8/23/12.
Accession Number: 20120823–5034.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–2507–000.
Applicants: Southwest Power Pool, Inc.
Description: 2208R1 Ensign Wind, LLC GIA to be effective 7/24/2012.
Filed Date: 8/23/12.
Accession Number: 20120823–5062.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–2508–000.
Applicants: PacifiCorp.
Description: OATT Revised Section 14 to be effective 10/23/2012.
Filed Date: 8/23/12.
Accession Number: 20120823–5063.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–2509–000.
Applicants: California Independent System Operator Corporation.
Description: California Independent System Operator Corporation submits tariff filing per 35: 2012–08–23 CAISO Filing in Compliance with July 24, 2012 Order (ER12–1855–000) to be effective 7/25/2012.
Filed Date: 8/23/12.
Accession Number: 20120823–5101.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–2510–000.
Applicants: Brandon Shores LLC.
Description: Brandon Shores Section 205 to be effective 10/8/2012.
Filed Date: 8/23/12.
Accession Number: 20120823–5118.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–2511–000.
Applicants: C.P. Crane LLC.
Description: CP Crane Section 205 to be effective 10/8/2012.
Filed Date: 8/23/12.
Accession Number: 20120823–5120.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–2512–000.
Applicants: H.A. Wagner LLC.
Description: HA Wagner Section 205 to be effective 10/8/2012.
Filed Date: 8/23/12.
Accession Number: 20120823–5121.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–2513–000.
Applicants: Raven Power Marketing LLC.
Description: Raven Power Section 205 to be effective 10/8/2012.
Filed Date: 8/23/12.
Accession Number: 20120823–5122.
Comments Due: 5 p.m. ET 9/13/12.

Docket Numbers: ER12–2514–000.
Applicants: Susterra Energy, LLC.
Description: Susterra Energy MBR Application and Initial MBR Tariff to be effective 10/23/2012.
Filed Date: 8/24/12.
Accession Number: 20120824–5023.
Comments Due: 5 p.m. ET 9/14/12.

Docket Numbers: ER12–2515–000.
Applicants: Southern California Edison Company.
Description: Interconnection Facilities Agreement with The City of Riverside to be effective 8/25/2012.
Filed Date: 8/24/12.
Accession Number: 20120824–5037.
Comments Due: 5 p.m. ET 9/14/12.

Docket Numbers: ER12–2516–000.
Applicants: Cleco Power LLC.
Description: RS 37—ESIA with City of Natchitoches, Louisiana to be effective 8/24/2012.
Filed Date: 8/24/12.
Accession Number: 20120824–5038.
Comments Due: 5 p.m. ET 9/14/12.

Docket Numbers: ER12–2517–000.
Applicants: Southern California Edison Company.
Description: Amended SGIA & DSA to Site 12 4091(S) E. Francis St Bldg 5, Ontario, CA Project to be effective 10/24/2012.
Filed Date: 8/24/12.
Accession Number: 20120824–5043.
Comments Due: 5 p.m. ET 9/14/12.

Docket Numbers: ER12–2518–000.
Applicants: PJM Interconnection, L.L.C.
Description: Queue No. W2–022; Original Service Agreement No. 3386 to be effective 7/25/2012.
Filed Date: 8/24/12.
Accession Number: 20120824–5046.
Comments Due: 5 p.m. ET 9/14/12.

Docket Numbers: ER12–2519–000.
Applicants: Cleco Power LLC.
Description: Cleco Power LLC submits a Notice of Cancellation of Rate Schedule 14—ESIA with City of Natchitoches, Louisiana.
Filed Date: 8/24/12.
Accession Number: 20120824–5053.

Comments Due: 5 p.m. ET 9/14/12.

Docket Numbers: ER12–2520–000.

Applicants: California Independent System Operator Corporation

Description: 2012–08–24 CAISO Filing of Amended Service Agreement 2157 and Request for Waiver to be effective 10/1/2012.

Filed Date: 8/24/12.

Accession Number: 20120824–5102.

Comments Due: 5 p.m. ET 9/14/12.

Docket Numbers: ER12–2521–000.

Applicants: Louisville Gas and Electric Company.

Description: 08_24_12 OATT ITO Amend to be effective 9/1/2012.

Filed Date: 8/27/12.

Accession Number: 20120827–5003.

Comments Due: 5 p.m. ET 9/17/12.

Docket Numbers: ER12–2522–000.

Applicants: D & L Harris and Associates.

Description: Initial to be effective 8/28/2012.

Filed Date: 8/27/12.

Accession Number: 20120827–5026.

Comments Due: 5 p.m. ET 9/17/12.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR12–13–000.

Applicants: North American Electric Reliability Corporation.

Description: Request of the North American Electric Reliability Corporation for Acceptance of its 2013 Business Plan and Budget and the 2013 Business Plans and Budgets of Regional Entities and for Approval of Proposed Assessments to Fund Budgets.

Filed Date: 08/24/2012.

Accession Number: 20120824–5029.

Comment Date: 5 p.m. ET 9/14/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 27, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21641 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: CP12–503–000.

Applicants: CenterPoint Energy Gas Transmission Company, LLC and CenterPoint Energy—Mississippi River Transmission, LLC.

Description: Joint Capacity Lease Application.

Filed Date: 8/22/12.

Accession Number: 20120822–5123.

Comments Due: 5 p.m. ET 9/12/12.

Docket Numbers: RP12–959–000.

Applicants: Dauphin Island Gathering Partners.

Description: Negotiated Rates 2012–08–24 to be effective 8/24/2012.

Filed Date: 8/23/12.

Accession Number: 20120823–5123.

Comments Due: 5 p.m. ET 9/4/12.

Docket Numbers: RP12–960–000.

Applicants: Wyoming Interstate Company, L.L.C.

Description: WGR—Anadarko Permanent Release Filing to be effective 9/25/2012.

Filed Date: 8/24/12.

Accession Number: 20120824–5042.

Comments Due: 5 p.m. ET 9/5/12.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated August 27, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21643 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–1928–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Response of Midwest Independent Transmission System Operator, Inc. to the Commission's deficiency letter.

Filed Date: 8/27/12.

Accession Number: 20120827–5059.

Comments Due: 5 p.m. ET 9/17/12.

Docket Numbers: ER12–2523–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Brownton–GRE–NSP T–T to be effective 7/31/2012.

Filed Date: 8/27/12.

Accession Number: 20120827–5065.

Comments Due: 5 p.m. ET 9/17/12.

Docket Numbers: ER12–2524–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Sheas Lake–GRE–NSP T–T to be effective 8/10/2012.

Filed Date: 8/27/12.

Accession Number: 20120827–5068.

Comments Due: 5 p.m. ET 9/17/12.

Docket Numbers: ER12–2525–000.

Applicants: Southwest Power Pool, Inc.

Description: Revisions to Schedule 11—Base Plan Zonal Charge and Region Wide Charge to be effective 11/1/2012.

Filed Date: 8/27/12.

Accession Number: 20120827–5084.

Comments Due: 5 p.m. ET 9/17/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing

requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 27, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21642 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG12–98–000.
Applicants: Brookfield Smoky Mountain Hydropower LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Brookfield Smoky Mountain Hydropower LLC.
Filed Date: 8/14/12.
Accession Number: 20120814–5061.
Comments Due: 5 p.m. ET 9/4/12.

Docket Numbers: EG12–99–000.
Applicants: Horse Butte Wind I LLC.
Description: EWG Self-Certification of Horse Butte Wind I LLC.
Filed Date: 8/14/12.
Accession Number: 20120814–5065.
Comments Due: 5 p.m. ET 9/4/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–1470–001.
Applicants: Energia Sierra Juarez U.S., LLC.
Description: Energia Sierra Juarez U.S. LLC Revised MBR Tariff to be effective 10/1/2012.
Filed Date: 8/13/12.
Accession Number: 20120813–5129.
Comments Due: 5 p.m. ET 9/4/12.

Docket Numbers: ER12–1800–001.
Applicants: Public Service Company of New Mexico.
Description: OATT Attachment R Compliance Filing to be effective 7/15/2012.
Filed Date: 8/13/12.
Accession Number: 20120813–5125.
Comments Due: 5 p.m. ET 9/4/12.

Docket Numbers: ER12–2444–000.
Applicants: North Sky River Energy, LLC.
Description: North Sky River, LLC Market-Based Rate Tariff to be effective 10/13/2012.
Filed Date: 8/14/12.
Accession Number: 20120814–5043.
Comments Due: 5 p.m. ET 9/4/12.

Docket Numbers: ER12–2445–000.
Applicants: Dynegy South Bay, LLC.
Description: Notice of Cancellation to be effective 8/15/2012.
Filed Date: 8/14/12.
Accession Number: 20120814–5094.
Comments Due: 5 p.m. ET 9/4/12.

Docket Numbers: ER12–2446–000.
Applicants: MidAmerican Energy Company.
Description: Joint Pricing Zone Revenue Allocation Agreement to be effective 9/1/2012.
Filed Date: 8/14/12.
Accession Number: 20120814–5095.
Comments Due: 5 p.m. ET 9/4/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 14, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21649 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP12–39–000; RP12–39–001]

Algonquin Gas Transmission, LLC; Notice Establishing Deadline for Comments

On August 22, 2012, Algonquin Gas Transmission, LLC (Algonquin) filed a response to the Commission's August 10, 2012 Data Request in the captioned proceedings.

Notice is hereby given that participants in the captioned proceedings may file comments to Algonquin's Data Response on or before 5 p.m. Eastern time on Wednesday, September 5, 2012.

Dated: August 27, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21656 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL12–100–000]

Benjamin Riggs v. Rhode Island Public Utility Commission; Notice of Complaint

Take notice that on August 22, 2012, pursuant to Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure and Rule 206 of the Federal Power Act, Benjamin Riggs (Complainant) filed a formal complaint against the Rhode Island Public Utility Commission (Respondent) alleging that the Respondent approved a 20-year Purchase Power Agreement between Deepwater Wind Block Island, LLC and National Grid on August 16, 2010, as directed by the Rhode Island General Assembly; which appears to constitute a violation of the Federal Power Act, to include 16 U.S.C. 791 et seq., 16 U.S.C. 824, and the Commerce Clause of the U.S. Constitution.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on September 12, 2012.

Dated: August 28, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21663 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM11–20–000]

Automatic Underfrequency Load Shedding and Load Shedding Plans Reliability Standards; Notice of Compliance Filing

Take notice that on August 9, 2012, North American Electric Reliability Corporation submitted a compliance filing in response to the directives in Order No. 763.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on September 10, 2012.

Dated: August 27, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21659 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–2528–000]

High Mesa Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of High Mesa Energy, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is September 17, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 28, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21640 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–2444–000]

North Sky River Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of North Sky River Energy, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard

[1] *Automatic Underfrequency Load Shedding and Load Shedding Plans Reliability Standards,* 139 FERC ¶ 61,098, (Order No. 763) (2012).

to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is September 4, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 15, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–21650 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF12–7–000; Docket No. PF12–17–000]

Jordan Cove Energy Project LP, Pacific Connector Gas Pipeline LP; Notice of Extension of Comment Period and Additional Public Scoping Meetings for the Jordan Cove Liquefaction and Pacific Connector Pipeline Projects

This notice announces the extension of the public scoping process and comment period for Jordan Cove Energy Project LP's (Jordan Cove) proposed liquefaction project in Coos County, Oregon, in Docket No. PF12–7–000, and Pacific Connector Gas Pipeline LP's (Pacific Connector) proposed pipeline project crossing portions of Klamath, Jackson, Douglas, and Coos Counties, Oregon, in Docket No. PF12–17–000. In addition to extending the scoping period, the Commission staff will conduct two additional public scoping meetings, with dates and times to be announced at a later date. Please note that the scoping period will now close on October 29, 2012.

On August 2, 2012, the Federal Energy Regulatory Commission (FERC or Commission), in cooperation with the U.S. Department of Agriculture Forest Service (Forest Service), and the U.S. Department of the Interior Bureau of Land Management (BLM), issued a *Notice of Intent to Prepare an Environmental Impact Statement for the Planned Jordan Cove Liquefaction and Pacific Connector Pipeline Projects, Requests for Comments on Environmental Issues, and Notice of Public Scoping Meetings* (NOI). The NOI solicited comments on the potential environmental impacts of the proposed projects and announced the time and location of four public meetings. The environmental comments received will allow the staffs of the Commission, Forest Service, and BLM to focus attention on issues important to the public during our preparation of an Environmental Impact Statement (EIS) for the projects.

You can attend any of the scoping meetings to provide verbal comments.[1] In lieu of or in addition to providing comments at the meetings, you can submit written comments to the Commission. In order for your written comments to be considered and addressed in the EIS, they should be properly filed with the Commission. There are three methods you can use to submit your comments to the FERC. In all instances, please reference the docket numbers for these projects (PF12–7–000 and PF12–17–000) with your submission.

(1) You can file your comments electronically using the eComment feature located on the Commission's Web site (www.ferc.gov) under the Documents & Filings link. This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the eFiling feature located on the Commission's Web site (www.ferc.gov) under the Documents & Filings link. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing;'' or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

If you have questions about electronic filings with the FERC, feel free to call our information technology experts at FERC Online Support at 202–502–6652 or email *ferconlinesupport@ferc.gov;* or 202–502–8258 or email *efiling@ferc.gov.*

Dated: August 28, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21658 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

[1] Verbal comments at the public scoping meetings will be transcribed by a court reporter and placed into the public record for these proceedings.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP12–500–000]

CenterPoint Energy Gas Transmission Company, LLC; Notice of Request Under Blanket Authorization

Take notice that on August 15, 2012, CenterPoint Energy Gas Transmission Company, LLC (CenterPoint), 1111 Louisiana Street, Houston, Texas 77002, filed a prior notice request pursuant to sections 157.208, 157.211, and 157.216 of the Commission's regulations under the Natural Gas Act (NGA) and CenterPoint's blanket certificate issued in Docket Nos. CP82–384–000 and CP82–384–001 for authorization to replace and abandon certain deteriorated facilities located in Nevada County, Arkansas (Line A Replacement Project). Specifically, CenterPoint proposes to: (1) Replace a 7.3-mile, 18-inch and 20-inch diameter pipeline segment of Line A having an MAOP of 350 psig with 7.4 miles of new 12-inch diameter pipeline having an MAOP of 1000 psig; (2) extend Line A to a new replacement delivery point by constructing 0.7 miles of 12-inch diameter pipeline; (3) install replacement delivery taps and other appurtenant facilities; and (4) abandon two small lines—Line AM–189 (205 feet of 2-inch diameter line) and Line AM–10 (204 feet of 6-inch diameter line)—as well as certain metering and appurtenant facilities. It is indicated

that the Line A Replacement Project will create no new capacity and CenterPoint states that the project is necessary to continue to provide safe and reliable transportation services. The project is estimated to cost approximately $8.1 million, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Any questions concerning this application may be directed to Michelle Willis, Manager, Regulatory & Compliance, CenterPoint Energy Gas Transmission Company, LLC, P.O. Box 21734, Shreveport, Louisiana 71151, or call (318) 429–3708, or email at *Mitchelle.Willis@CenterPoint Energy.com*.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

This filing is available for review at the Commission or may be viewed on the Commission's web site at *http://www.ferc.gov,* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number filed to access the document. For assistance, please contact FERC Online Support at FERC *OnlineSupport@ferc.gov* or call toll-free at (866) 206–3676, or, for TTY, contact (202) 502–8659. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link. The Commission strongly encourages intervenors to file electronically.

Dated: August 28, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21662 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD11–9–000]

February 2011 Southwest Cold Weather Event Follow-up Technical Conference; Notice of Technical Conference

Take notice that the Federal Energy Regulatory Commission (Commission) will hold a technical conference on Tuesday, September 25, 2012 from 10 a.m. to 4 p.m. This conference will be led by Commission staff and will be held in the ERCOT Metro Center, 7620 Metro Center Drive, Austin, Texas 78744. The conference will be open for the public to attend.

The purpose of the conference is to discuss actions taken in response to the August 16, 2011 Report on Outages and Curtailments During the Southwest Cold Weather Event of February 1–5, 2011 that was prepared by the staffs of the Commission and the North American Electric Reliability Corporation. The conference will explore the progress made on the Report's recommendations and whether sufficient safeguards have been implemented to avert a repeat of the loss of generation due to severe cold weather issues that led to rolling blackouts affecting over 4 million customers and natural gas curtailments affecting an additional 50,000 customers.

Those interested in attending a conference are encouraged to register by close of business, September 18, 2012. You may register at the following Web page: *https://www.ferc.gov/whats-new/registration/rt-09-27-12-form.asp*.

The agenda for this conference will be issued at a later date. Information on this event will be posted on the Calendar of Events on the Commission's Web site, *www.ferc.gov*, prior to the event.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–1659 (TTY), or send a FAX to 202–208–2106 with the required accommodations.

For more information about this conference, please contact: Mark Hershfield, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8597, *mark.hershfield@ferc.gov.*

Dated: August 27, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21661 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD11–9–000]

February 2011 Southwest Cold Weather Event Follow-up Technical Conference; Notice of Technical Conference

Take notice that the Federal Energy Regulatory Commission (Commission) will hold a Technical Conference on Thursday, September 27, 2012, from 10 a.m. to 4 p.m. This conference will be led by Commission staff and will be held in the African American Performing Arts Center 310 San Pedro Drive Northeast, Albuquerque, New Mexico 87108. The conference will be open for the public to attend.

The purpose of the conference is to discuss actions taken in response to the August 16, 2011 Report on Outages and Curtailments During the Southwest Cold Weather Event of February 1–5, 2011 that was prepared by the staffs of the Commission and the North American Electric Reliability Corporation. The conference will explore the progress made on the Report's recommendations and to determine if sufficient safeguards have been implemented to avert a repeat of the loss of approximately 700 megawatts of generation in WECC due to severe cold weather issues. This resulted in 1,000 megawatts of load shedding which affected over 250,000 customers in the WECC region. In addition, the conference will cover the disruption of natural gas supply to over 30,000 customers in New Mexico.

Those interested in attending a conference are encouraged to register by close of business, September 20, 2012. You may register at the following Web page: *https://www.ferc.gov/whats-new/registration/rt-09-27-12-form.asp*.

The agenda for this conference will be issued at a later date. Information on this event will be posted on the Calendar of Events on the Commission's Web site, *www.ferc.gov*, prior to the event.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–1659 (TTY), or send a FAX

to 202–208–2106 with the required accommodations.

For more information about this conference, please contact: Mark Hershfield, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8597, *Mark.Hershfield@ferc.gov*.

Dated: August 27, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–21660 Filed 8–31–12; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Savings and Loan Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and the Board's Regulation LL (12 CFR part 238) to acquire shares of a savings and loan holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than September 18, 2012.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President), 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Billy D. Cole and Joy Y. Cole,* St. Joseph, Missouri; Nancy Stonner, Blue Springs, Missouri; Norma Cole, Redmond, Washington; Mary Benson, New York, New York; and Thomas Cole, Liberty, Missouri; as a group acting in concert, to acquire control of St. Joseph Bancorp, Inc., and thereby indirectly acquire control of Midwest Federal Savings and Loan Association of St. Joseph, both in St. Joseph, Missouri.

Board of Governors of the Federal Reserve System, August 29, 2012.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2012–21693 Filed 8–31–12; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than September 18, 2012.

A. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *Gapstow Capital Partners, L.P.; CJA Private Equity Financial Restructuring Master Fund I, L.P.; CJA Private Equity Financial Restructuring Fund I, Ltd., and its investors; CJA Private Equity Financial Restructuring GP I, Ltd.; Christopher J. Acito & Associates GP, LLC; Christopher J. Acito; and Jack T. Thompson;* all of New York, New York; and Timothy S.F. Jackson, Newtown, Connecticut; to acquire voting shares of Oregon Pacific Bancorp, and thereby indirectly acquire voting shares of Oregon Pacific Banking Co. (doing business as Oregon Pacific Bank), both in Florence, Oregon.

Board of Governors of the Federal Reserve System, August 29, 2012.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2012–21694 Filed 8–31–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day-12-12RI]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 and send comments to Ron Otten, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Information Collection on foreign-born, migrant, refugee and other mobile populations with current or future ties to the United States—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), requests approval of a new ''generic clearance'' to better understand the health status, risk factors for disease and other health outcomes among foreign-born, migrant, refugee and other mobile populations with current or future ties to the United States. Insights gained from information collections will assist in the planning, implementation and improvement of disease prevention and control activities.

The information collection for which approval is sought is in accordance with DGMQ's mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations, and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. This

mission is supported by delegated legal authorities.

Section 361 of the Public Health Service (PHS) Act (42 USC 264) authorizes the Secretary of Health and Human Services (HHS) to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries or possessions into the United States and from one state or possession into any other state or possession. These regulations are codified in 42 Code of Federal Regulations (CFR) Parts 70 and 71.

The Secretary of Health and Human Services also has the legal authority to establish regulations outlining the requirements for the medical examination of aliens before they may be admitted into the United States. This authority is provided under Section 212(a)(1)(A) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(1)(A)) and Section 325 of the Public Health Service Act. These regulations are codified in 42 CFR part 34, which establish requirements that determine whether aliens can be admitted into the United States.

Successful implementation of DGMQ's regulatory authority and public health mission requires a variety of information collections with foreign-born, migrant and other mobile populations with current or future ties to the United States. These include but are not limited to: Immigrants, international travelers, asylees and refugees, expatriates, border region residents, temporary migrants, and permanent alien residents.

Numerous types of information will be collected under the auspices of this generic OMB clearance. These include, but are not limited to, knowledge, attitudes, beliefs, behavioral intentions, practices, behaviors, skills, self-efficacy, and health information needs and sources.

The proposed generic clearance is needed for DGMQ to fulfill its regulatory authority and public health mission, and will allow DGMQ to quickly collect important health-related information from the aforementioned hard-to-reach populations in order to improve routine and emergency public health programs and activities.

DGMQ staff proposes that data collection methods for this package will include but are not limited to: interviews, focus groups, and surveys. Depending on the specific purpose, data collection methods may be conducted either in-person, by telephone, on paper, or online. Data may be collected in quantitative and/or qualitative forms. Each proposed information collection will submit the tools used for data collection, including screenshots of web-based surveys, in the statement provided to OMB.

DGMQ estimates that 59,550 respondents will be screened in order for 19,850 to be involved in information collection activities each year. It is estimated that information collection activities will total 21,992 burden hours per year.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Foreign-born, migrant, refugee and other mobile populations.	Screeners for Surveys, Focus Groups, Interviews.	39,700	1	10/60	6,617
Foreign-born, migrant, refugee and other mobile populations.	Surveys	19,200	1	45/60	14,400
Foreign-born, migrant, refugee and other mobile populations.	Focus Groups, Interviews	650	1	1.5	975
Total					21,992

Dated: August 28, 2012.

Ron A, Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–21720 Filed 8–31–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 77 FR 43837—43841, dated July 26, 2012) is amended to reflect the reorganization of the Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and functional statements for the Program Services Branch (CGCB), and Applied Science Evaluation Branch (CGCC), within the Division of State and Local Readiness (CGC), and insert the following:

Program Services Branch (CGCB). (1) Provides consultation and technical assistance to state, territorial, tribal and local health departments in management and operation of activities to support public health preparedness, response and recovery including the infrastructure and systems necessary to manage and use deployed Division of Strategic National Stockpile (DSNS) assets; (2) facilitates partnerships between public health preparedness programs at federal, state, and local levels to ensure their consistency, sharing promising practices, and integration; (3) collaborates with and supports other divisions in OPHPR and other national centers across CDC to ensure high quality technical assistance is available to the grantees on preparedness capabilities; (4) supervises federal field staff providing technical assistance to state and local public health preparedness programs; (5) provides oversight to partnership organization cooperative agreements and maintains a strong working relationship with national partners; (6) monitors activities of cooperative agreements and grants of partners and state, local, tribal and territorial organizations to assure program objectives and key performance

indicators are achieved including reviews of Cities Readiness Initiative response plans; (7) provides assistance to state and local governments and public health agencies in engaging communities of major metropolitan areas to prepare for effective responses to large scale public health events; (8) provides health communications guidance and products before, during, and after an event to assist state/local public health departments in developing risk communicating strategies and messages; and (9) collaborates with the DSNS Response and Logistics Branches during exercises or upon a federal deployment of DSNS assets.

Applied Science and Evaluation Branch (CGCC). (1) Assesses the effectiveness of the Public Health Emergency Preparedness (PHEP) Cooperative Agreement;

(2) provide analytic support and evaluation expertise to the Division of State and Local Readiness and the Office of Public Health Preparedness and Response; (3) conducts, integrates, translates, and leverages interdisciplinary preparedness science; (4) fosters innovation and efficiency in evaluation and research through collaboration with healthcare and health security partners; and (5) develops evidence based recommendations to improve the quality of decision-making on preparedness, response and recovery activities.

Delete in its entirety the title and functional statements for the Office of the Director (CGE1), within the Division of Strategic National Stockpile (CGE), and insert the following:

Office of the Director (CGE1). (1) Conducts the executive planning and management of the division; (2) plans strategies and methods for educating the public health and emergency response communities about the Strategic National Stockpile (SNS) and its effective use; (3) represents the DSNS in state, local, and federally sponsored exercises to test community response to a catastrophic health event; (4) directs and monitors a comprehensive strategy for managing and executing the critical systems in operating a successful commercial good manufacturing practice compliance program; (5) provides medical, pharmaceutical, and scientific oversight of the SNS formulary; (6) partners with other governmental agencies, public health organizations, and commercial entities with interest and involvement in DSNS activities and information; (7) coordinates the Stockpile Configuration Management Board that is responsible for reviewing, reconciling, and adjusting SNS package and kit design and contents to maintain consistency with medical, scientific, resource, and end user requirements; (8) provides leadership, guidance, and technical integration of preparedness planning across the public health, healthcare, and emergency management sectors; (9) provides status of DSNS assets and deployment strategies to inform development and refinement of SNS guidance and communications to PHEP awardees; (10) serves as the point of contact for federal agencies, non-governmental organizations, and partners for initiatives and issues relating to the contents, management, deployment and use of DSNS assets; (11) develops and implements innovative strategies and solutions to reduce the burden of medical countermeasure distribution and dispensing from state and local public health agencies; (12) collaborates with Division of State and Local Readiness (DSLR) to promote and encourage PHEP awardees to pilot and implement private-public partnerships and initiatives to enhance medical countermeasure distribution and dispensing capabilities; (13) provides guidance to prepare healthcare systems partners for medical surge events and supply chain awareness, access, to public sector pathways; and (14) develops and leverages systems to manage, track and report the disposition of deployed SNS assets.

Delete in its entirety the title and functional statements for the Program Preparedness Branch (CGEC).

After item (12) of the functional statement for the Response Branch (CGEE), add the following: (13) supports response capabilities with state and local medical countermeasure receipt, distribution and dispensing training courses and exercise; and (14) coordinate staff training in support of the SNS response capabilities.

After item (8) of the functional statement for the Operations Branch (CGFB), Division of Select Agents and Toxins (CGF), add the following: and (9) performs inspections of foreign select agent laboratories in accordance with National Institutes of Health/National Institute of Allergy and Infectious Diseases agreements.

Delete item (2) of the functional statement for the Program Services Branch (CGFD), and insert the following: (2) processes permit applications to import etiological agents, hosts, and vectors of human disease (not limited to select agents) into the United States from international sources.

Dated: August 16, 2012.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2012–21522 Filed 8–31–12; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 77 FR 43837–43841, dated July 26, 2012) is amended to reorganize the Epidemiology and Analysis Program Office, Office of Surveillance, Epidemiology and Laboratory Services, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows: Delete in its entirety the titles and functional statements for the Division of Epidemiology and Analytic Methods (CPKB) and the Division of Community Preventive Services (CPKC) and insert the following:

Division of Epidemiologic and Analytic Methods for Population Health (CPKE). (1) Provides leadership and overall direction for execution of programs that support the development and dissemination of epidemiological and analytical methods for improving population health, and that identify what works in community preventive services; (2) establishes division goals, objectives and priorities and assures alignment with EAPO and CDC goals, objectives and priorities; (3) provides leadership and guidance for a portfolio of projects and activities that address cross cutting topics including measurement and assessment of population health, burden of disease, health disparities, social determinants of health, and community preventive services; (4) supports the development and dissemination of publications and reports on cross cutting topics and community preventive services; (5) monitors progress in implementation of division projects and activities that support the achievement of CDC and EAPO goals, objectives, and priorities; (6) provides oversight and approval of

scientific products including manuscripts, Web sites, reports, and other documents; (7) assures compliance with all federal rules and regulations regarding research with human subjects; (8) provides division-level management, administration, support services, and coordinates with appropriate offices on program and administrative matters; and (9) develops curriculum, training, and consultation services for CDC and other federal and non-federal partners to foster the development of skills in epidemiologic and analytic methodologies, and systematic reviews.

Office of the Director (CPKE1). (1) Provides leadership and guidance on strategic planning and implementation, program priority setting, and policy development, to advance the mission of the division, EAPO and CDC; (2) develops goals, objectives, and budget; monitors progress and allocation of resources, and reports accomplishments, future directions, and resource requirements; (3) develops, implements and evaluates long term research and programmatic agendas for analytical and epidemiologic activities and the Community Guide; (4) facilitates scientific, policy and program collaboration among divisions and centers, and between CDC and other federal/non-federal partners; (5) promotes advancement of science throughout the division, supports program evaluation, and ensures that research meets the highest standards in the field; (6) provides epidemiologic and analytic expertise and consultation to planning, projects, policies and program activities; (7) advises the Office of the Director of EAPO on matters relating to epidemiologic and analytic methods and the Community Guide, and coordinates division responses to requests for technical assistance or information on activities supported by the division; (8) develops and produces communication tools and public affairs strategies to meet the needs of division programs and mission; and (9) represents the division at official professional and scientific meetings, both within and outside of CDC.

Analytic Tools and Methods Branch (CPKEB). (1) Supports the development and dissemination of cross-cutting analytical methodology, including but not limited to advanced statistical methods, forecasting, geospatial methods, meta-analysis, and economic analysis; (2) supports and conducts applied research that expands the scope of analytic methods capabilities and public health science; (3) provides assistance and consultation on analytical methodology to other units within CDC; (4) identifies complex system models and logistics simulation models and evaluates and assesses their validity and utility for public health practice; (5) maintains an inventory of up-to-date information on models relevant to public health and facilitates access to the models by other units within CDC; (6) develops and applies new and existing quantitative methodologies and simulation and decision support tools to assist CDC programs including emergency preparedness and response activities; (7) develops, maintains, and improves epidemiologic tools for data collection, data management, and data analysis, including Epi Info; (8) provides training, technical assistance, and support to public health partners and entities using Epi Info for outbreak investigations and other public health monitoring activities; (9) collaborates with national and global partners to conceive and develop open-source public health tools for outbreak management, surveillance, and research applications; (10) participates with CDC and other federal and non-federal partners in developing indicators, methods, and statistical procedures for assessing and monitoring the health of communities and measuring the effectiveness of community interventions; and (11) participates with CDC and other federal and non-federal partners in developing indicators, methods, and statistical procedures for measuring and reporting social determinants of health.

Community Guide Branch (CPKEC). (1) Convenes and supports the independent Community Preventive Services Task Force (CPSTF); (2) oversees production of the systematic reviews that serve as the foundation for CPSTF findings and recommendations; (3) coordinates and manages large and diverse teams of internal and external partners in the systematic review process; (4) participates with other CDC programs, HHS, and non-governmental partners in developing and/or refining methods for conducting systematic reviews; (5) assists CDC and other federal and non-federal partners in understanding, using, and communicating methods for conducting systematic reviews; (6) produces and promotes the use of the Guide to Community Preventive Services (aka Community Guide); (7) communicates the Community Guide reviews, recommendations, and research needs in the American Journal of Preventive Medicine and the Morbidity and Mortality Weekly Report (MMWR) publications as well as via other journals, books, documents, the world wide Web, and other media; (8) participates with other CDC programs, HHS and non-governmental partners in disseminating Community Guide reviews, recommendations, and research needs to appropriate audiences throughout the U.S. health care and public health systems, and their multisectoral partners; (9) participates with other CDC programs, HHS, and other federal and non-governmental partners in developing policies, and processes for referencing Community Guide findings in research and programmatic funding announcements, with the aim of increasing use of Community Guide findings and filling evidence gaps; (10) participates with other CDC programs, HHS, and non-governmental partners in developing and/or refining methods for implementing Community Guide recommendations; (11) provides consultations for implementing Community Guide recommended strategies; (12) participates in the development of national and regional public/private partnerships to enhance prevention research and the translation of evidence into policy and action; (13) assists CDC and other federal and non-federal partners in linking reviews of evidence to guidelines development and/or program implementation; and (14) designs and conducts programmatic, process and outcome evaluation strategies for all stages of development and diffusion of the Community Guide.

Dated: August 16, 2012.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2012–21521 Filed 8–31–12; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–906]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send

comments regarding this burden estimate 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: The Fiscal Soundness Reporting Requirements; Use: The Centers for Medicare and Medicaid Services (CMS) is assigned responsibility for overseeing the on-going financial performance for all Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) sponsors and Program of All-Inclusive Care for the Elderly (PACE) organizations. Specifically, CMS needs the requested collection of information to establish that contracting entities within those programs maintain fiscally sound organizations. The revised fiscal soundness reporting form combines MAO, PDP, 1876 Cost Plans, Demonstration Plans and PACE organizations. Entities contracting in these programs currently submit all documentation being requested. Specifically, all contracting organizations must submit annual independently audited financial statements one time per year. The MAOs with a net loss, a negative net worth or both must file three quarterly statements. Currently there are approximately 44 MAOs filing quarterly financial statements. The PDPs must also file three unaudited quarterly financial statements. The PACE organizations are required to file 3 quarterly financial statements for the first three years in the program. Additionally, PACE organizations with a net loss, a negative net worth or both must file statements as well.

The information collection request is being revised to include one additional data element for PACE organizations only, Total Subordinated Liabilities. The addition of the new data element will actually reduce the time to analyze the financial standing of PACE organizations because we will no longer have to contact the PACE organizations to establish whether or not the organization's total liabilities calculation includes subordinated debt. *Form Number:* CMS–906 (OCN: 0938–0469); *Frequency:* Annually, Quarterly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 648; *Total Annual Responses:* 1,281; *Total Annual Hours:* 428. (For policy questions regarding this collection contact Joe Esposito at 410–786–1129. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *November 5, 2012:*

1. *Electronically.* You may submit 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) 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: CMS–R–284 (OCN 0938–0345), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 29, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–21671 Filed 8–31–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Care and Development Fund Plan for States/Territories for FFY 2014–2015 (ACF–118).

OMB No.: 0970–0114.

Description: The Child Care and Development Fund (CCDF) Plan (the Plan) for States and Territories is required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990, as amended (Pub. L. 101–508, Pub. L. 104–193, and 42 U.S.C. 9858). The implementing regulations for the statutorily required Plan are set forth at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF–118, is required biennially, and remains in effect for two years. The Plan provides ACF and the public with a description of, and assurance about, the States' and Territories' child care programs. The ACF–118 is currently approved through April 30, 2014, making it available to States and Territories needing to submit Plan Amendments through the end of the FY 2013 Plan Period. However, on July 1, 2013, States and Territories will be required to submit their FY 2014–2015 Plans for approval by September 30, 2013. Consistent with the statute and regulations, ACF requests revision of the ACF–118 with minor corrections and modifications. The Tribal Plan (ACF–118a) will be addressed under a separate notice.

Respondents: State and Territory CCDF Lead Agencies (56).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–118	56	0.50	162.5	4,550

Estimated Total Annual Burden Hours: 4,550.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and

Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–21695 Filed 8–31–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–0458]

Determination That ALOXI (Palonosetron Hydrochloride) Capsules, 0.5 Milligram (Base), Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ALOXI (palonosetron hydrochloride (HCl)) Capsules, 0.5 milligram (mg) (base), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for palonosetron HCl capsules, 0.5 mg (base), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993–0002, 301–796–3543.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), is the subject of NDA 22–233, held by Helsinn Healthcare, and initially approved on August 22, 2008. ALOXI is indicated for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Helsinn Healthcare has never marketed ALOXI (palonosetron HCl) Capsules, 0.5 mg (base). In previous instances (see, e.g., 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc. submitted a citizen petition dated May 7, 2012 (Docket No. FDA–2012–P–0458), under 21 CFR 10.30, requesting that the Agency determine whether ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–21652 Filed 8–31–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Refugee Resettlement

[C.F.D.A. Number 93.584]

Notice of FY 2012 Refugee Targeted Assistance Formula Awards to States and Wilson/Fish Alternative Project Grantees

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Notice of awards.

SUMMARY: The Office of Refugee Resettlement, Administration for Children and Families (ACF), announces the allocation of Refugee Targeted Assistance formula awards to States and Wilson/Fish Alternative Project grantees. The purpose of the Targeted Assistance program is to provide employment and other resettlement services to refugees, Amerasians, asylees, Cuban and Haitian entrants, victims of trafficking, and Iraqis and Afghans with Special Immigrant Visas. The grant allocations are awarded to States on behalf of counties that have had high levels of arrivals of the eligible populations. The awards supplement available refugee resettlement resources to ensure that refugees and other eligible populations become employed and self-sufficient as soon as possible. Awards are determined by the number of the eligible populations residing in each county during the two-year period from October 1, 2009, to September 30, 2011.

Targeted Assistance allocations are available on the ORR Web page. The table of FY 2012 Allocations to Counties and Targeted Assistance Areas and the Table of FY 2012 Allocations to States may be found at: *http://www.acf.hhs.gov/programs/orr/policy/fy2012_formula_allocations_targeted_assistance.htm.*

DATES: The awards are effective immediately. Funds must be obligated by September 30, 2013, and funds must be expended by September 30, 2014.

FOR FURTHER INFORMATION CONTACT: Henley Portner, Office of the Director, Office of Refugee Resettlement, (202) 401–5363, *Henley.Portner@acf.hhs.gov.*

Statutory Authority: Section 412(c)(2)(A) of the Immigration and Nationality Act (INA) (8 U.S.C. 1522).

Eskinder Negash,

Director, Office of Refugee Resettlement.

[FR Doc. 2012–21584 Filed 8–31–12; 8:45 am]

BILLING CODE 4184–46–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2012–0017]

Privacy Act of 1974; Department of Homeland Security U.S. Immigration and Customs Enforcement—005 Trade Transparency Analysis and Research (TTAR) System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of amendment of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to amend a current Department of Homeland Security system of records titled, ''Department of Homeland Security/Immigration and Customs Enforcement-005 Trade Transparency Analysis and Research (TTAR) System of Records.'' This system of records is being modified to include new categories of individuals, categories of records, and purposes. The system is also being updated to update, consolidate, and clarify the existing routine uses, to reflect a proposed change to the retention period of the system's data, and to update and simplify the description of the record sources. The data in the TTAR system of records is generally maintained in the ICE Data Analysis and Research Trade Transparency System (DARTTS), which is a software application and data repository that conducts analysis of trade and financial data to identify statistically anomalous transactions that may warrant investigation for money laundering or other import-export crimes. Additionally, an update to the Privacy Impact Assessment for DARTTS has been posted on the Department's privacy web site (see *www.dhs.gov/privacy*). The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before October 4, 2012. This updated system will be effective October 4, 2012.

ADDRESSES: You may submit comments, identified by docket number DHS–2012–0017 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

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

FOR FURTHER INFORMATION CONTACT: Lyn Rahilly, Privacy Officer, (202–732–3300), U.S. Immigration and Customs Enforcement, 500 12th Street SW., Mail Stop 5004, Washington, DC 20536, email: *ICEPrivacy@dhs.gov,* or Jonathan R. Cantor, Acting Chief Privacy Officer, (202–343–1717), Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) U.S. Immigration and Customs Enforcement (ICE) proposes to amend a current DHS system of records titled ''DHS/ICE–005 Trade Transparency Analysis and Research (TTAR) System of Records.'' This system of records is being modified to include new categories of individuals, categories of records, and purposes. The system is also being updated to update, consolidate, and clarify the existing routine uses, to reflect a proposed change to the retention period of the data, and to update and simplify the description of the record sources.

With the previously-published DARTTS PIA update, ICE is also notifying the public of three other changes to the TTAR SORN's associated IT system, DARTTS. First, ICE is expanding the use of DARTTS within DHS to permit select U.S. Customs and Border Protection (CBP) customs officers and import specialists to access and use the system to conduct trade transparency analysis. These CBP employees use DARTTS in support of the CBP mission to enforce U.S. trade laws and ensure the collection of all

lawfully owed revenue from trade activities.

Second, ICE is establishing a separate instance of DARTTS for use by foreign government partners that operate trade transparency units and have customs information sharing agreements with the United States. This new ''Foreign DARTTS'' system is maintained in a secure, web-based environment hosted by ICE. Foreign DARTTS permits authorized foreign partners to use the DARTTS tools to analyze a more limited set of DARTTS data in support of their own trade-based investigations. Third, DARTTS will be modified in the near future to permit authorized ICE and CBP personnel to access DARTTS via mobile devices. The DARTTS PIA update is available at *www.dhs.gov/privacy*.

The TTAR system of records and its associated IT system, DARTTS, are owned by ICE Homeland Security Investigations (HSI) and maintained for the purpose of enforcing criminal and civil laws pertaining to trade through trade transparency. Trade transparency is the concept of examining U.S. and foreign trade data to identify anomalies in patterns of trade. Such anomalies can indicate trade-based money laundering or other import-export crimes that HSI is responsible for investigating, such as contraband smuggling, trafficking of counterfeit goods, misclassification of goods, and the over- or under-valuation of goods to hide the proceeds of illegal activities.

As part of the trade transparency investigative process, DHS law enforcement personnel must understand the relationships between importers and exporters and the financing for a set of trade transactions to determine which transactions are suspicious and warrant investigation. The TTAR system of records supports the operation of DARTTS, which is a software application and data repository that conducts analysis of trade and financial data to identify statistically anomalous transactions that may warrant investigation for money laundering or other import-export crimes. DARTTS is specifically designed to make this investigative process more efficient by automating the analysis and identification of anomalies for the investigator. While DARTTS does increase the efficiency of data analysis, it does not allow DHS law enforcement personnel to obtain any data they could not otherwise access in the course of their law enforcement activities.

Consistent with DHS's information sharing mission, information stored in the DHS/ICE–005 TTAR System of Records may be shared with other DHS components. In accordance with the routine uses set forth in this system of records notice, this information may also be disclosed externally to federal, state, local, tribal, territorial, foreign, or international government agencies. This sharing will only take place after DHS determines that the receiving component or agency has a need to know the information to carry out national security, law enforcement, immigration, intelligence, or other functions consistent with the aforementioned routine uses.

II. Changes to the System of Records

In this amendment, DHS is expanding the categories of individuals covered by this system of records to include two new categories: Specially Designated Nationals (SDN) as defined by 31 CFR 500.306, and individuals identified in TECS subject records created by ICE and CBP. The SDN List is an economic and trade sanctions program based on U.S. foreign policy and national security goals against targeted foreign countries and regimes, terrorists, international narcotics traffickers, and other threats to the national security, foreign policy or economy of the United States. Including the SDN List in DARTTS allows HSI users to quickly identify international trade and/or financial transactions that are associated with a specially designated individual or entity, which allows HSI to take appropriate investigative actions in a timely and more efficient manner.

TECS subject records includes violators or suspected violators of laws enforced or administered by ICE and CBP; witnesses associated with ICE and CBP enforcement actions; persons who own or operate businesses, property, vehicles or other property that is in a TECS subject record; and individuals applying for a license issued by DHS or for which DHS conducts a background investigation in support of the licensing agency. Including ICE and CBP subject records in DARTTS allows users to quickly determine when an entity being researched in DARTTS is already part of a pending HSI investigation or was involved in an investigation that is now closed.

In this amendment, DHS is also including three new categories of records that are covered by this system of records: (1) TECS subject records related to an ICE or CBP law enforcement matter; (2) Customs or Homeland Security licensing information, related to applications by individuals or businesses to hold a specific license issued by DHS or for which DHS conducts a background investigation in support of the licensing agency; and (3) Information obtained from the SDN List maintained by the U.S. Department of the Treasury. DHS is also restructuring the categories of records into related groups instead of simply listing the data elements.

In this amendment, DHS is modifying and clarifying the system location to make clear that this system of records describes data maintained in DARTTS. DHS is also modifying the authority citations to include additional authorities that support the ICE and CBP mission for which trade transparency analysis is performed. DHS has also added citations to authorities that protect some of the information in DARTTS, such as the Trade Secrets Act and the Bank Secrecy Act.

In this amendment, DHS is also broadening the purpose section to include the civil enforcement aspects of CBP's mission that the system will now support. DHS is also adding two additional purposes associated with the launch of Foreign DARTTS to describe the reasons the system will be used by foreign government partners. Finally, DHS has added a new purpose that describes the law enforcement, homeland security, and public safety purposes that all ICE law enforcement systems are generally maintained to support.

In this amendment, DHS is proposing to reword several routine uses to improve their clarity and to reduce redundancy. DHS is also deleting one routine use as it was found to be redundant to other existing routine uses. Finally, DHS is proposing to add the following four routine uses: (1) To permit sharing with courts, magistrates, counsel, parties and witnesses when relevant and necessary to litigation to which DHS is a party or in which it has an interest (Routine Use N); (2) to permit sharing with prospective parties and their counsel in advance of the initiation of formal litigation proceedings for settlement negotiation purposes (Routine Use O); (3) to permit sharing with other domestic or foreign agencies or entities for information or assistance in processing a claim for redress in connection with the operations of a DHS component or program (Routine Use P); and (4) to permit sharing with former employees of DHS when DHS requires information or consultation assistance from them regarding a matter within that person's former area of responsibility (Routine Use Q). The new proposed routine uses are intended to permit information sharing in the event that information covered by this system of records becomes relevant to an actual or potential claim in litigation or other proceedings, to a pending request from

an individual for redress from DHS, or in the event that a matter arises in which DHS must share information with a former employee to obtain information or consultation assistance from that individual.

In this amendment, DHS is also notifying the public of its intention to modify the retention period of information maintained in this system of records. Currently, DARTTS data is maintained in production for five years, archived for an additional five years, and then deleted. DHS proposes to maintain the data in production for ten years and then delete the data. The retention period is also proposed to change from five to ten years for the original CD–ROMs, external storage devices, or electronic data transfers containing raw data that is input into DARTTS.

Finally, in this amendment, DHS is simplifying and updating the description of the record sources for this system of records. The U.S. Department of the Treasury is being added because it is the source for the SDN List.

The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. This updated system will be included in the Department of Homeland Security's inventory of record systems.

III. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which the U.S. Government collects, maintains, uses, and disseminates individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the amended DHS/ICE–005 Trade Transparency Analysis and Research System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

System of Records

DHS/ICE–005

SYSTEM NAME:

Trade Transparency Analysis and Research (TTAR) System

SECURITY CLASSIFICATION:

Sensitive But Unclassified

SYSTEM LOCATION:

Records are maintained in the Data Analysis and Research for Trade Transparency System (DARTTS), which is an IT system owned and operated by U.S. Immigration and Customs Enforcement (ICE) and maintained in a Department of Homeland Security (DHS) data center. The DARTTS application is maintained on the ICE Network and also at ICE Attaché Offices abroad.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include:

(1) Individuals who, as importers, exporters, shippers, transporters, brokers, owners, purchasers, consignees, or agents thereof, participate in the import or export of goods to or from the United States or to or from nations with which the United States has entered an agreement to share trade information;

(2) Individuals who participate in financial transactions that are reported to the U.S. Treasury Department under the Bank Secrecy Act or other U.S. financial crimes laws and regulations (*e.g.,* individuals who participate in cash transactions exceeding $10,000; individuals who participate in a reportable suspicious financial transaction);

(3) Specially Designated Nationals as defined by 31 CFR § 500.306; and

(4) Individuals identified in TECS subject records created by ICE and U.S. Customs and Border Protection (CBP), including violators or suspected violators of laws enforced or administered by ICE and CBP; witnesses associated with ICE and CBP enforcement actions; persons who own or operate businesses, property, vehicles or other property that is in a TECS subject record; and individuals applying for a license issued by DHS or for which DHS conducts a background investigation in support of the licensing agency.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in this system include:

(1) Biographic and other identifying information about individuals, including names; dates of birth; Social Security/tax identification numbers; passport information (number and country of issuance); citizenship; location and contact information (such as home, business, and email addresses and telephone numbers); and other identification numbers (*e.g.,* Alien Registration Number, driver's license number, etc.).

(2) Customs, trade, and financial data associated with an individual, including trade identifier numbers (*e.g.,* Importer ID, Exporter ID, Manufacturer ID); account numbers (*e.g.,* bank account, electronic fund transfer number); description and/or value of trade goods; country of origin/export; description and/or value of financial transactions; vehicle, vessel and/or aircraft information; and other business information.

(3) TECS subject records related to an ICE or CBP law enforcement matter.

(4) Customs or Homeland Security licensing information, related to applications by individuals or businesses to hold or retain a Customs broker's license, or operate a Customs-bonded warehouse, or be a bonded carrier or bonded cartman.

(5) Information obtained from the Specially Designated Nationals List maintained by the U.S. Department of the Treasury, including individual's name, aliases, address, date of birth, place of birth, citizenship, nationality, passport information, and program under which designation was made.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Tariff Act of 1930, as amended, 19 U.S.C. Chapter 4; 18 U.S.C. 545 (Smuggling goods into the United States); 18 U.S.C. 1956 (Laundering of Monetary Instruments); 19 U.S.C. 1484 (Entry of Merchandise); 18 U.S.C. 544 (Smuggling goods out of the United States); 18 U.S.C. 371 (Conspiracy); and 50 U.S.C. 1701–1706 (International Emergency Economic Powers Act); 19 U.S.C. 2071 note (Cargo Information). Certain information in this system of records is also regulated under 18 U.S.C. 1905 (Trade Secrets Act) and 31 U.S.C. 5311–5330 (Bank Secrecy Act).

PURPOSE(S):

The purpose of this system is to support:

(1) The enforcement of criminal and civil laws pertaining to trade, financial crimes, smuggling, and fraud, and the collection of all lawfully owned revenue from trade activities, specifically through the analysis of raw financial and trade data in order to identify potential violations of U.S. criminal and civil laws pertaining to trade, financial activities, smuggling, and fraud;

(2) Existing criminal law enforcement investigations into related criminal activities and civil enforcement actions to recover revenue and assess fines and penalties;

(3) The sharing of raw trade data and analytical capabilities with foreign government partners to further those governments' abilities to identify, disrupt, and prosecute criminal and civil violations of laws pertaining to trade, financial activities, smuggling, and fraud;

(4) The cooperation and collaboration between the United States and foreign government partners on investigations into transnational activities that violate criminal and civil laws pertaining to trade, financial activities, smuggling, and fraud; and

(5) The identification of potential criminal activity, immigration violations, and threats to homeland security: to uphold and enforce the law; and to ensure public safety.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. § 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. § 552a(b)(3) as follows:

A. To the Department of Justice (DOJ) (including United States Attorneys' Offices) or other federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

(1) DHS or any component thereof;

(2) Any employee of DHS in his/her official capacity;

(3) Any employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or

(4) the United States or any agency thereof, is a party to the litigation or has an interest in such litigation.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or other federal government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. §§ 2904 and 2906.

D. To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To agencies, entities, and persons when:

(1) DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

(2) DHS has determined that as a result of the suspected or confirmed compromise there is a risk of: Identity theft or fraud, harm to the economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

(3) The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, interns, trainees, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To federal, state, local, tribal, territorial, or foreign government agencies, as well as to other individuals and organizations during the course of an investigation by DHS or the processing of a matter under DHS's jurisdiction, or during a proceeding within the purview of the immigration and nationality laws, when DHS deems that such disclosure is necessary to carry out its functions and statutory mandates or to elicit information required by DHS to carry out its functions and statutory mandates.

H. To federal, state, local, tribal, territorial, or foreign government agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, license, or treaty where DHS determines that the information would assist in the enforcement of civil, criminal, or regulatory laws.

I. To federal, state, local, tribal, or territorial government agencies, or other entities or individuals, or through established liaison channels to selected foreign governments, in order to provide intelligence, counterintelligence, or other information for the purposes of national security, intelligence, counterintelligence, or antiterrorism activities authorized by U.S. law, Executive Order, or other applicable national security directive.

J. To federal, state, local, tribal, territorial, or foreign government agencies or organizations, or international organizations, lawfully engaged in collecting law enforcement intelligence, whether civil or criminal, to enable these entities to carry out their law enforcement responsibilities, including the collection of law enforcement intelligence.

K. To international, foreign, intergovernmental, and multinational government agencies, authorities, and organizations in accordance with law and formal or informal international arrangements.

L. To federal and foreign government intelligence or counterterrorism agencies or components where DHS becomes aware of an indication of a threat or potential threat to national or international security, or where such disclosure is to support the conduct of national intelligence and security investigations or assist in antiterrorism efforts.

M. To federal, state, local, tribal, territorial, international, or foreign government agencies or multinational governmental organizations where DHS desires to exchange relevant data for the purpose of developing, testing, or implementing new software or technology whose purpose is related to the purpose of this system of records.

N. To courts, magistrates, administrative tribunals, opposing counsel, parties, and witnesses, in the course of immigration, civil, or criminal proceedings (including discovery, presentation of evidence, and settlement negotiations) before a court or adjudicative body when any of the following is a party to or have an interest in the litigation:

(1) DHS or any component thereof;

(2) Any employee of DHS in his/her official capacity;

(3) Any employee of DHS in his/her individual capacity where the government has agreed to represent the employee; or

(4) The United States, where DHS determines that litigation is likely to affect DHS or any of its components;

and when DHS determines that use of such records is relevant and necessary to the litigation and is compatible with

the purposes for which the records were collected.

O. To prospective claimants and their attorneys for the purpose of negotiating the settlement of an actual or prospective claim against DHS or its current or former employees, in advance of the initiation of formal litigation or proceedings.

P. To federal, state, local, tribal, territorial, international, or foreign government agencies or entities for the purpose of consulting with those agencies or entities:

(1) To assist in making a determination regarding redress for an individual in connection with the operations of a DHS component or program;

(2) To verify the identity of an individual seeking redress in connection with the operations of a DHS component or program; or

to verify the accuracy of information submitted by an individual who has requested redress on behalf of another individual.

Q. To a former employee of DHS for the purpose of responding to an official inquiry by federal, state, local, tribal, or territorial government agencies or professional licensing authorities; or facilitating communications with a former employee that may be necessary for personnel-related matters or other official purposes where DHS requires information or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

R. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

Records may be retrieved by any of the personal identifiers stored in the system including name, business address, home address, importer ID, exporter ID, broker ID, manufacturer ID, Social Security number, trade and tax identifying numbers, passport number, or account number. Records may also be retrieved by non-personal information such as transaction date, entity/institution name, description of goods, value of transactions, and other information.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

ICE is in the process of modifying the records schedule for the information maintained in this system of records. Currently the data is maintained in the DARTTS system for five years, archived for an additional five years and then deleted. ICE is now proposing to maintain the data in DARTTS for ten years and then delete the data. The original CD–ROMs, external storage devices or electronic data transfers containing raw data that is uploaded into DARTTS would also be retained for ten years to ensure data integrity and for system maintenance purposes.

SYSTEM MANAGER AND ADDRESS:

Unit Chief, Trade Transparency Unit, ICE Homeland Security Investigations, 500 12th Street SW., Mail Stop 5103, Washington, DC 20536.

NOTIFICATION PROCEDURE:

The Secretary of Homeland Security has exempted this system from notification, access, and amendment because of the law enforcement nature of the information. These exemptions also apply to the extent that information in this system of records is recompiled or is created from information contained in other systems of records. To the extent that a record is exempted in a source system, the exemption will continue to apply. However, ICE will review requests on a case by case to determine if release of the information is appropriate. After conferring with the appropriate component or agency, as applicable, DHS may waive applicable exemptions in appropriate circumstances and where it would not appear to interfere with or adversely affect the law enforcement purposes of the systems from which the information is recompiled or in which it is contained. Additionally, ICE and DHS are not exempting any records that were ingested or indexed by TTAR where the source system of records already provides access and/or amendment under the Privacy Act. Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the ICE Freedom of Information Act Officer whose contact information can be found at *http://www.dhs.gov/foia* under ''contacts.'' If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. § 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov* or 1–866–431–0486. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created;
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records; and
- If your request is seeking records pertaining to another living individual,

you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records are obtained from U.S. Customs and Border Protection (CBP), U.S. Department of Commerce, U.S. Department of the Treasury, and foreign countries pursuant to international agreements or arrangements.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

The Secretary of Homeland Security has exempted portions of this system. Pursuant to 5 U.S.C. 552a(j)(2) of the Privacy Act, portions of this system are exempt from 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(5) and (e)(8); (f); and (g). Pursuant to 5 U.S.C. 552a(k)(2), this system is exempt from the following provisions of the Privacy Act, subject to the limitations set forth in those subsections: 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), and (f).

Dated: August 16. 2012.

Jonathan R. Cantor,

Acting Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2012–21691 Filed 8–31–12; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2012–0472]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding Information Collection Requests (ICRs), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a revision to the following collections of information: 1625–0016, Welding and Hot Work Permits; Posting of Warning Signs; 1625–0023, Barge Fleeting Facility Records; 1625–0038, Plan Approval and Records for Tank, Passenger, Cargo, and Miscellaneous Vessels, Mobile Offshore Drilling Units, Nautical School Vessels and Oceanographic Research Vessels—46 CFR subchapters D, H, I, I–A, R and U; and 1625–0039, Declaration of Inspection Before Transfer of Liquid Cargo in Bulk. Our ICRs describe the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before October 4, 2012.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2012–0472] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at *http://www.regulations.gov.* (b) To OIRA by email via: *OIRA-submission@omb.eop.gov*.

(2) *Mail:* (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

Copies of the ICRs are available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–611), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2100 2ND ST. SW., STOP 7101, WASHINGTON DC 20593–7101.

FOR FURTHER INFORMATION: Contact Ms. Kenlinishia Tyler, Office of Information Management, telephone 202–475–3652 or fax 202–475–3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collections. There is one ICR for each Collection.

The Coast Guard invites comments on whether these ICRs should be granted based on the Collections being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collections; (2) the accuracy of the estimated burden of the Collections; (3) ways to enhance the quality, utility, and clarity of information subject to the Collections; and (4) ways to minimize the burden of the Collections on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICRs referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG 2012–0472], and must be received by October 4, 2012. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG–2012–0472], indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (via *http://www.regulations.gov*), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov*, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**, but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov*, and type ''USCG–2012–0472'' in the ''Keyword'' box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to *http://www.regulations.gov*, click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0472'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Numbers: 1625–0016, 1625–0023, 1625–0038 and 1625–0039.

Privacy Act

Anyone can search the electronic form of comments received in 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 a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (77 FR 32657, June 1, 2012) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments.

Information Collection Requests

1. *Title:* Welding and Hot Work Permits; Posting of Warning Signs.
OMB Control Number: 1625–0016.
Type of Request: Revision of a currently approved collection.
Respondents: Owners and operators of certain waterfront facilities and vessels.
Abstract: This information collection helps to ensure that waterfront facilities and vessels are in compliance with safety standards. A permit must be issued prior to welding or hot work at certain waterfront facilities; and, the posting of warning signs is required on certain facilities.
Forms: CG–4201.
Burden Estimate: The estimated burden has increased from 425 hours to 546 hours a year.

2. *Title:* Barge Fleeting Facility Records.
OMB Control Number: 1625–0023.
Type of Request: Revision of a currently approved collection.
Respondents: Operators of barge fleeting facilities.
Abstract: This collection of information requires the person-in-charge of a barge fleeting facility to keep records of twice daily inspections of barge moorings and movements of barges and hazardous cargo in and out of the facility.
Forms: None.
Burden Estimate: The estimated burden has decreased from 60,390 hours to 50,453 hours a year.

3. *Title:* Plan Approval and Records for Tank, Passenger, Cargo, and Miscellaneous Vessels, Mobile Offshore Drilling Units, Nautical School Vessels and Oceanographic Research Vessels—46 CFR subchapters D, H, I, I–A, R and U.
OMB Control Number: 1625–0038.
Type of Request: Revision of a currently approved collection.
Respondents: Shipyards, designers, and manufacturers of certain vessels.
Abstract: This collection requires the shipyard, designer or manufacturer for the construction of a vessel to submit plans, technical information and operating manuals to the Coast Guard.
Forms: None.
Burden Estimate: The estimated burden has increased from 2,970 hours to 3,589 hours a year.

4. *Title:* Declaration of Inspection Before Transfer of Liquid Cargo in Bulk.
OMB Control Number: 1625–0039.
Type of Request: Revision of a currently approved collection.
Respondents: Persons-in-charge of transfers.
Abstract: A Declaration of Inspection (DOI) documents the transfer of oil and hazardous materials, to help prevent spills and damage to a facility or vessel. Persons-in-charge of the transfer operations must review and certify compliance with procedures specified by the terms of the DOI.
Forms: None.
Burden Estimate: The estimated burden has decreased from 67,825 hours to 62,514 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: August 27, 2012.

R.E. Day,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 2012–21736 Filed 8–31–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2012–0733]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0071, Boat Owner's Report, Possible Safety Defect. Our ICR

describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before November 5, 2012.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2012–0733] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT). To avoid duplicate submissions, please use only one of the following means:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251. To ensure your comments are received in a timely manner, mark the fax, to attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–611), ATTN PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2100 2ND ST. SW., STOP 7101, WASHINGTON, DC 20593–7101.

FOR FURTHER INFORMATION: Contact Ms. Kenlinishia Tyler, Office of Information Management, telephone 202–475–3652, or fax 202–475–3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2012–0733], and must be received by November 5, 2012. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the ''Privacy Act'' paragraph below.

Submitting comments: If you submit a comment, please include the docket number [USCG–2012–0733], indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (*via http://www.regulations.gov*), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit your comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**; but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov*, and type ''USCG–2012–0733'' in the ''Keyword'' box. If you submit your comments by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0733'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can search the electronic form of comments received in 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 a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Information Collection Request

Title: Boat Owner's Report, Possible Safety Defect.

OMB Control Number: 1625–0071.

SUMMARY: The collection of information provides a means for consumers who believe their recreational boats or designated associated equipment contain substantial risk defects or fail to comply with Federal safety standards to report the deficiencies to the Coast Guard for investigation and possible remedy.

Need: Title 46 U.S.C. 4310 gives the Coast Guard the authority to require manufacturers of recreational boats and certain items of designated associated

equipment to notify owners and remedy: (1) Defects that create a substantial risk of personal injury to the public; and (2) failures to comply with applicable Federal safety standards.

Forms: CG–5578.

Respondents: Owners and users of recreational boats and items of designated associated equipment.

Frequency: One time.

Burden Estimate: The estimated annual burden has increased from 17.8 hours to 20.5 hours a year.

Dated: August 24, 2012.

R.E. Day,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 2012–21719 Filed 8–31–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2012–0279]

Notification of the Imposition of Conditions of Entry for Certain Vessels Arriving to the United States From the Republic of Yemen

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The United States Coast Guard announces that it will impose conditions of entry on vessels arriving from the country of the Republic of Yemen, with the exception of vessels arriving from the Ash Shihr Terminal, the Balhalf LNG Terminal, and the Port of Hodeidah.

DATES: The policy announced in this notice will become effective September 18, 2012.

ADDRESSES: This notice is part of docket USCG–2012–0279 and is available online by going to *http://www.regulations.gov*, inserting ''USCG–2012–0279'' in the ''Keyword'' box, and then clicking ''Search.'' This material is also available for inspection and copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329. This policy is also available at *www.homeport.uscg.mil* under the Maritime Security tab; International Port Security Program (ISPS Code); Port Security Advisory link.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call Mr. Michael Brown, International Port Security Evaluation Division, United States Coast Guard, telephone 202–372–1081. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826 or (toll free) 1–800–647–5527.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Title 46, Section 70110, United States Code, enacted as part of section 102(a) of the Maritime Transportation Security Act of 2002 (Pub. L. 107–295, Nov. 25, 2002) authorizes the Secretary of Homeland Security to impose conditions of entry on vessels requesting entry into the United States arriving from ports that are not maintaining effective anti-terrorism measures. It also requires public notice of the ineffective anti-terrorism measures. The Secretary has delegated to the United States Coast Guard authority to carry out the provisions of this section. See Department of Homeland Security Delegation No. 0170.1, sec. 97. Previous notices have imposed or removed conditions of entry on vessels arriving from certain countries, and those conditions of entry and the countries they pertain to remain in effect except as modified below. All such notices are available for review online by going to *http://homeport.uscg.mil*, clicking on the ''Maritime Security'' and then ''International Port Security Program'' tabs, and then following the link.

The Coast Guard has determined that ports in the Republic of Yemen are not maintaining effective anti-terrorism measures. Inclusive to this determination is an assessment that the Republic of Yemen presents significant risk of introducing instruments of terror into international maritime commerce. Inclusive to this determination is also an assessment of significant deficiencies in the Republic of Yemen's legal regime, designated authority oversight, access control, and cargo control. The Coast Guard notified the Department of State of these determinations pursuant to 46 U.S.C. 70110(c).

The United States notified the Republic of Yemen of this determination on December 18, 2011, and identified steps necessary to improve the anti-terrorism measures in place at their respective ports (46 U.S.C. 70109(a)). The Republic of Yemen has not offered a response to our communications on this determination. To date, the United States cannot confirm that the identified deficiencies have been corrected.

Accordingly, on September 18, 2012, the Coast Guard will impose certain conditions of entry on vessels that visited ports in the Republic of Yemen, with the exception of vessels arriving from the Ash Shihr Terminal, the Balhalf LNG Terminal, and the Port of Hodeidah, during their last five port calls. Vessels must meet the following conditions of entry:

- Implement measures per the ship's security plan equivalent to Security Level 2 while in a port in the Republic of Yemen. As defined in the ISPS Code and incorporated herein, ''Security Level 2'' refers to the ''level for which appropriate additional protective security measures shall be maintained for a period of time as a result of heightened risk of a security incident.''
- Ensure that each access point to the ship is guarded and that the guards have total visibility of the exterior (both landside and waterside) of the vessel while the vessel is in ports in the Republic of Yemen.
- Guards may be provided by the ship's crew, however additional crewmembers should be placed on the ship if necessary to ensure that limits on maximum hours of work are not exceeded and/or minimum hours of rest are met. Alternatively, security may be provided by outside security forces approved by the ship's master and Company Security Officer. As defined in the ISPS Code and incorporated herein, ''Company Security Officer'' refers to the ''person designated by the Company for ensuring that a ship security assessment is carried out; that a ship security plan is developed, submitted for approval, and thereafter implemented and maintained and for liaison with port facility security officers and the ship security officer.''
- Attempt to execute a Declaration of Security while in port in the Republic of Yemen.
- Log all security actions in the ship's log.
- Report actions taken to the cognizant Coast Guard Captain of the Port prior to arrival into U.S. waters.
- Based on the findings of the Coast Guard boarding or examination, vessels may be required to ensure that each access point to the ship is guarded by armed, private security guards and that they have total visibility of the exterior (both landside and waterside) of the vessel while in U.S. ports. The number and position of the guards must be acceptable to the cognizant Coast Guard Captain of the Port prior to the vessel's arrival.

With this notice, the current list of countries not maintaining effective anti-terrorism measures is as follows: Cambodia, Cameroon, Comoros, Cote d'Ivoire, Cuba, Equatorial Guinea, Guinea-Bissau, Indonesia, Iran, Liberia, Madagascar, Sao Tome and Principe, Syria, Timor-Leste, Venezuela, and Yemen. This current list is also available in the policy notice available on the Homeport system as described in the **ADDRESSES** section above.

This notice is issued under authority of 46 U.S.C. 70110(a)(3).

Dated: August 20, 2012.

Peter V. Neffenger,

USCG, Deputy Commandant for Operations.

[FR Doc. 2012–21715 Filed 8–31–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4066–DR; Docket ID FEMA–2012–0002]

Vermont; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Vermont (FEMA–4066–DR), dated June 22, 2012, and related determinations.

DATES: *Effective Date:* August 22, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Mark H. Landry, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of James N. Russo as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–21700 Filed 8–31–12; 8:45 am]

BILLING CODE 9110–23–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2011–0008]

Aviation Security Advisory Committee (ASAC) Meeting

AGENCY: Transportation Security Administration, DHS.

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Transportation Security Administration (TSA) will hold a meeting of the Aviation Security Advisory Committee (ASAC) on September 18, to discuss the recommendations of its sub-committees. This meeting will be open to the public.

DATES: The Committee will meet on Tuesday, September 18, 2012, from 1:30 p.m. to 4 p.m. This meeting may end early if all business is completed.

Submit comments by September 11, 2012, on the reports to be considered by the committee.

ADDRESSES: The meeting will be held at the Transportation Security Administration Systems Integration Facility, located at 3701 West Post Office Road, Ronald Reagan Washington National Airport (DCA), Arlington, VA 22202.

We invite your comments on the Report on the Actions of the Air Cargo Security Sub-committee and the Report on the Actions of the International Aviation Sub-committee, placed in the public docket. You may submit comments on these reports, identified by the TSA docket number to this action (Docket No. TSA–2011–0008), to the Federal Docket Management System (FDMS), a government-wide, electronic docket management system, using any one of the following methods:

Electronically: You may submit comments through the Federal eRulemaking portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Mail, In Person, or Fax: Address, hand-deliver, or fax your written comments to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; fax (202) 493–2251. The Department of Transportation (DOT), which maintains and processes TSA's official regulatory dockets, will scan the submission and post it to FDMS.

See **SUPPLEMENTARY INFORMATION** for format and other information about comment submissions.

FOR FURTHER INFORMATION CONTACT: Dean Walter, ASAC Designated Federal Officer, Transportation Security Administration (TSA–28), 601 12th Street South, Arlington, VA 20598–4028, *Dean.Walter@dhs.gov,* 571–227–2645.

SUPPLEMENTARY INFORMATION:

Comments Invited

To facilitate public participation, TSA invites interested persons to participate in this action by submitting written comments, data, or views on the issues to be considered by the committee as listed in the ''Meeting Summary'' section below. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from this action. See **ADDRESSES** above for information on where to submit comments.

With each comment, please identify the docket number at the beginning of your comments. TSA encourages commenters to provide their names and addresses. The most helpful comments reference a specific portion of the document, explain the reason for any recommended change, and include supporting data. You may submit comments and material electronically, in person, by mail, or fax as provided under **ADDRESSES**, but please submit your comments and material by only one means. If you submit comments by mail or delivery, submit them in an unbound format, no larger than 8.5 by 11 inches, suitable for copying and electronic filing.

If you would like TSA to acknowledge receipt of comments submitted by mail, include with your comments a self-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

TSA will file all comments to our docket address, as well as items sent to the address or email under **FOR FURTHER INFORMATION CONTACT**, in the public

docket, except for comments containing confidential information and sensitive security information (SSI).[1] Should you wish your personally identifiable information redacted prior to filing in the docket, please so state. TSA will consider all comments that are in the docket on or before the closing date for comments and will consider comments filed late to the extent practicable. The docket is available for public inspection before and after the comment closing date.

Handling of Confidential or Proprietary Information and Sensitive Security Information (SSI) Submitted in Public Comments

Do not submit comments that include trade secrets, confidential commercial or financial information, or SSI to the public regulatory docket. Please submit such comments separately from other comments on the action. Comments containing this type of information should be appropriately marked as containing such information and submitted by mail to the address listed in **FOR FURTHER INFORMATION CONTACT** section.

TSA will not place comments containing SSI in the public docket and will handle them in accordance with applicable safeguards and restrictions on access. TSA will hold documents containing SSI, confidential business information, or trade secrets in a separate file to which the public does not have access, and place a note in the public docket explaining that commenters have submitted such documents. TSA may include a redacted version of the comment in the public docket. If an individual requests to examine or copy information that is not in the public docket, TSA will treat it as any other request under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the Department of Homeland Security's (DHS') FOIA regulation found in 6 CFR part 5.

Reviewing Comments in the Docket

Please be aware that anyone is able to search the electronic form of all comments in any of our dockets by the name of the individual who submitted the comment (or signed the comment, if an association, business, labor union, etc., submitted the comment). You may review the applicable Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477), or you may visit *http://DocketInfo.dot.gov.*

You may review TSA's electronic public docket on the Internet at *http://www.regulations.gov.* In addition, DOT's Docket Management Facility provides a physical facility, staff, equipment, and assistance to the public. To obtain assistance or to review comments in TSA's public docket, you may visit this facility between 9:00 a.m. to 5:00 p.m., Monday through Friday, excluding legal holidays, or call (202) 366–9826. This docket operations facility is located in the West Building Ground Floor, Room W12–140 at 1200 New Jersey Avenue SE, Washington, DC 20590.

Availability of Committee Documents

You can get an electronic copy using the Internet by—

(1) Searching the electronic Federal Docket Management System (FDMS) web page at *http://www.regulations.gov;* or

(2) Accessing the Government Printing Office's web page at *http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR* to view the daily published **Federal Register** edition; or accessing the ''Search the **Federal Register** by Citation'' in the ''Related Resources'' column on the left, if you need to do a Simple or Advanced search for information, such as a type of document that crosses multiple agencies or dates.

In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section. Make sure to identify the docket number of this action.

Meeting Summary

Notice of this meeting is given under section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). ASAC operates under the authority of 46 U.S.C. 70112 and provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Administrator of TSA on matters affecting civil aviation security.

This meeting is open to the public, but attendance is limited to 75 people. The meeting will be held at the TSA Systems Integration Facility, which is a secure facility, at 3701 West Post Office Road, DCA Airport, Arlington, VA 22202. Members of the public must register in advance with their full name and company/association to attend. In addition, members of the public must make advance arrangements to present oral statements at the meeting. The public comment period will be held during the meeting from approximately 3:30 p.m. to 4:00 p.m., depending on the meeting progress. Speakers are requested to limit their comments to three minutes. Written statements may also be presented to the Committee. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than September 11, 2012, to register to attend the meeting and/or to speak at the meeting. Written statements shall also be submitted no later than September 11, 2012. Anyone in need of assistance or a reasonable accommodation for the meeting should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Meeting Agenda

The agenda for the meeting is as follows:

- Report on the actions of the Air Cargo Security Sub-committee.
- Report on the actions of the International Aviation Sub-committee.
- Status reports on the actions of the—
  - Risk-Based Security Sub-committee;
  - General Aviation Sub-committee; and
  - Passenger Advocacy Sub-committee.
- Other aviation security topics.
- Public question/comment period.

Issued in Arlington, Virginia, on August 27, 2012.

John P. Sammon,

Assistant Administrator, Security Policy and Industry Engagement.

[FR Doc. 2012–21631 Filed 8–31–12; 8:45 am]

BILLING CODE 9110–05–P

[1] ''Sensitive Security Information'' or ''SSI'' is information obtained or developed in the conduct of security activities, the disclosure of which would constitute an unwarranted invasion of privacy, reveal trade secrets or privileged or confidential information, or be detrimental to the security of transportation. The protection of SSI is governed by 49 CFR part 1520.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR 5604–N–09]

Notice of Proposed Information Collection for Public Comment: OneCPD Technical Assistance and Capacity Building Needs Assessment

AGENCY: Office of the Assistant Secretary for Community Planning and Development, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice of proposed information collection.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* November 5, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB Control number and should be sent to: Colette Pollard, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4160, Washington, DC 20410–5000; telephone (202) 402–3400, (this is not a toll-free number) or email Ms. Pollard at *Colette_Pollard@hud.gov* for a copy of proposed forms, or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Julie Hovden, Director, Technical Assistance Division, Office of Technical Assistance and Management, CPD, Department of Housing and Urban Development, 451 7th Street SW., Room 7218, Washington, DC 20410; telephone (202) 708–3176 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: OneCPD Technical Assistance and Capacity Building Needs Assessment.

Description of the need for the information proposed: The OneCPD Needs Assessment will enhance a grantee's awareness of their functional capacity to effectively and efficiently administer and manage programs funded by CPD and enable HUD and the TA provider to better understand the scope of assistance needed by each grantee and to target appropriate TA resources to grantees. It will also enable HUD to identify trends in TA needs across grantees and assist in prioritizing the development of tools, products and group learning activities to benefit CPD grantees and subrecipients.

Members of the affected public: Grantees and subrecipient organizations receiving funding to operate and manage programs administered by the Office of Community Planning and Development (CPD).

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: 180 respondents × 176.4 average hours per response = 31,752 hours annually.

Status of proposed information collection: New Collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C Chapter 35, as amended.

Dated: August 27, 2012.

Clifford Taffet,

General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2012–21711 Filed 8–31–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5374–N–43]

Buy American Exceptions Under the American Recovery and Reinvestment Act of 2009

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: In accordance with the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–05, approved February 17, 2009) (Recovery Act), and implementing guidance of the Office of Management and Budget (OMB), this notice advises that certain exceptions to the Buy American requirement of the Recovery Act have been determined applicable for work using Capital Fund Recovery Formula and Competition (CFRFC) grant funds. Specifically, an exception was granted to the Shelby County Housing Authority for the purchase and installation of ductless mini-split heating and cooling systems for the Kefauver Terrace project project.

FOR FURTHER INFORMATION CONTACT: Donald J. LaVoy, Deputy Assistant Secretary for Office of Field Operations, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4112, Washington, DC, 20410–4000, telephone number 202–402–8500 (this is not a toll-free number); or Dominique G. Blom, Deputy Assistant Secretary for Public Housing Investments, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4130, Washington, DC 20410–4000, telephone number 202–402–8500 (this is not a toll-free number). Persons with hearing- or speech-impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: Section 1605(a) of the Recovery Act provides that none of the funds appropriated or made available by the Recovery Act may be used for a project for the construction, alteration, maintenance, or repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project are produced in the United States. Section 1605(b) provides that the Buy American requirement shall not apply in any case or category in which the head of a Federal department or agency finds that: (1) Applying the Buy American requirement would be inconsistent with the public interest; (2) iron, steel, and the relevant manufactured goods are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality, or (3) inclusion of iron, steel, and manufactured goods will increase the cost of the overall project by more than 25 percent. Section 1605(c) provides that if the head of a Federal department or agency makes a determination pursuant to section 1605(b), the head of the department or agency shall publish a detailed written justification in the **Federal Register**.

In accordance with section 1605(c) of the Recovery Act and OMB's implementing guidance published on April 23, 2009 (74 FR 18449), this notice advises the public that, on August 8, 2012, upon request of the Shelby County Housing Authority, HUD granted an exception to applicability of the Buy American requirements with respect to work, using CFRFC grant funds, in connection with the Kefauver Terrace project. The exception was granted by HUD on the basis that the relevant manufactured goods (ductless mini-split heating and cooling systems) are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality.

Dated: August 24, 2012.

Deborah Hernandez,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2012–21706 Filed 8–31–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO320000 L19900000 PO0000]

Renewal of Approved Information Collection; OMB Control No. 1004–0025

AGENCY: Bureau of Land Management, Interior.

ACTION: 60-Day notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act, the Bureau of Land Management (BLM) invites public comments on, and plans to request approval to continue, the collection of information under the General Mining Law. The Office of Management and Budget (OMB) has assigned control number 1004–0025 to this information collection.

DATES: Submit comments on the proposed information collection by November 5, 2012.

ADDRESSES: Comments may be submitted by mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: to Jean Sonneman at 202–245–0050.

Electronic mail: Jean_Sonneman@blm.gov.

Please indicate ''Attn: 1004–0025'' regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Sonia Santillan, at 202–912–7123. Persons who use a telecommunication device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, to leave a message for Ms. Santillan.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act, 44 U.S.C. 3501–3521, require that interested members of the public and affected agencies be given an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8 (d) and 1320.12(a)). This notice identifies an information collection that the BLM plans to submit to OMB for approval. The Paperwork Reduction Act 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.

The BLM will request a 3-year term of approval for this information collection activity. Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany our submission of the information collection requests to OMB.

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 following information is provided for the information collection:

Title: 43 CFR Parts 3860 and 3870.

OMB Control Number: 1004–0025.

Summary: On its face, the General Mining Law (30 U.S.C. 29, 30, and 39) authorizes a holder of an unpatented claim for hardrock minerals to apply for fee title (patent) to the federal land (as well as minerals) embraced in the claim. Since 1994, a rider on the annual appropriation bill for the Department of the Interior has prevented the BLM from processing mineral patent applications unless the applications were grandfathered under the initial legislation. While grandfathered applications are rare at present, the approval to collect the information continues to be necessary because of the possibility that the moratorium will be lifted.

Frequency of Collection: Once.

Description of Respondents: Owners of unpatented mining claims and mill sites upon the public lands, and of reserved mineral lands of the United States, National Forests, and National Parks.

Estimated Annual Burdens: 10 responses and 496 hours.

Jean Sonneman,

Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2012–21670 Filed 8–31–12; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L19100000–BJ0000–LRCME1R04774]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on October 4, 2012.

DATES: Protests of the survey must be filed before October 4, 2012 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Marvin Montoya, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5124 or (406) 896–5009, *Marvin_Montoya@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Regional Director, Rocky Mountain Region, Bureau of Indian Affairs, and was necessary to determine the boundaries of tribal trust lands.

The lands we surveyed are:

Principal Meridian, Montana

T. 27 N., R 52 E.

The plat, in one sheet, representing the dependent resurvey of a portion of the subdivisional lines, the adjusted original meanders of the former left bank of the Missouri River, downstream, through section

29 and a portion of section 30, a portion of the subdivision of sections 29 and 30, and a certain division of accretion line and the subdivision of sections 29 and 30, and the survey of the meanders of the present left bank of the Missouri River, downstream, through sections 29 and 30 and certain division of accretion lines, in Township 27 North, Range 52 East, Principal Meridian, Montana, was accepted August 13, 2012.

We will place a copy of the plat, in one sheet, and related field notes we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in one sheet, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in one sheet, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

Steve L. Toth,

Acting Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 2012–21644 Filed 8–31–12; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L19100000–BJ0000–LRCME1G05121]

Notice of Filing of Plats of Survey; South Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on October 4, 2012.

DATES: Protests of the survey must be filed before October 4, 2012 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Marvin Montoya, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5124 or (406) 896–5009, *Marvin_Montoya@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Regional Director, Great Plains Region, Bureau of Indian Affairs, Aberdeen, South Dakota, and was necessary to determine individual and tribal trust lands.

The lands we surveyed are:

Fifth Principal Meridian, South Dakota

T. 94 N., R. 61 W.

The plat, in three sheets, representing the dependent resurvey of portions of the west boundary, the subdivisional lines, and the subdivision of section 18, and the subdivision of section 18, and the survey of a portion of the meanders of the present left bank of Chouteau Creek, through section 18, Township 94 North, Range 61 West, Fifth Principal Meridian, South Dakota, was accepted August 13, 2012.

We will place a copy of the plat, in three sheets, and related field notes we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in three sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in three sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. chapter 3.

Steve L. Toth,

Acting Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 2012–21645 Filed 8–31–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–018–1430–01; CACA 52573]

Notice of Proposed Withdrawal and Opportunity for Public Meeting; California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Assistant Secretary of the Interior for Policy, Management and Budget proposes to withdraw, on behalf of the Bureau of Land Management (BLM), approximately 6,737.42 acres of public lands from location and entry under the United States mining laws for a period of 20 years to protect natural resources and recreation values associated with the congressionally designated Auburn Reservoir Site and Recreation Area. This notice temporarily segregates the land for up to 2 years from mining while various studies and analyses are made to support a final decision on the withdrawal application.

DATES: Comments should be received on or before December 3, 2012.

ADDRESSES: Comments should be sent to the BLM, Mother Lode Field Office, 5152 Hillsdale Circle, El Dorado Hills, California 95762.

FOR FURTHER INFORMATION CONTACT: Jodi Lawson, Realty Specialist, BLM, Mother Lode Field Office, 916–941–3139. 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 purpose of the proposed withdrawal is to provide long-term protection of lands associated with the congressionally designated Auburn Dam Reclamation project area while a decision on future development of the site is pending. The site is currently managed as a recreation area; therefore, a withdrawal will also preserve riparian areas, wildlife habitat, scenic quality, and public recreation opportunities. The lands will remain open to leasing under the mineral leasing laws. Any previously authorized grants or rights-of-way located on the lands described in this notice will not be affected by this notice. The lands are described as follows:

Mount Diablo Meridian

T. 12 N., R. 8 E.,
- Sec. 12, S½SW¼;
- Sec. 25, North Extension of the Wilhelm Lode Mineral Survey No. 6091.

T. 12 N., R. 9 E.,
- Sec. 1, lots 10 and 11;
- Sec. 4, lots 12, 13, 14, and S½NE¼;
- Sec. 5, lots 19, 20, and 21;
- Sec. 18, lot 1.

T. 13 N., R. 9 E.,
- Sec. 1, that portion of unpatented Mineral Survey No. 2653 lying in the NE¼;
- Sec. 2, lots 1, 2, and 7, N½SW¼, SW¼SW¼, and N½SE¼SW¼;
- Sec. 11, lot 2 and S½SW¼;
- Sec. 13, SE¼SE¼;

Sec. 22, N½SW¼ and SW¼SW¼;
Sec. 23, Mineral Survey U–3;
Sec. 25, SE¼NE¼, W½NW¼SE¼, W½W½W½SW¼SE¼, and Summit Hill Consolidated Quartz Mine;
Sec. 28, NW¼SW¼, N½SW¼SW¼, E½SW¼SW¼SW¼, and W½SE¼SW¼SW¼;
Sec. 32, lots 4 and 5;
Sec. 34, lot 4.
T. 13 N., R. 10 E.,
Sec. 2, lot 1, and lots 3 to 15, inclusive;
Sec. 9, lots 8, 12, and 13, and SW¼NE¼;
Sec. 10, lots 1 to 10, inclusive, E½NE¼, E½NW¼, SW¼NW¼, and SE¼SE¼;
Sec. 11, lot 1 and SW¼NE¼;
Sec. 18, lots 1 to 4, inclusive, S½ of lot 5, S½ of lot 8, lots 11 and 13;
Sec. 19, lot 24;
Sec. 20, lots 1, 2, 3, and 8, N½NE¼, and SE¼NE¼;
Sec. 30, lots 1, 5, and 6, S½NE¼, and NE¼SE¼.
T. 14 N., R. 9 E.,
Sec. 1, lot 5, Gitaway Quartz Mine, Blue Rock Quartz Mine, and S½NW¼;
Sec. 12, N½ and SE¼;
Sec. 13, NE¼;
Sec. 24, S½;
Sec. 25, lots 9 to 13, inclusive, and lots 15 to 22, inclusive, NE¼SE¼, S½SW¼, and SW¼SE¼;
Sec. 35, lots 5, 6, and 7, NE¼, E½NW¼, SW¼SW¼, and E½SE¼;
Sec. 36, lots 2, 3, 7, 8, 9, 14, and 22, and NW¼.
T. 14 N., R. 10 E.,
Sec. 7, lots 6, 15, 27, 28, 42, and 45;
Sec. 18, lots 2 to 7, inclusive, and lots 10 to 15, inclusive;
Sec. 30, lots 4, 8, 9, 10, lots 15 to 18, inclusive, NE¼, E½NW¼, SE¼SW¼, and SW¼SE¼.
T. 15 N., R. 9 E.,
Sec. 36, E½NW¼SW¼, unsurveyed S½SE¼SW¼, and unsurveyed SW¼SE¼.

The areas described aggregate 6,737.42 acres, more or less, in El Dorado and Placer Counties.

The BLM's petition has been approved by the Assistant Secretary for Policy, Management and Budget. Therefore, the petition constitutes a withdrawal proposal of the Secretary of the Interior (43 CFR 2310.1–3(e)).

The use of a right-of-way, interagency, or cooperative agreement would not adequately constrain non-discretionary uses that could irrevocably destroy the area's cultural resources, scenic, and recreational values of the Auburn Dam area. There are no suitable alternative sites for the requested withdrawal associated with the Auburn Dam Project area.

Until December 3, 2012, all persons who wish to submit comments, suggestions, or to request a public meeting in connection with the proposed withdrawal may present their views in writing, by the date specified above to the Field Manager, BLM Mother Lode Field Office, 5152 Hillsdale Circle, El Dorado Hills, California 95762.

Comments, including names and street addresses for respondents, will be available for public review at the BLM's Mother Lode Field Office, during regular business hours, 7:30 a.m. to 4:00 p.m., Monday through Friday, except holidays. Individual respondents may request confidentiality. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

Notice is hereby given that at least one public meeting will be held in connection with the proposed withdrawal. Upon determination of the time and place, a notice will be published in both the **Federal Register** and a local newspaper at least 30 days prior to the scheduled date of the meetings. All interested persons who desire additional public meetings for the purpose of being heard on the proposed withdrawal must submit a written request to the Field Manager, Mother Lode Field Office, BLM, 5152 Hillsdale Circle, El Dorado Hills, California, no later than December 3, 2012.

For a period until September 4, 2014, the lands will be segregated from location and entry under the United States mining laws, but not from leasing under the mineral leasing laws, unless the application is denied or canceled or the withdrawal is approved prior to that date.

Licenses, permits, cooperative agreement, or discretionary land use authorizations of a temporary nature that will not significantly impact the values to be protected by the withdrawal may be allowed with the approval of the authorized officer of the BLM during the temporary segregative period.

The application will be processed in accordance with the regulations set forth in 43 CFR 2310.1–2.

Cynthia Staszak,

Associate Deputy State Director, Natural Resources, California State Office.

[FR Doc. 2012–21673 Filed 8–31–12; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTCO2000–L14300000.ET0000; MTM 102716]

Notice of Proposed Withdrawal Modification and Transfer of Administrative Jurisdiction; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Assistant Secretary of the Interior for Policy, Management and Budget proposes to modify Public Land Order (PLO) No. 1843, on behalf of the Bureau of Land Management (BLM), to transfer administrative jurisdiction of 5.16 acres of National Forest System (NFS) land from the U.S. Forest Service (USFS) to the BLM. The BLM would be the primary agency with responsibility and liability for the uses and activities on the land.

DATES: Comments must be received on or before December 3, 2012.

ADDRESSES: Comments should be sent to the Bureau of Land Management, Miles City Field Manager, 111 Garryowen Road, Miles City, Montana 59301–0940.

FOR FURTHER INFORMATION CONTACT: Pam Wall, BLM, Miles City Field Office, 111 Garryowen Road, Miles City, Montana 59301–0940, 406–233–2846, *pwall@blm.gov,* or Sandra Ward, BLM, Montana State Office, 406–896–5052, *sward@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 either of the above individuals. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with either of the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Assistant Secretary of the Interior for Policy, Management and Budget proposes to modify Public Land Order (PLO) No. 1843 to transfer administrative jurisdiction from the

USFS to the BLM for the following described NFS land which is currently withdrawn from all forms of appropriation under the public land laws, including the United States mining laws, but not the mineral leasing laws:

Principal Meridian, Montana

Fort Howes Work Center

T. 6 S., R. 45 E., section 24, and T. 6 S., R. 46 E., section 19, being more particularly described as follows:

Commencing at the E¼ section corner of section 24, T. 6 S., R. 45 E., Principal Meridian Montana; thence S. 18°50′00″ E., 317.36 feet to a ⅝ in. rebar with a plastic cap at the point of beginning; thence N. 76°54′06″ W., 405.51 feet to a ⅝ in. rebar with a plastic cap; thence N. 41°06′39″ W., 128.12 feet to a ⅝ in. rebar with a plastic cap; thence N. 6°31′31″ E., 56.77 feet to a ⅝ in. rebar with a plastic cap; thence N. 28°24′35″ E., 138.99 feet to a ⅝ in. rebar with a plastic cap; thence N. 48°56′30″ E., 326.99 feet to a ⅝ in. rebar with a plastic cap; thence S. 76°44′47″ E., 263.17 feet to a ⅝ in. rebar with a plastic cap; thence S. 10°26′26″ W., 530.30 feet to the point of beginning.

The area described contains 5.16 acres, more or less, in Powder River County.

The purpose of the proposed withdrawal modification and transfer of administrative jurisdiction is to protect the significant Federal investment in the administrative and fire facilities to be built. The BLM would be the primary agency with responsibility and liability for the uses and activities on the land.

The use of a right-of-way, interagency or cooperative agreement would not provide adequate protection.

There are no suitable alternative sites available.

Water will not be needed to fulfill the purpose of the withdrawal modification and transfer of administrative jurisdiction.

On or before December 3, 2012, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal modification and transfer of administrative jurisdiction may present their views in writing to the BLM Miles City Field Manager at the address above.

Comments and records relating to the proposed withdrawal, including names and addresses of respondents, will be available for public review in the BLM Miles City Field Office at the address indicated above during regular business hours. Before including your address, phone number, email address, or other personal identifying information in your comment, be advised 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 from public review your personal identifying information, we cannot guarantee that we will be able to do so.

This withdrawal modification application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

Gary P. Smith,

Acting Chief, Branch of Land Resources.

[FR Doc. 2012–21672 Filed 8–31–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–IMRO–YELL–11188; 2310–0070–422]

Winter Use Plan, Supplemental Draft Environmental Impact Statement, Yellowstone National Park

AGENCY: National Park Service, Interior.

ACTION: Notice of additional comment period for draft supplemental environmental impact statement.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service (NPS) announces the opening of an additional comment period on the Draft Supplemental Environmental Impact Statement (Draft SEIS) for a Winter Use Plan for Yellowstone National Park, located in Idaho, Montana, and Wyoming.

DATES: The NPS will accept comments from the public for 30 days from the date the Environmental Protection Agency publishes its notice of the additional comment period.

ADDRESSES: Information is available for public review and comment online at *http://parkplanning.nps.gov/YELL* (click on the link to the 2012 Supplemental Winter Use Plan EIS), and at Yellowstone National Park headquarters, Mammoth Hot Springs, WY.

FOR FURTHER INFORMATION CONTACT: Wade Vagias, P.O. Box 168, Yellowstone National Park, WY 82190; telephone (307) 344–2035.

SUPPLEMENTARY INFORMATION: The NPS has decided, in response to numerous requests from members of the public, to open an additional comment period on the Draft SEIS. The original comment period was open for 45 days, ending on August 20, 2012. The NPS Notice of Availability of the Draft SEIS was published in the **Federal Register** on June 29, 2012 (77 FR 38824–38825) and the EPA Notice of Availability, which formally opened the comment period, was published on July 6, 2012 (77 FR 40037). The NPS held public meetings on the Draft SEIS in Jackson, Wyoming, on July 16, 2012; West Yellowstone, Montana, on July 17, 2012; Bozeman, Montana, on July 18, 2012; and Cody, Wyoming, on July 19, 2012. The NPS is opening an additional public comment period that will run for 30 days from the date the EPA publishes its notice of the additional comment period in the **Federal Register**.

Four alternatives are considered in the Draft SEIS. Alternative 1, the no-action alternative, would not permit public over-snow vehicle (OSV) use in Yellowstone but would allow for approved non-motorized use to continue. Alternative 1 has been identified as the environmentally preferable alternative. Alternative 2 would manage OSV use at the same levels as the 2011/2012 interim rule (318 best available technology (BAT) snowmobiles and 78 snowcoaches per day). Sylvan Pass would remain open. Alternative 3 would initially allow for the same level of use as alternative 2 (318 BAT snowmobiles and 78 snowcoaches per day), but would transition to snowcoaches only over a three-year period beginning in the 2017/2018 winter season. Upon complete transition, there would be 0 snowmobiles and up to 120 snowcoaches per day in the park, and Sylvan Pass would be closed.

Alternative 4 is the NPS preferred alternative. This alternative would manage OSV use by transportation events. A total of 110 transportation events would be allowed in the park each day. A transportation event would initially equal one snowcoach or one group of snowmobiles (average of 7 snowmobiles per group, averaged over the winter use season; groups could not exceed a maximum of 10 snowmobiles). Operators would decide whether to use their daily allocation of transportation events for snowmobiles or snowcoaches, but no more than 50 daily transportation events could come from snowmobiles. OSV use would continue to be 100 percent guided, with four transportation events per day (one per gate) of up to 5 snowmobiles each allocated for non-commercially guided access. BAT requirements for snowmobiles would remain the same as the BAT requirements in the 2011/2012 interim regulation until the 2017/2018 winter season, at which time additional sound and air emission requirements would be implemented. BAT requirements for snowcoaches would also be implemented beginning in the 2017/2018 season. If OSVs meet additional

established standards for air and sound emissions beyond those required for BAT, the group size of snowmobiles would be allowed to increase from an average of 7 to an average of 8 per transportation event, and snowcoaches would be allowed to increase from one to two snowcoaches per transportation event. These changes would allow for an increase in visitation while reducing transportation-generated noise and air impacts. Sylvan Pass would remain open.

If you wish to comment on the Draft SEIS, you may submit your comments by any one of several methods. We encourage you to comment via the Internet at *http://parkplanning.nps.gov/YELL* (click on the link to the 2012 Supplemental Winter Use Plan EIS). You may also comment by mail to: Yellowstone National Park, Winter Use Draft SEIS, P.O. Box 168, Yellowstone NP, WY 82190. Finally, you may hand deliver your comments to: Management Assistant's Office, Headquarters Building, Mammoth Hot Springs, Yellowstone National Park, Wyoming. Comments will not be accepted by fax, email, or in any other way than those specified above. Bulk comments in any format (hard copy or electronic) submitted on behalf of others will not be accepted.

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: August 30, 2012.

Herbert C. Frost,

Associate Director, Natural Resource Stewardship and Science National Park Service.

[FR Doc. 2012–21829 Filed 8–31–12; 8:45 am]

BILLING CODE 4312–CT–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–365–366 and 731–TA–734–735 (Third Review)]

Certain Pasta From Italy and Turkey; Institution of Five-year Reviews Concerning the Countervailing and Antidumping Duty Orders on Certain Pasta From Italy and Turkey

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)) (the Act) to determine whether revocation of the countervailing and antidumping duty orders on certain pasta from Italy and Turkey would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission;[1] to be assured of consideration, the deadline for responses is October 4, 2012. Comments on the adequacy of responses may be filed with the Commission by November 19, 2012. For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207), as most recently amended at 74 FR 2847 (January 16, 2009).

DATES: *Effective Date:* September 4, 2012.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.— On July 24, 1996, the Department of Commerce issued countervailing and antidumping duty orders on imports of certain pasta from Italy and Turkey (61 FR 38544). Following the first five-year reviews by Commerce and the Commission, effective November 16, 2001, Commerce issued a continuation of the countervailing and antidumping duty orders on imports of certain pasta from Italy and Turkey (66 FR 57703). Following the second five-year reviews by Commerce and the Commission, effective October 12, 2007, Commerce issued a continuation of the countervailing and antidumping duty orders on certain pasta from Italy and Turkey (72 FR 58052). The Commission is now conducting third reviews to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. It will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The *Subject Countries* in these reviews are Italy and Turkey.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original and subsequent five-year review determinations, the Commission defined the *Domestic Like Product* as all dry pasta. One Commissioner defined the *Domestic Like Product* differently in the original and expedited first five-year review determinations.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original and subsequent five-year review determinations, the Commission defined the *Domestic Industry* as all domestic producers of dry pasta. One Commissioner defined the *Domestic Industry* differently in the original and expedited first five-year review determinations.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 12–5–274, expiration date June 30, 2014. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

manufacturer or through its selling agent.

Participation in the reviews and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation. The Commission's designated agency ethics official has advised that a five-year review is not considered the ''same particular matter'' as the corresponding underlying original investigation for purposes of 18 U.S.C. § 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 73 FR 24609 (May 5, 2008). This advice was developed in consultation with the Office of Government Ethics. Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR § 201.15, even if the corresponding underlying original investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the reviews. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these reviews must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is October 4, 2012. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is November 19, 2012. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to electronic filing have been amended. The amendments took effect on November 7, 2011. See 76 FR 61937 (Oct. 6, 2011) and the newly revised Commission's Handbook on E-Filing, available on the Commission's Web site at *http://edis.usitc.gov.* Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the reviews you do not need to serve your response).

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determinations in the reviews.

Information To Be Provided in Response to This Notice of Institution: If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject Merchandise* in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in these reviews by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the countervailing and antidumping duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2006.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2011, except as noted (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (i.e., the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country(ies),* provide the following information on your firm's(s') operations on that product during calendar year 2011 (report quantity data in pounds and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from each *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from each *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country(ies),* provide the following information on your firm's(s') operations on that product during calendar year 2011 (report quantity data in pounds and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *Subject Country* (i.e., the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in each *Subject Country* after 2006, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in each *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: These reviews are being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

Issued: August 27, 2012.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–21488 Filed 8–31–12; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

Record of Vote of Meeting Closure

(Public Law 94–409) (5 U.S.C. Sec. 552b)

I, Isaac Fulwood, of the United States Parole Commission, was present at a meeting of said Commission, which started at approximately 12:00 p.m., on

Tuesday, August 21, 2012, at the U.S. Parole Commission, 90 K Street NE., Third Floor, Washington, DC 20530. The purpose of the meeting was to discuss original jurisdiction cases pursuant to 28 CFR Section 2.27. Four Commissioners were present, constituting a quorum when the vote to close the meeting was submitted.

Public announcement further describing the subject matter of the meeting and certifications of the General Counsel that this meeting may be closed by votes of the Commissioners present were submitted to the Commissioners prior to the conduct of any other business. Upon motion duly made, seconded, and carried, the following Commissioners voted that the meeting be closed: Isaac Fulwood, Jr., Cranston J. Mitchell, Patricia K. Cushwa and J. Patricia Wilson Smoot.

In witness whereof, I make this official record of the vote taken to close this meeting and authorize this record to be made available to the public.

Dated: August 27, 2012.

Isaac Fulwood,

Chairman, U.S. Parole Commission.

[FR Doc. 2012–21668 Filed 8–30–12; 11:15 am]

BILLING CODE 4410–31–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; H–1B Technical Skills Training Grants and H–1B Jobs and Innovation Accelerator Challenge Grants

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) proposal titled, ''H–1B Technical Skills Training Grants and H–1B Jobs and Innovation Accelerator Challenge Grants,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before October 4, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain*, on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov*.

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov*.

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR is to obtain OMB approval under the PRA to implement data collection requirements for grant performance for both the H–1B Technical Skills Training Grants (SGA/DFA PY–10–13) and the H–1B Jobs and Innovation Accelerator Challenge Grants (SGA/DFA PY–10–15). This reporting structure features standardized data collection on program participants and quarterly narrative, performance, and Management Information System report formats. All data collection and reporting will be done by grantee organizations or their sub-grantees.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. For additional information, see the related notice published in the **Federal Register** on January 23, 2012 (77 FR 3284).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB ICR Reference Number 201201–1205–004. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: H–1B Technical Skills Training Grants and H–1B Jobs and Innovation Accelerator Challenge Grants.

OMB ICR Reference Number: 201201–1205–004.

Affected Public: Individuals or Households; Private Sector—not for profit institutions; and State, Local, or Tribal Governments.

Total Estimated Number of Respondents: 15,151.

Total Estimated Number of Responses: 31,208.

Total Estimated Annual Burden Hours: 47,080.

Total Estimated Annual Other Costs Burden: $0.

Dated: August 28, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–21723 Filed 8–31–12; 8:45 am]

BILLING CODE 4510–FT–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,565]

The Travelers Indemnity Company, Personal Insurance Remittance Center, Hartford, CT; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated August 9, 2012, workers requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of The Travelers

Indemnity Company, Personal Insurance Remittance Center, Hartford, Connecticut (Travelers-PIRC). The determination was issued on June 27, 2012 and the Notice of Determination was published in the **Federal Register** on July 18, 2012 (77 FR 42337). The subject workers are engaged in activities related to the supply of remittance payment processing services related to premium payments.

The initial investigation resulted in a negative determination based on the findings that Travelers-PIRC did not shift the supply of remittance payment processing services (or like or directly competitive services) to a foreign country, or acquire the supply of such services from a foreign country. Rather, the services formerly supplied by Travelers-PIRC are being performed by a third-party vendor in Texas which also provides a new service that is supplied on a limited, intermittent basis by a resource in India.

The initial investigation also revealed that Travelers-PIRC did not increase its reliance on imports of like or directly competitive services.

In the request for reconsideration, the workers allege that the ''limited, intermittent * * * resource in India'' is ''an entire unit in India, literally processing an integral and essential part of the daily work flow, each and every day, and on a regularly scheduled basis. Without this unit, the processing of the vendor would fail in its ability to process an important part of the daily work load.'' The request included non-proprietary support material.

The Department has carefully reviewed the request for reconsideration and the existing record, and will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974, as amended.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 20th day of August, 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–21622 Filed 8–31–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,603]

Accellent

Including On-Site Leased Workers From Aerotek, Corporate Management Group (CMG), Marathon Staffing, And Excel Personnel, Inc., Englewood, Colorado; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 18, 2012, applicable to workers of Accellent, Englewood, Colorado, including on-site leased workers from Aerotek, Corporate Management Group (CMG), and Marathon Staffing. The Department's notice of determination was published in the **Federal Register** on July 10, 2012 (77 FR 40641).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The workers were engaged in production of medical device components.

The company reports that workers leased from Excel Personnel, Inc. were employed on-site at the Englewood, Colorado location of Accellent. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Excel Personnel, Inc. working on-site at the Englewood, Colorado location of Accellent.

The amended notice applicable to TA–W–81,603 is hereby issued as follows:

All workers of Accellent, including on-site leased workers from Aerotek, Corporate Management Group (CMG), Marathon Staffing, and Excel Personnel, Inc., Englewood, Colorado, who became totally or partially separated from employment on or after May 10, 2010, through June 18, 2014, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC this 21st day of August, 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–21618 Filed 8–31–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–74,205]

River Bend Industries, LLC, Including On-Site Leased Workers From FirstStaff, Trac Staffing, and Worksource, Inc., Fort Smith, Arkansas; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on August 2, 2010, applicable to workers of River Bend Industries, LLC including on-site leased workers from FirstStaff, Trac Staffing, Worksource, Inc., Fort Smith, Arkansas. The Department's notice of determination was published in the **Federal Register** on August 23, 2010 (75 FR 51846).

At the request of the State of Arkansas, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of plastic parts for appliances.

The company reports that workers leased from Trac Staffing and Worksource, Inc. were employed on-site at the Fort Smith, Arkansas location of River Bend Industries, LLC. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Trac Staffing and Worksource, Inc., working on-site at the Fort Smith, Arkansas location of River Bend Industries.

The amended notice applicable to TA–W–74,205 is hereby issued as follows:

All workers of River Bend Industries, LLC, including on-site leased workers from FirstStaff, Trac Staffing and Worksource, Inc., Fort Smith, Arkansas, who became totally or partially separated from employment on or after May 10, 2009, through August 2, 2012, and all workers in the group threatened with

total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC this 21st day of August, 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–21621 Filed 8–31–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,637]

Horton Automatics, Inc., a Subsidiary of Overhead Door Corporation Including On-Site Leased Workers From Remedy Intelligent Staffing Corpus Christi, TX; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 15, 2012, applicable to workers of Horton Automatics, Inc., a subsidiary of Overhead Door Corporation, including on-site leased workers from Remedy Intelligent Staffing, Corpus Christi, Texas. The workers are engaged in activities related to the production of automatic sliding, swinging, and revolving doors. The notice was published in the **Federal Register** on July 2, 2012 (77 FR 9267).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. New information from the company, shows that the correct name of the subject firm in its' entirety should read Horton Automatics, Inc., a subsidiary of Overhead Door Corporation, including on-site leased workers from Remedy Intelligent Staffing, Corpus Christi, Texas.

Accordingly, the Department is amended this certification to correct the name of the subject firm to read Horton Automatics, Inc., a subsidiary of Overhead Door Corporation, including on-site leased workers from Remedy Intelligent Staffing, Corpus Christi, Texas.

The amended notice applicable to TA–W–81,637 is hereby issued as follows:

All workers from Horton Automatics, Inc., a subsidiary of Overhead Door Corporation, including on-site leased workers from Remedy Intelligent Staffing, Corpus Christi, Texas, who became totally or partially separated from employment on or after May 18, 2011, through June 15, 2014, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1074, as amended.

Signed at Washington, DC, this 13th day of August 2012.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–21623 Filed 8–31–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of *August 13, 2012 through August 17, 2012.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,532	Verizon Data Services LLC, System Database Administration Group	Temple Terrace, FL	April 14, 2011.
81,532A	Verizon Data Services LLC, System Database Administration Group	Alexandria, VA	April 14, 2011.
81,532AA	Verizon Data Services LLC, System Database Administration Group	Cedar Rapids, IA	April 14, 2011.
81,532B	Verizon Data Services LLC, System Database Administration Group	Alpharetta, GA	April 14, 2011.
81,532BB	Verizon Data Services LLC, System Database Administration Group	Irving, TX	April 14, 2011.
81,532C	Verizon Data Services LLC, System Database Administration Group, Infovision & Infinite Computing, etc.	Ashburn, VA	April 14, 2011.
81,532CC	Verizon Data Services LLC, System Database Administration Group	Jackson, CA	April 14, 2011.
81,532D	Verizon Data Services LLC, System Database Administration Group	Austin, TX	April 14, 2011.
81,532DD	Verizon Data Services LLC, System Database Administration Group	Lakeland, FL	April 14, 2011.
81,532E	Verizon Data Services LLC, System Database Administration Group	Boise, ID	April 14, 2011.
81,532EE	Verizon Data Services LLC, System Database Administration Group	Laurel, MS	April 14, 2011.
81,532F	Verizon Data Services LLC, System Database Administration Group	Boston, MA	April 14, 2011.
81,532FF	Verizon Data Services LLC, System Database Administration Group	Leander, TX	April 14, 2011.
81,532G	Verizon Data Services LLC, System Database Administration Group	Bristow, VA	April 14, 2011.
81,532GG	Verizon Data Services LLC, System Database Administration Group	Littleton, CO	April 14, 2011.
81,532H	Verizon Data Services LLC, System Database Administration Group	Cary, NC	April 14, 2011.
81,532HH	Verizon Data Services LLC, System Database Administration Group	Mountville, SC	April 14, 2011.
81,532I	Verizon Data Services LLC, System Database Administration Group	Centreville, VA	April 14, 2011.
81,532II	Verizon Data Services LLC, System Database Administration Group	North Potomac, VA	April 14, 2011.
81,532J	Verizon Data Services LLC, System Database Administration Group	Chesterfield, VA	April 14, 2011.
81,532JJ	Verizon Data Services LLC, System Database Administration Group	Oakton, VA	April 14, 2011.
81,532K	Verizon Data Services LLC, System Database Administration Group	Clemmons, NC	April 14, 2011.
81,532KK	Verizon Data Services LLC, System Database Administration Group	Piscataway, NJ	April 14, 2011.
81,532L	Verizon Data Services LLC, System Database Administration Group	Clinton, MS	April 14, 2011.
81,532LL	Verizon Data Services LLC, System Database Administration Group	Richardson, TX	April 14, 2011.
81,532M	Verizon Data Services LLC, System Database Administration Group, Crossfire.	Colorado Springs, CO	April 14, 2011.
81,532MM	Verizon Data Services LLC, System Database Administration Group	Rye Brook, NY	April 14, 2011.
81,532N	Verizon Data Services LLC, System Database Administration Group	Dade City, FL	April 14, 2011.
81,532NN	Verizon Data Services LLC, System Database Administration Group	San Antonio, TX	April 14, 2011.
81,532O	Verizon Data Services LLC, System Database Administration Group	Denver, CO	April 14, 2011.
81,532OO	Verizon Data Services LLC, System Database Administration Group	Sandusky, OH	April 14, 2011.
81,532P	Verizon Data Services LLC, System Database Administration Group	Elkridge, MD	April 14, 2011.
81,532PP	Verizon Data Services LLC, System Database Administration Group	Silver Spring, MD	April 14, 2011.
81,532Q	Verizon Data Services LLC, System Database Administration Group	Evergreen, CO	April 14, 2011.
81,532QQ	Verizon Data Services LLC, System Database Administration Group	Springfield, VA	April 14, 2011.
81,532R	Verizon Data Services LLC, System Database Administration Group	Fairfax, VA	April 14, 2011.
81,532RR	Verizon Data Services LLC, System Database Administration Group	Tampa, FL	April 14, 2011.
81,532S	Verizon Data Services LLC, System Database Administration Group	Fairview, TN	April 14, 2011.
81,532SS	Verizon Data Services LLC, System Database Administration Group	Tulsa, OK	April 14, 2011.

TA–W No.	Subject firm	Location	Impact date
81,532T	Verizon Data Services LLC, System Database Administration Group	Fort Wayne, IN	April 14, 2011.
81,532TT	Verizon Data Services LLC, System Database Administration Group	Whitmore Lake, MI	April 14, 2011.
81,532U	Verizon Data Services LLC, System Database Administration Group	Freehold, NJ	April 14, 2011.
81,532UU	Verizon Data Services LLC, System Database Administration Group	White Plains, NY	April 14, 2011.
81,532V	Verizon Data Services LLC, System Database Administration Group	Germantown, MD	April 14, 2011.
81,532VV	Verizon Data Services LLC, System Database Administration Group	Williston Park, NY	April 14, 2011.
81,532W	Verizon Data Services LLC, System Database Administration Group	Herndon, VA	April 14, 2011.
81,532WW	Verizon Data Services LLC, System Database Administration Group	Winooski, VT	April 14, 2011.
81,532X	Verizon Data Services LLC, System Database Administration Group	Highland Ranch, CO	April 14, 2011.
81,532Y	Verizon Data Services LLC, System Database Administration Group	Hilliard, OH	April 14, 2011.
81,532Z	Verizon Data Services LLC, System Database Administration Group	Hillsborough, NJ	April 14, 2011.
81,587	South Carolina Yutaka Technologies, Inc., Cardington Yutaka Technologies, Allstaff Employment, Services, LLC, Skills.	Lugoff, SC	May 7, 2011.
81,798	CoreLogic Consumer Services, LLC, CoreLogic, Call Center Operations, Action Staffing, Aerotek, Appleone, etc.	Des Moines, IA	July 12, 2011.
81,805	Texas/New Mexico Newspapers Partnership, Medianews Group, RM Personnel and Account Temps.	El Paso, TX	June 30, 2011.
81,807	CoreLogic, Inc. LLC, CoreLogic, Inc., Matrix Resources	Westlake, TX	July 17, 2011.
81,816	Powertex, Inc.	Rouses Point, NY	July 19, 2011.
81,823	Champion Photochemistry Incorporated, Manpower and Kelly Services.	Rochester, NY	July 24, 2011.
81,832	The Bank of New York Mellon, Billing and Revenue Operations, Addison Serach, BNG Consulting, etc.	Brooklyn, NY	July 26, 2011.
81,836	THQ Inc., Quality Assurance Division, Zero Chaos	Phoenix, AZ	July 26, 2011.
81,853	GrafTech U.S.A. LLC, GrafTech International Holdings, Inc	St. Marys, PA	August 2, 2011.
81,869	Hartford Financial Services Group, Inc., Operations/Personal Lines/Support Services Division.	Simsbury, CT	August 6, 2011.
81,875	Darly Custom Technology, Inc., Engineering Design and Drafting Dept., Off-Site Workers from Arizona.	Windsor, CT	August 9, 2011.
81,876	Hartford Financial Services Group, Inc., Operations/Commercial/Group Benefits/List Bill Division.	Overland Park, KS	August 8, 2011.
81,877	Hartford Financial Services Group, Inc., Operations/Commercial/Biss/Claim Coding Division.	Clinton, NY	August 8, 2011.
81,877A	Hartford Financial Services Group, Inc., Operations/Commercial Markets/Biss/Claim Coding Division.	San Antonio, TX	August 8, 2011.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criteria under paragraphs (a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
81,414	TE Connectivity, CIS-Appliances Division, Kelly Services	Jonestown, PA.	
81,802	Southeast Poultry, Inc.	Rogers, AR.	
81,819	Medical Card System, Inc.	De Pere, WI.	

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

TA–W No.	Subject firm	Location	Impact date
81,788	ConAgra Foods, Conagra Commercial Division, Aid Temporary Services and Manpower Staffing.	Batesville, AR.	

I hereby certify that the aforementioned determinations were issued during the period of *August 13, 2012 through August 17, 2012.* These determinations are available on the Department's Web site *tradeact/taa/taa search form.cfm* under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Dated: August 22, 2012.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–21620 Filed 8–31–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than September 14, 2012.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than September 14, 2012.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC this 22nd day of August 2012.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[19 TAA petitions instituted between 8/13/12 and 8/17/12]

TA–W	Subject firm (Petitioners)	Location	Date of institution	Date of petition
81886	Monroe Gray (Workers)	Cameron, LA	08/13/12	08/13/12
81887	Pearson (Workers)	Glenview, IL	08/13/12	08/09/12
81888	Anvil Knitwear, Inc. (Company)	Hamer, SC	08/14/12	08/06/12
81889	MasterBrand Cabinets, Inc. (Company)	Martinsville, VA	08/14/12	08/10/12
81890	Artisans, Inc. (Company)	Glen Flora, WI	08/14/12	08/13/12
81891	Sheridan Book, Inc. (State/One-Stop)	Chelsea, MI	08/14/12	08/13/12
81892	Basileus Company LLC (State/One-Stop)	Manlius, NY	08/15/12	08/14/12
81893	Asah Kasol Spandex America (Company)	Goose Creek, SC	08/15/12	08/14/12
81894	WS Packaging Group, Inc. (Workers)	Franklin, PA	08/15/12	08/14/12
81895	Medimedia Health, Inc. (Workers)	Yardley, PA	08/15/12	08/14/12
81896	SolarMarkt dba Session Solar (Workers)	Scotts Valley, CA	08/16/12	08/15/12
81897	Sentinel & Enterprise (State/One-Stop)	Fitchburg, MA	08/16/12	08/15/12
81898	Color Service, Inc. (State/One-Stop)	Monterey Park, CA	08/16/12	08/15/12
81899	Accuride Corporation (Company)	Henderson, KY	08/16/12	08/15/12
81900	Gunite Corporation (Company)	Elkhart, IN	08/16/12	08/16/12
81901	iPacesetters (Workers)	Eau Claire, WI	08/17/12	08/15/12
81902	DTI (Formerly Dan Chem) (Workers)	Danville, VA	08/17/12	08/17/12
81903	Senco Brands, Inc. (Workers)	Cinti, OH	08/17/12	08/01/12
81904	American Showa, Inc. (Company)	Blanchester, OH	08/17/12	08/16/12

[FR Doc. 2012–21619 Filed 8–31–12; 8:45 am]

BILLING CODE 4510–FN–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 12–09]

Notice of the September 13, 2012, Millennium Challenge Corporation Board of Directors Meeting; Sunshine Act Meeting

AGENCY: Millennium Challenge Corporation.

TIME AND DATE: 3 p.m. to 5 p.m., Thursday, September 13, 2012.

PLACE: Department of State, 2201 C Street NW., Washington, DC 20520.

FOR FURTHER INFORMATION CONTACT: Information on the meeting may be obtained from Melvin F. Williams, Jr., Vice President, General Counsel and Corporate Secretary via email at *corporatesecretary@mcc.gov* or by telephone at (202) 521–3600.

STATUS: Meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The Board of Directors (the ''Board'') of the Millennium Challenge Corporation (''MCC'') will hold a meeting to discuss the Selection Criteria & Methodology Report, impact evaluations, completion risks in compact implementation countries, update on Mali wind-up, and gender. The agenda items are expected to involve the consideration of classified information and the meeting will be closed to the public.

Dated: August 29, 2012.

Melvin F. Williams, Jr.,

VP/General Counsel and Corporate Secretary, Millennium Challenge Corporation.

[FR Doc. 2012–21786 Filed 8–30–12; 11:15 am]

BILLING CODE 9211–03–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 12–08]

Report on Countries That Are Candidates for Millennium Challenge Account Eligibility in Fiscal Year 2013 and Countries That Would Be Candidates but for Legal Prohibitions

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: Section 608(d) of the Millennium Challenge Act of 2003 requires the Millennium Challenge Corporation to publish a report that identifies countries that are ''candidate countries'' for Millennium Challenge Account assistance during FY 2013. The report is set forth in full below.

Dated: August 29, 2012.

Melvin F. Williams, Jr.,

VP/General Counsel and Corporate Secretary, Millennium Challenge Corporation.

Report on Countries That Are Candidates for Millennium Challenge Account Eligibility for Fiscal Year 2013 and Countries That Would Be Candidates but for Legal Prohibitions

Summary

This report to Congress is provided in accordance with section 608(a) of the Millennium Challenge Act of 2003, as amended, 22 U.S.C. §§ 7701, 7707(a) (the Act).

The Act authorizes the provision of Millennium Challenge Account (MCA) assistance for countries that enter into a Millennium Challenge Compact with the United States to support policies and programs that advance the progress of such countries to achieve lasting economic growth and poverty reduction. The Act requires the Millennium Challenge Corporation (MCC) to take a number of steps in selecting countries with which MCC will seek to enter into a compact, including (a) determining the countries that will be eligible for MCA assistance for fiscal year (FY) 2013 based on a country's demonstrated commitment to (i) just and democratic governance, (ii) economic freedom, and (iii) investments in its people; and (b) considering the opportunity to reduce poverty and generate economic growth in the country. These steps include the submission of reports to the congressional committees specified in the Act and the publication of notices in the **Federal Register** that identify:

The countries that are ''candidate countries'' for MCA assistance for FY 2013 based on their per capita income levels and their eligibility to receive assistance under U.S. law and countries that would be candidate countries but for specified legal prohibitions on assistance (section 608(a) of the Act);

The criteria and methodology that the MCC Board of Directors (Board) will use to measure and evaluate the relative policy performance of the ''candidate countries'' consistent with the requirements of subsections (a) and (b) of section 607 of the Act in order to determine ''eligible countries'' from among the ''candidate countries'' (section 608(b) of the Act); and

The list of countries determined by the Board to be ''eligible countries'' for FY 2013, identification of such countries with which the Board will seek to enter into compacts, and a justification for such eligibility determination and selection for compact negotiation (section 608(d) of the Act).

This report is the first of three required reports listed above.

Candidate Countries for FY 2013

The Act requires the identification of all countries that are candidates for MCA assistance for FY 2013 and the identification of all countries that would be candidate countries but for specified legal prohibitions on assistance. MCC's FY 2012 Appropriations Act, enacted in December 2011 as part of the Consolidated Appropriations Act, 2012 (Pub. L. 112–74) (the FY 2012 Appropriations Act), redefined low income candidate countries for FY 2012 [1] as the 75 poorest countries as identified by the World Bank and provided that a country that changes in the fiscal year from low income to lower middle income (or vice versa) will retain its candidacy status in its former income category for the fiscal year and two subsequent fiscal years.

The provisions of the FY 2012 Appropriations Act that supersede sections 606(a) and (b) of the Act provide that for FY 2013, a country shall be a candidate for MCA assistance if it:

Meets one of the following tests:

Has a per capita income that is not greater than the World Bank's lower middle income country threshold for such fiscal year ($4,035 GNI per capita for FY 2013); and is among the 75 lowest per capita income countries, as identified by the World Bank; or

Has a per capita income that is not greater than the World Bank's lower middle income country threshold for such fiscal year ($4,035 GNI per capita for FY 2013); but is not among the 75 lowest per capita income countries as identified by the World Bank;

And

Is not ineligible to receive U.S. economic assistance under part I of the Foreign Assistance Act of 1961, as amended (the Foreign Assistance Act), by reason of the application of the Foreign Assistance Act or any other provision of law.

The revised candidate list for FY 2012 established the baseline of those countries for purposes of determining income levels. Due to the provisions requiring countries to retain their former income classification, changes from the low income to lower middle income categories in FY 2013 will go into effect for FY 2016. Countries changing from the lower middle income category to the upper middle income category do not retain their former income classification.

Pursuant to section 606(c) of the Act, the Board identified the following countries as candidate countries under the Act for FY 2013. In so doing, the Board referred to the prohibitions on assistance as applied to countries in the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2012, Pub. L. 112–74, Div. I. (the SFOAA). All section references identified as prohibitions on assistance to a given country are taken from Title VII of the SFOAA, unless another statue is identified.

Candidate Countries: Low Income Category

Afghanistan
Bangladesh
Benin
Bhutan
Bolivia
Burkina Faso
Burundi
Cambodia
Central African Republic
Chad
Comoros
Cote D'Ivoire
Congo, Democratic Republic of
Congo, Republic of the
Djibouti
Egypt, Arab Republic
Ethiopia
Gambia, The
Georgia
Ghana
Guatemala
Haiti
Honduras
India
Indonesia
Iraq
Kenya
Kiribati
Kyrgyz Republic
Lao PDR
Lesotho
Liberia
Malawi
Mauritania
Micronesia
Moldova
Mongolia
Mozambique
Nepal
Niger
Nigeria
Pakistan
Papua New Guinea
Philippines
Rwanda
Sao Tome and Principe
Senegal

[1] The changes to the Act enacted in the FY 2012 Appropriations Act applied specifically to the FY 2012 selection process. However, in advance of the FY 2013 appropriations act, the language from the FY 2012 Appropriations Act serves as the basis for the FY 2013 Candidate Country Report.

Sierra Leone
Solomon Islands
Somalia
South Sudan
Sri Lanka
Tajikistan
Tanzania
Timor-Leste
Togo
Uganda
Uzbekistan
Vanuatu
Vietnam
Yemen
Zambia

Candidate Countries: Lower Middle Income Category

Albania
Armenia
Belize
Cape Verde
El Salvador
Guyana *
Kosovo
Marshall Islands
Morocco
Paraguay
Samoa
Tonga
Ukraine

* According to the FY 2013 income data, Swaziland (listed under prohibited countries) would have moved up and out of the LIC category and Guyana would have moved back into the LIC category. However, due to the provisions in the FY 2012 Appropriations Act allowing countries to retain their former income classification, both countries will be held in their previous income classification for this year and the next two fiscal years.

Countries That Would Be Candidate Countries but for Legal Prohibitions That Prohibit Assistance

Countries that would be considered candidate countries for FY 2013, but are ineligible to receive United States economic assistance under part I of the Foreign Assistance Act by reason of the application of any provision of the Foreign Assistance Act or any other provision of law are listed below. As noted above, this list is based on legal prohibitions against economic assistance that apply as of September 1, 2012.

Prohibited Countries: Low Income Category

Burma is subject to numerous restrictions, including but not limited to section 570 of the FY 1997 Foreign Operations, Export Financing, and Related Programs Appropriations Act (Pub. L. 104–208), which prohibits assistance to the government of Burma until it makes measurable and substantial progress in improving human rights practices and implementing democratic government, and due to its status as a major drug-transit or major illicit drug producing country for FY 2012 (Presidential Determination No. 2011–16 (9/15/2011)).

Cameroon is subject to section 7031(b) regarding budget transparency.

Eritrea is subject to restrictions due to its status as a Tier III country under the Trafficking Victims Protection Act, as amended, 22 U.S.C. sections 7101 et seq.

Guinea is subject to section 7031(b) regarding budget transparency.

Guinea-Bissau is subject to section 7008 of the SFOAA, which prohibits assistance to the government of a country whose duly elected head of government is deposed by military coup or decree.

Madagascar is subject to section 7008 of the SFOAA, which prohibits assistance to the government of a country whose duly elected head of government is deposed by military coup or decree and also section 7031(b) regarding budget transparency.

Mali is subject to section 7008 of the SFOAA, which prohibits assistance to the government of a country whose duly elected head of government is deposed by military coup or decree.

Nicaragua is subject to section 7031(b) regarding budget transparency.

North Korea is subject to numerous restrictions, including section 7007 of the SFOAA which prohibits any direct assistance to the government.

Sudan is subject to numerous restrictions, including but not limited to section 620A of the Foreign Assistance Act which prohibits assistance to governments supporting international terrorism, section 7012 of the SFOAA and section 620(q) of the Foreign Assistance Act, both of which prohibit assistance to countries in default in payment to the U.S. in certain circumstances, section 7008 of the SFOAA, which prohibits assistance to the government of a country whose duly elected head of government is deposed by military coup or decree, and section 7043(f).

Swaziland is subject to section 7031(b) regarding budget transparency.

Syria is subject to numerous restrictions, including but not limited to 620A of the Foreign Assistance Act which prohibits assistance to governments supporting international terrorism, section 7007 of the SFOAA which prohibits direct assistance, and section 7012 of the SFOAA and section 620(q) of the Foreign Assistance Act, both of which prohibit assistance to countries in default in payment to the U.S. in certain circumstances.

Zimbabwe is subject to several restrictions, including section 7043(j)(2) which prohibits assistance (except for macroeconomic growth assistance) to the central government of Zimbabwe, unless the Secretary of State determines and reports to Congress that the rule of law has been restored in Zimbabwe.

Prohibited Countries: Lower Middle Income Category

Fiji is subject to section 7008 of the SFOAA, which prohibits assistance to the government of a country whose duly elected head of government is deposed by military coup or decree.

Countries identified above as candidate countries, as well as countries that would be considered candidate countries but for the applicability of legal provisions that prohibit U.S. economic assistance, may be the subject of future statutory restrictions or determinations, or changed country circumstances, that affect their legal eligibility for assistance under part I of the Foreign Assistance Act by reason of application of the Foreign Assistance Act or any other provision of law for FY 2013.

[FR Doc. 2012–21682 Filed 8–29–12; 4:15 pm]

BILLING CODE 9211–03–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 12–071]

NASA Advisory Council; Science Committee; Planetary Science Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Science Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Tuesday, October 2, 2012, 8:30 a.m. to 5:30 p.m., and Wednesday, October 3, 2012, 8:30 a.m. to 4:30 p.m., Local Time.

ADDRESSES: This meeting will take place at NASA Headquarters, 300 E Street SW., Room 6H45, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4452, fax (202) 358–4118, or *mnorris@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. The meeting will also be available telephonically and by WebEx. Any interested person may call the USA toll free conference call number 800–619–8846, pass code PSS, to participate in this meeting by telephone. The WebEx link is *https://nasa.webex.com/,* the meeting number on October 2 is 991 184 838, password PSS@Oct2; the meeting number on October 3 is 997 149 734, password PSS@Oct3. The agenda for the meeting includes the following topics:

—Planetary Science Division Update

—Mars Exploration Program Update

—Mars Science Laboratory/Curiosity Update

—Mars Program Planning Group Update

—Discovery Program Update

—Planetary Science Division Senior Review Update

—Research and Analysis Update

—Reports from Analysis and Assessment Groups

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID to Security before access to NASA Headquarters. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee; and home address to Marian Norris via email at *mnorris@nasa.gov* or by fax at (202) 358–4118. U.S. citizens and green card holders are requested to submit their name and affiliation 3 working days prior to the meeting to Marian Norris.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration and Space Administration.

[FR Doc. 2012–21655 Filed 8–31–12; 8:45 am]

BILLING CODE P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 12–070]

NASA Federal Advisory Committees

AGENCY: National Aeronautics and Space Administration.

ACTION: Annual invitation for public nominations by U.S. citizens for service on NASA Federal advisory committees.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration, and in accordance with the Memorandum for the Heads of Executive Departments and Agencies signed on December 17, 2010, signed by the Director of the Office of Science and Technology Policy (OSTP), Executive Office of the President, NASA announces its annual invitation for public nominations for service on NASA Federal advisory committees. U.S. citizens may nominate individuals and also submit self-nominations for consideration as potential members of NASA's Federal advisory committees. NASA's Federal advisory committees have member vacancies from time to time throughout the year, and NASA will consider nominations and self-nominations to fill such intermittent vacancies. NASA is committed to selecting members to serve on its Federal advisory committees based on their individual expertise, knowledge, experience, and current/past contributions to the relevant subject area.

DATES: The deadline for NASA receipt of all public nominations is October 1, 2012.

ADDRESSES: Nominations and self-nominations from interested U.S. citizens must be sent to NASA in letter form, be signed, and must include the name of specific NASA Federal advisory committee of interest for NASA consideration. Nominations and self-nomination letters are limited to specifying interest in only one (1) NASA Federal advisory committee per year. The following additional information is required to be attached to each nomination and self-nomination letter (i.e., cover letter): (1) Professional resume (one-page maximum); (2) professional biography (one-page maximum). Please submit the nomination as a single package containing cover letter and both required attachments electronically to: *hq-nasanoms@mail.nasa.gov.* All public nomination packages must be submitted electronically via email to NASA; paper-based documents sent through postal mail (hard-copies) will not be accepted. **Note:** Nomination letters that are noncompliant with inclusion of the three (3) mandatory documents listed above will not receive further consideration by NASA.

FOR FURTHER INFORMATION CONTACT: To view charters and obtain further information on NASA's Federal advisory committees, please visit the NASA Advisory Committee Management Division Web site noted below. For any questions, please contact Ms. Susan Burch, Advisory Committee Specialist, Advisory Committee Management Division, Office of International and Interagency Relations, NASA Headquarters, Washington, DC 20546, (202) 358–0550.

SUPPLEMENTARY INFORMATION: NASA's five (5) currently chartered Federal advisory committees are listed below. The individual charters may be found at the NASA Advisory Committee Management Division's Web site at *http://oiir.hq.nasa.gov/acmd.html:*

• *NASA Advisory Council*—The NASA Advisory Council (NAC) provides advice and recommendations to the NASA Administrator on Agency programs, policies, plans, financial controls, and other matters pertinent to the Agency's responsibilities. The NAC consists of the Council and eight (8) Committees: Aeronautics; Audit, Finance and Analysis; Commercial Space; Education and Public Outreach; Human Exploration and Operations; Information Technology Infrastructure; Science; and Technology and Innovation. NOTE: All nominations for the NASA Advisory Council must indicate the specific entity of interest, i.e., either the Council or one of its eight (8) Committees.

• *Aerospace Safety Advisory Panel*—The Aerospace Safety Advisory Panel provides advice and recommendations to the NASA Administrator and the Congress on matters related to safety, and performs such other duties as the NASA Administrator may request.

• *International Space Station (ISS) Advisory Committee*—The ISS Advisory Committee provides advice and recommendations to the NASA Associate Administrator for Human

Exploration and Operations Mission Directorate on all aspects related to the safety and operational readiness of the ISS. It addresses additional issues and/or areas of interest identified by the NASA Associate Administrator for Human Exploration and Operations Mission Directorate.

• *International Space Station (ISS) National Laboratory Advisory Committee*—The ISS National Laboratory Advisory Committee monitors, assesses, and makes recommendations to the NASA Administrator regarding effective utilization of the ISS as a national laboratory and platform for research, and such other duties as the NASA Administrator may request.

• *National Space-Based Positioning, Navigation and Timing (PNT) Advisory Board*—The National Space-Based PNT Advisory Board provides advice to the PNT Executive Committee (comprised of nine stakeholder Federal agencies, of which NASA is a member) on U.S. space-based PNT policy, planning, program management, and funding profiles in relation to the current state of national and international space-based PNT services.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2012–21654 Filed 8–31–12; 8:45 am]

BILLING CODE P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that the agency has submitted to OMB for approval the information collections described in this notice. The public is invited to comment on the proposed information collections pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted to OMB at the address below on or before October 4, 2012 to be assured of consideration.

ADDRESSES: Send comments to Mr. Nicholas A. Fraser, Desk Officer for NARA, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5167; or electronically mailed to *Nicholas_A._Fraser@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collection and supporting statement should be directed to Tamee Fechhelm at telephone number 301–837–1694 or fax number 301–713–7409.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. NARA published a notice of proposed collection for this information collection on June 21, 2012 (77 FR 37442 and 37443). No comments were received. NARA has submitted the described information collections to OMB for approval.

In response to this notice, comments and suggestions should address one or more of the following points: (a) Whether the proposed information collections are necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA's estimate of the burden of the proposed information collections; (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 the use of information technology; and (e) whether small businesses are affected by this collection. In this notice, NARA is soliciting comments concerning the following information collections:

1. *Title:* Request to Microfilm Records.
OMB number: 3095–0017.
Agency form number: None.
Type of review: Regular.
Affected public: Companies and organizations that wish to microfilm archival holdings in the National Archives of the United States or a Presidential library for micropublication.
Estimated number of respondents: 2.
Estimated time per response: 10 hours.
Frequency of response: On occasion (when respondent wishes to request permission to microfilm records).
Estimated total annual burden hours: 20
Abstract: The information collection is prescribed by 36 CFR 1254.92. The collection is prepared by companies and organizations that wish to microfilm archival holdings with privately-owned equipment. NARA uses the information to determine whether the request meets the criteria in 36 CFR 1254.94, to evaluate the records for filming, and to schedule use of the limited space available for filming.

2. *Title:* Request to film, photograph, or videotape at a NARA facility for news purposes.
OMB number: 3095–0040.
Agency form number: None.
Type of review: Regular.
Affected public: Business or other for-profit, not-for-profit institutions.
Estimated number of respondents: 660.
Estimated time per response: 10 minutes.
Frequency of response: On occasion.
Estimated total annual burden hours: 110
Abstract: The information collection is prescribed by 36 CFR 1280.48. The collection is prepared by organizations that wish to film, photograph, or videotape on NARA property for news purposes. NARA needs the information to determine if the request complies with NARA's regulation, to ensure protections of archival holdings, and to schedule the filming appointment.

3. *Title:* Request to use NARA facilities for events.
OMB number: 3095–0043.
Agency form number: None.
Type of review: Regular.
Affected public: Not-for-profit institutions, individuals or households, business or other for-profit, Federal government.
Estimated number of respondents: 22.
Estimated time per response: 30 minutes.
Frequency of response: On occasion.
Estimated total annual burden hours: 11.
Abstract: The information collection is prescribed by 36 CFR 1280.80. The collection is prepared by organizations that wish to use NARA public areas for an event. NARA uses the information to determine whether or not we can accommodate the request and to ensure that the proposed event complies with NARA regulations.

Dated: August 23, 2012.

Michael L. Wash,

Executive for Information Services/CIO.

[FR Doc. 2012–21709 Filed 8–31–12; 8:45 am]

BILLING CODE P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA)

publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

DATES: Requests for copies must be received in writing on or before October 4, 2012. Once the appraisal of the records is completed, NARA will send a copy of the schedule. NARA staff usually prepare appraisal memorandums that contain additional information concerning the records covered by a proposed schedule. These, too, may be requested and will be provided once the appraisal is completed. Requesters will be given 30 days to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting Records Management Services (ACNR) using one of the following means:

Mail: NARA (ACNR), 8601 Adelphi Road, College Park, MD 20740–6001

Email: request.schedule@nara.gov.

FAX: 301–837–3698

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports should so indicate in their request.

FOR FURTHER INFORMATION CONTACT: Margaret Hawkins, Director, National Records Management Program (ACNR), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. Telephone: 301–837–1799. Email: *request.schedule@nara.gov*.

SUPPLEMENTARY INFORMATION: Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media neutral unless specified otherwise. An item in a schedule is media neutral when the disposition instructions may be applied to records regardless of the medium in which the records are created and maintained. Items included in schedules submitted to NARA on or after December 17, 2007, are media neutral unless the item is limited to a specific medium. (See 36 CFR 1225.12(e).)

No Federal records are authorized for destruction without the approval of the Archivist of the United States. This approval is granted only after a thorough consideration of their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and whether or not they have historical or other value.

Besides identifying the Federal agencies and any subdivisions requesting disposition authority, this public notice lists the organizational unit(s) accumulating the records or indicates agency-wide applicability in the case of schedules that cover records that may be accumulated throughout an agency. This notice provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction). It also includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it too includes information about the records. Further information about the disposition process is available on request.

Schedules Pending

1. Department of Agriculture, Forest Service (N1–95–10–7, 10 items, 1 temporary item). Records related to geographic information system coordination. Proposed for permanent retention are fire dispatch logs, land transfer case files, records of high-level officials, special maps, surveys, and sign and poster guidelines.

2. Department of Defense, Office of the Secretary of Defense (N1–330–11–8, 2 items, 2 temporary items). Records relating to school accident and injury reports.

3. Department of Defense, Office of the Secretary of Defense (N1–330–11–9, 1 item, 1 temporary item). Records relating to the Pentagon force technical surveillance countermeasures investigations, including findings and mitigating recommendations.

4. Department of Health and Human Services, Centers for Medicare & Medicaid Services (DAA–0440–2012–0008, 1 item, 1 temporary item). Certifications, amendments, and other records related to the administration of the Medicaid program by each state.

5. Department of the Interior, Office of the Assistant Secretary of Indian Affairs (N1–75–09–7, 6 items, 1 temporary item). Scanned images of student scholastic and health documents that fail to meet archival standards. The original documents are saved in the corresponding paper files for permanent retention. Proposed for permanent retention are master files of an electronic information system containing information about Native American students.

6. Department of the Interior, Office of the Secretary (N1–48–11–1, 34 items, 4 permanent items). Records of the Office of Environmental Policy and Compliance, including records relating to environmental compliance, stewardship and partnerships, environmental reviews, and resource protection and planning. Proposed for permanent retention are environmental policy files, central hazardous materials fund site files for which the office has direct cleanup and restoration responsibility, sustainability reports and plans, and historically significant incident response files.

7. Department of the Interior, Office of the Secretary (DAA–0048–2012–0003, 1 item, 1 temporary item). Reference papers collected and used by the regulatory staff to respond to routine information requests from members of Congress and the courts.

8. Department of Justice, Antitrust Division (N1–60–11–5, 1 item, 1 temporary item). Ad hoc system reports about class action lawsuits. Proposed for permanent retention are master files of the electronic information system used to track class action lawsuits.

9. Department of the Navy, Agency-wide (DAA–0344–2012–0001, 2 items, 2

temporary items). Master files of an electronic information system containing information on explosive devices used for reference purposes by the Explosive Ordnance Disposal community of the Armed Services.

10. Department of State, Bureau of Diplomatic Security (DAA–0059–2011–0010, 3 items, 3 temporary items). Investigative case files of criminal and administrative misconduct involving personnel, contractors, and dependents at posts abroad and administrative misconduct by Department employees and contractors domestically. Also included are master files of an electronic information system that provides case tracking and management of information related to investigative cases.

11. Department of the Treasury, Internal Revenue Service (N1–58–11–1, 8 items, 8 temporary items). Master files, outputs, and documentation for an electronic system used to administer a low-income housing program. Also includes forms and other administrative records from this program.

12. National Oceanic and Atmospheric Administration, National Marine Fisheries Service (N1–370–12–2, 2 items, 2 temporary items). Master files of an electronic information system used to track appeals. Also includes appeals case files.

13. National Oceanic and Atmospheric Administration, National Environmental Satellite, Data and, Information Services (DAA–0370–2012–0001, 1 item, 1 temporary item). Non-disclosure agreements that prohibit unauthorized disclosure of information related to satellite systems and vendors.

Paul M. Wester, Jr.,

Chief Records Officer for the U.S. Government.

[FR Doc. 2012–21713 Filed 8–31–12; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits cancelled under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits cancelled under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

SUPPLEMENTARY INFORMATION: The permits were issued to Raytheon Polar Services Company (RPSC), the civilian support contractor to the National Science Foundation's Office of Polar Programs. On March 31, 2012, the contract expired and a new civilian support contractor, Lockheed Martin, Antarctic Support Contract took over on April 1, 2012. Effective on August 30, 2012, the following Raytheon Permits will be cancelled:

Permit No. 2012–009
Permit No. 2011–008
Permit No. 2011–009
Permit No. 2011–010
Permit No. 2011–011
Permit No. 2011–012
Permit No. 2011–013
Permit No. 2011–014
Permit No. 2011–015

Lockheed Martin has been issued some permits to replace those held by the previous support contractor. A notice of permits issued was published in the **Federal Register** on August 21, 2012.

Nadene G. Kennedy,

Permit Officer.

[FR Doc. 2012–21609 Filed 8–31–12; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0205]

Biweekly Notice;

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

Background

Pursuant to Section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC) is publishing this regular biweekly notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from August 8, 2012, to August 21, 2012. The last biweekly notice was published on August 21, 2012, (77 FR 50534).

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and are publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2012–0205.

You may submit comments by any of the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0205. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov*.
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2012–0205 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, by the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0205.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. Documents may be viewed in ADAMS by performing a search on the document date and docket number.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One

White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2012–0205 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS, and the NRC does not edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information in their comment submissions that they do not want to be publicly disclosed. Your request should state that the NRC will not edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in section 50.92 of Title 10 of the Code of Federal Regulations (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held

would take place before the issuance of any amendment.

All documents filed in the NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov*, or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html*, by email at *MSHD.Resource@nrc.gov*, or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/*, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as Social Security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Non-timely filings will not be entertained absent a determination by the presiding officer that the petition or request should be granted or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii).

For further details with respect to this license amendment application, see the application for amendment which is available for public inspection at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are

accessible electronically through ADAMS in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC's PDR Reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*.

Calvert Cliffs Nuclear Power Plant, LLC, Docket Nos. 50–317 and 50–318, Calvert Cliffs Nuclear Power Plant, Units 1 and 2, Calvert County, Maryland

Date of amendments request: July 2, 2012.

Description of amendments request: The amendment would revise Technical Specification (TS) 5.5.16 by increasing the calculated peak containment internal pressure (P_a) from 49.4 pounds per square inch gauge (psig) to 49.7 psig for the design basis loss-of-coolant accident (LOCA). In support of the revised P_a, the amendment would also revise the initial internal containment pressure limit in TS 3.6.4 by decreasing the upper bound initial pressure limit from 1.8 psig to 1.0 psig.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to P_a and the initial containment pressure limit does not alter the assumed initiators to any analyzed event. The probability of an accident previously evaluated will not be increased by this proposed change. The change in P_a and the initial containment pressure limit will not affect radiological dose consequence analyses. The radiological dose consequence analyses assume a certain containment atmosphere leak rate based on the maximum allowable containment leakage rate, which is not affected by the change in P_a. The Title 10 of the Code of Federal Regulations (10 CFR) Part 50, Appendix J containment leak rate testing program will continue to ensure that containment leakage remains within the leakage assumed in the offsite dose consequence analyses.

Therefore, operation of the facility in accordance with the proposed change to TSs 3.6.4 and 5.5.16 will not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different type of accident from any accident previously evaluated?

Response: No.

The proposed change provides a higher P_a than currently described in the TS. This change is a result of an increase in the mass and energy release input for the LOCA containment response analysis. The P_a remains below the containment design pressure of 50 psig because of the change in the initial containment pressure limit, which is an initial condition of the peak pressure calculation. This change does not involve any alteration in the plant configuration, no new or different type of equipment will be installed, or make changes in the methods governing normal plant operation.

Therefore, operation of the facility in accordance with the proposed change to TSs 3.6.4 and 5.5.16 would not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The P_a remains below the containment design pressure of 50 psig. Since the radiological consequence analyses are based on the maximum allowable containment leakage rate, which is not being revised, the change in the calculated peak containment pressure does not represent a significant change in the margin of safety.

Therefore, operation of the facility in accordance with the proposed change to TSs 3.6.4 and 5.5.16 does not involve a significant reduction in the margin of safety.

The Nuclear Regulatory Commission (NRC) staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendments request involves no significant hazards consideration.

Attorney for licensee: Steven L. Miller, General Counsel, Constellation Energy Nuclear Group, LLC, 100 Constellation Way, Suite 200c, Baltimore, MD 21202.

NRC Branch Chief: George Wilson.

Dominion Nuclear Connecticut, Inc., Docket No. 50–336, Millstone Power Station, Unit 2, New London County, Connecticut

Date of amendment request: July 31, 2012.

Description of amendment request: The proposed amendment would revise the Millstone Power Station, Unit 2 (MPS2) Technical Specification requirements regarding steam generator tube inspections and reporting as described in TSTF–510, Revision 2, ''Revision to Steam Generator Program Inspection Frequencies and Tube Sample Selection;'' however, Dominion Nuclear Connecticut, Inc. is proposing minor variations and deviations from TSTF–510.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises the Steam Generator (SG) Program to modify the frequency of verification of SG tube integrity and SG tube sample selection. A steam generator tube rupture (SGTR) event is one of the design basis accidents that are analyzed as part of a plant's licensing basis. The proposed SG tube inspection frequency and sample selection criteria will continue to ensure that the SG tubes are inspected such that the probability of a SGTR is not increased. The consequences of a SGTR are bounded by the conservative assumptions in the design basis accident analysis. The proposed change will not cause the consequences of a SGTR to exceed those assumptions. The proposed change to reporting requirements and clarifications of the existing requirements have no affect on the probability or consequences of SGTR.

Therefore, it is concluded that this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes to the SG Program will not introduce any adverse changes to the plant design basis or postulated accidents resulting from potential tube degradation. The proposed change does not affect the design of the SGs or their method of operation. In addition, the proposed change does not impact any other plant system or component.

Therefore, it is concluded that this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in the margin of safety?

Response: No.

The SG tubes in pressurized water reactors are an integral part of the reactor coolant pressure boundary and, as such, are relied upon to maintain the primary system's pressure and inventory. As part of the reactor coolant pressure boundary, the SG tubes are unique in that they are also relied upon as a heat transfer surface between the primary and secondary systems such that heat can be removed from the primary system. In addition, the SG tubes also isolate the radioactive fission products in the primary coolant from the secondary system. In summary, the safety function of a SG is maintained by ensuring the integrity of its tubes.

Steam generator tube integrity is a function of the design, environment, and the physical condition of the tube. The proposed change does not affect tube design or operating environment. The proposed change will continue to require monitoring of the

physical condition of the SG tubes such that there will not be a reduction in the margin of safety compared to the current requirements.

Therefore, it is concluded that the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Senior Counsel, Dominion Resources Services, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.

NRC Branch Chief: George A. Wilson.

Dominion Nuclear Connecticut, Inc., Docket No. 50–423, Millstone Power Station, Unit 3, New London County, Connecticut

Date of amendment request: July 31, 2012.

Description of amendment request: The proposed amendment would revise the Millstone Power Station, Unit 3 (MPS3) Technical Specification requirements regarding steam generator tube inspections and reporting as described in TSTF–510, Revision 2, ''Revision to Steam Generator Program Inspection Frequencies and Tube Sample Selection;'' however, Dominion Nuclear Connecticut, Inc. is proposing minor variations and deviations from TSTF–510.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises the Steam Generator (SG) Program to modify the frequency of verification of SG tube integrity and SG tube sample selection. A steam generator tube rupture (SGTR) event is one of the design basis accidents that are analyzed as part of a plant's licensing basis. The proposed SG tube inspection frequency and sample selection criteria will continue to ensure that the SG tubes are inspected such that the probability of a SGTR is not increased. The consequences of a SGTR are bounded by the conservative assumptions in the design basis accident analysis. The proposed change will not cause the consequences of a SGTR to exceed those assumptions. The proposed change to reporting requirements and clarifications of the existing requirements have no affect on the probability or consequences of SGTR.

Therefore, it is concluded that this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes to the SG Program will not introduce any adverse changes to the plant design basis or postulated accidents resulting from potential tube degradation. The proposed change does not affect the design of the SGs or their method of operation. In addition, the proposed change does not impact any other plant system or component.

Therefore, it is concluded that this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in the margin of safety?

Response: No.

The SG tubes in pressurized water reactors are an integral part of the reactor coolant pressure boundary and, as such, are relied upon to maintain the primary system's pressure and inventory. As part of the reactor coolant pressure boundary, the SG tubes are unique in that they are also relied upon as a heat transfer surface between the primary and secondary systems such that heat can be removed from the primary system. In addition, the SG tubes also isolate the radioactive fission products in the primary coolant from the secondary system. In summary, the safety function of a SG is maintained by ensuring the integrity of its tubes.

Steam generator tube integrity is a function of the design, environment, and the physical condition of the tube. The proposed change does not affect tube design or operating environment. The proposed change will continue to require monitoring of the physical condition of the SG tubes such that there will not be a reduction in the margin of safety compared to the current requirements.

Therefore, it is concluded that the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Senior Counsel, Dominion Resources Services, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.

NRC Branch Chief: George A. Wilson.

Exelon Generation Company, LLC (EGC), Docket Nos. STN 50–456 and STN 50–457, Braidwood Station, Units 1 and 2 (Braidwood), Will County, Illinois; Docket Nos. STN 50–454 and STN 50–455, Byron Station, Units 1 and 2 (Byron), Ogle County, Illinois

Date of amendment request: June 6, 2012.

Description of amendment request: The proposed amendment would modify Braidwood and Byron Technical Specifications (TS) to add a Note to Surveillance Requirements (SR) 3.3.1.7, 3.3.1.8, and 3.3.1.12 in TS 3.3.1, ''Reactor Trip System (RTS) Instrumentation,'' and SRs 3.3.2.2 and 3.3.2.6 in TS 3.3.2, ''Engineered Safety Features Actuation System (ESFAS) Instrumentation,'' to exclude the Solid State Protection System input relays from the Channel Operational Test Surveillance for RTS and ESFAS Functions with installed bypass capability which the U.S. Nuclear Regulatory Commission (NRC) approved by letters dated March 30, 2012, and April 9, 2012.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The Reactor Protection System (RPS) and ESFAS provide plant protection and are part of the accident mitigating response. The RTS and ESFAS functions do not themselves act at a precursor or an initiator for any transient or design basis accident. Therefore, the proposed change does not significantly increase the probability of any accident previously evaluated.

The proposed change does not alter the design assumptions, conditions, or configuration of the facility. The structural and functional integrity of the RTS and ESFAS, and any other plant system, is unaffected. The proposed change does not alter or prevent the ability of any structures, systems, and components from performing their intended function to mitigate the consequences of an initiating event within the applicable acceptance criteria. Surveillance testing in the bypass condition will not cause any design or analysis acceptance criteria to be exceeded

The impact of using bypass testing capability upon nuclear safety have been previously evaluated by the NRC and determined to be acceptable in [Westinghouse Atomic Power] WCAP 10271–P–A, Revision 1, WCAP 14333–P–A, Revision 1, and WCAP 15376–P–A, Revision 1. Thus, testing in bypass does not involve

a significant increase in the probability or consequences of an accident previously evaluated.

Implementation of the bypass testing capability does not affect the integrity of the fission product barriers utilized for the mitigation of radiological dose consequences as a result of an accident. The plant response as modeled in the safety analyses is unaffected by this change. Hence, the release used as input to the dose calculations are unchanged from those previously assumed.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not result in a change in the manner in which the RTS and ESFAS provide plant protection. The RTS and ESFAS will continue to have the same setpoints after the proposed change in implemented. In addition, no new failure modes are being created for any plant equipment. The change does not result in the creation of any changes to the existing accident scenarios nor do they create any new or different accident scenarios. The types of accidents defined in the UFSAR [Updated Final Safety Analysis Report] continue to represent the credible spectrum of events to be analyzed which determine safe operation.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

No safety analyses are changed or modified as a result of the proposed TS change to reflect installed bypass testing capability. The proposed change does not alter the manner in which the safety limits, limiting safety system setpoints, of limiting conditions for operation are determined. Margins associated with the current applicable safety analyses acceptance criteria are unaffected. The current safety analyses remain bounding since their conclusions are not affected by performing surveillance testing in bypass. The safety systems credited in the safety analyses will continue to be available to perform their mitigation functions.

Redundant RTS and ESFAS trains are maintained, and diversity with regard of the signals that provide reactor trip and engineered safety features actuation is also maintained. All signals credited as primary or secondary, and all operator actions credited in the accident analyses will remain the same. The proposed change will not result in plant operation in a configuration outside the design basis. Although there was no attempt to quantify any positive human factors benefit due to excluding the relays from the [Channel Operational Text] COT Surveillance for those RTS and ESFAS Functions that have installed bypass test capability, it is expected that there would be a new benefit due to a reduced potential for spurious reactor trips and actuations associated with testing.

Implementation of the proposed change is expected to result in an overall improvement of safety, as reduced testing will result in fewer inadvertent reactor trips, less frequent actuation of ESFAF components, less frequent distraction of operations personnel with significant affecting RTS and ESFAS reliability.

Therefore, the proposed change does not result in a significant reduction in the margin of safety.

Based on the above evaluation, EGC concludes that the proposed amendments do not involve a significant hazards consideration under the standards set forth in 10 CFR 50.92, (c), and, accordingly, a finding of no significant hazards consideration is justified.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

Attorney for licensee: Mr. Bradley J. Fewell, Associate General Counsel, Exelon Nuclear 4300 Winfield Road, Warrenville, IL 60555.

NRC Branch Chief: Michael I. Dudek.

Exelon Generation Company, LLC, and PSEG Nuclear LLC, Docket Nos. 50–277 and 50–278, Peach Bottom Atomic Power Station, Units 2 and 3, York and Lancaster Counties, Pennsylvania

Date of application for amendments: July 18, 2012.

Description of amendment request: The proposed amendment would revise the Technical Specifications (TSs) for Peach Bottom Atomic Power Station (PBAPS), Units 2 and 3 to change the operability requirements for the normal heat sink (NHS). The NHS for PBAPS is the Susquehanna River. Currently, in accordance with TS 3.7.2, the NHS is considered operable with a maximum water temperature of 90 °F. However, TS 3.7.2 also currently contains provisions to allow plant operation to continue if the NHS water temperature exceeds the 90 °F limit. Specifically, the NHS is still considered operable as long as the NHS temperature: (1) does not exceed 92 °F and; (2) is verified at least once per hour to be less than or equal to 90 °F when averaged over the previous 24-hour period. The proposed amendment would change the NHS water temperature limit such that the NHS would be considered operable as long as the maximum water temperature was less than or equal to 92 °F.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change allows plant operation to continue if the Normal Heat Sink (NHS) temperature does not exceed 92 °F. The water temperature limit imposed for the NHS exists to ensure the ability of safety systems to mitigate the consequences of an accident and does not involve the prevention or identification of any precursors of an accident. The water temperature of the NHS cannot adversely affect the initiator of any accident previously evaluated. This change does not affect the normal operation of the plant to the extent that any accident previously evaluated would be more likely to occur.

The safety objective of the water temperature limit for the NHS is to ensure that the heat removal capability of the Emergency Service Water (ESW) and High Pressure Service Water (HPSW) Systems is adequate to allow safety related equipment that is relied upon to mitigate the consequences of an accident or operational transient to perform its design function. The design basis heat removal capability of the affected components and systems is maintained at the NHS temperature limit, thus ensuring that the affected safety related components continuously perform their safety related function at the NHS temperature limit. The limits for equipment degradation ensure that the affected components continue to perform their design basis function. Consequently, the affected components maintain their design basis capability as previously assumed in [the] plant safety analyses.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequence of a previously evaluated accident.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change allows plant operation to continue if the Normal Heat Sink (NHS) temperature does not exceed 92 °F. The method of operation of components (heat exchangers, coolers, etc.), which rely on the NHS for cooling, is not altered by this activity. The water temperature limit imposed for the NHS exists to ensure the ability of plant safety equipment to mitigate the consequences of an accident and does not have the potential to create an accident initiator. This activity does not involve a physical change to any plant structure, system or component that is considered an accident initiator. The design basis heat removal capability of the affected components is maintained.

This license amendment request does not involve any changes to the operation, testing, or maintenance of any safety-related, or

otherwise important to safety systems. All systems important to safety will continue to be operated and maintained within their design bases.

Therefore, no new failure modes are introduced and the possibility of a new or different kind of accident is not created.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

Operation of PBAPS, Units 2 and 3 under the NHS temperature limit (92 °F) does not reduce the margin of safety as defined in the basis for any Technical Specification. Technical Specification Surveillance Requirement (SR) 3.7.2.2 defines the value for satisfying the Limiting Condition for Operation for the temperature of the NHS. A portion of the Technical Specification Bases for SR 3.7.2.2 states:

Verification of the Normal Heat Sink temperature ensures that the heat removal capability of the ESW and HPSW Systems is within the DBA [design-basis accident] analysis.

The basis for SR 3.7.2.2 has not changed as a result of the proposed [change]. The heat removal capability of the components that rely on the ESW and HPSW Systems for cooling is based on the Technical Specification temperature limit (92 °F) of the NHS and the performance capability of the equipment. Periodic testing and cleaning are required to verify and ensure that the assumed degree of degradation is not reached. The limits for equipment degradation ensure that affected components continue to perform their design basis function.

Therefore, since the design basis capability of the affected components is maintained at the NHS temperature limit (92 °F), this change does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for Licensee: Mr. J. Bradley Fewell, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Kennett Square, PA 19348.

NRC Branch Chief: Meena K. Khanna.

FirstEnergy Nuclear Operating Company, et al., Docket Nos. 50–334 and 50–412, Beaver Valley Power Station, Units 1 and 2, Beaver County, Pennsylvania

Date of amendment request: July 25, 2012.

Description of amendment request: The proposed amendment would modify Technical Specification (TS) 3.1.3 to allow the normally required near-end of life Moderator Temperature Coefficient (MTC) measurement to not be performed under certain conditions. If these specified conditions are met, the MTC measurement would be replaced by a calculated value.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below, with NRC edits in brackets:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

This amendment request would change the near-end of life (EOL) moderator temperature coefficient (MTC) surveillance requirement (SR) to allow [] the required MTC measurement [to be eliminated] under certain conditions. This change would not result in physical alteration of a plant structure, system or component, or installation of new or different types of equipment. Modification of the surveillance requirement under certain conditions would not affect the probability of accidents previously evaluated in the Updated Final Safety Analysis Report (UFSAR) or cause a change to any of the dose analyses associated with the UFSAR accidents because accident mitigation functions would remain unchanged. Existing MTC TS limits would remain unchanged and would continue to be satisfied.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

This amendment request would change the near EOL MTC SR to allow [] the required MTC measurement [to be eliminated] under certain conditions. No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of the proposed change. No physical plant alterations are made as a result of the proposed change. The proposed change does not challenge the performance or integrity of any safety related system. MTC is a variable that must remain within limits but is not an accident initiator.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

This amendment request would change the near EOL MTC SR to allow [] the required MTC measurement to be eliminated under certain conditions. The margin of safety associated with the acceptance criteria of accidents previously evaluated in the UFSAR is unchanged. The proposed change would have no affect on the availability, operability, or performance of the safety-related systems and components. A change to a surveillance is proposed based on an alternate method of confirming that the surveillance requirement is met. The Technical Specification limiting condition for operation (LCO) limits for MTC remain unchanged.

The Technical Specifications establish limits for the moderator temperature coefficient based on assumptions in the UFSAR accident analyses. Applying the conditional [elimination of] the moderator temperature coefficient measurement changes the method of meeting the surveillance requirement; however this change does not modify the TS values and ensures adherence to the current TS limits. The basis for derivation of the moderator temperature coefficient limits from the moderator density coefficient assumed in the accident analysis would not change.

Therefore, the margin of safety as defined in the TS is not reduced and the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and based on this review, with the edits noted above, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David W. Jenkins, FirstEnergy Nuclear Operating Company, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

NRC Branch Chief: Meena Khanna.

Florida Power and Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Plant, Units 3 and 4, Miami-Dade County, Florida

Date of amendment request: July 16, 2012, as supplemented by letter dated August 10, 2012.

Description of amendment request: The proposed amendments would modify Technical Specification (TS) requirements regarding steam generator tube inspections and reporting as described in Technical Specification Task Force Traveler 510, Revision 2, ''Revision to Steam Generator Program Inspection Frequencies and Tube Sample Selection.'' The proposed changes would revise TS 3/4.4.5, ''Steam Generator (SG) Tube Integrity,'' TS 6.8.4.j, ''Steam Generator (SG) Program.'' and TS 6.9.1.8, ''Steam Generator Tube Inspection Report.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises the Steam Generator (SG) Program to modify the frequency of verification of SG tube integrity

and SG tube sample selection. A steam generator tube rupture (SGTR) event is one of the design basis accidents that are analyzed as part of a plant's licensing basis. The proposed SG tube inspection frequency and sample selection criteria will continue to ensure that the SG tubes are inspected such that the probability of a SGTR is not increased. The consequences of a SGTR are bounded by the conservative assumptions in the design basis accident analysis. The proposed change will not cause the consequences of a SGTR to exceed those assumptions.

Therefore, it is concluded that this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes to the Steam Generator Program will not introduce any adverse changes to the plant design basis or postulated accidents resulting from potential tube degradation. The proposed change does not affect the design of the SGs or their method of operation. In addition, the proposed change does not impact any other plant system or component.

Therefore, it is concluded that this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The SG tubes in pressurized water reactors are an integral part of the reactor coolant system pressure boundary and, as such, are relied upon to maintain the primary system's pressure and inventory. As part of the reactor coolant system pressure boundary, the SG tubes are unique in that they are also relied upon as a heat transfer surface between the primary and secondary systems such that residual heat can be removed from the primary system. In addition, the SG tubes also isolate the radioactive fission products in the primary coolant from the secondary system. In summary, the safety function of a SG is maintained by ensuring the integrity of its tubes.

Steam generator tube integrity is a function of the design, environment, and the physical condition of the tube. The proposed change does not affect tube design or operating environment. The proposed change will continue to require monitoring of the physical condition of the SG tubes such that there will not be a reduction in the margin of safety compared to the current requirements.

Therefore, it is concluded that the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: M.S. Ross, Attorney, Florida Power & Light, P.O. Box 14000, Juno Beach, Florida 33408–0420.

NRC Acting Branch Chief: Jessie F. Quichocho.

Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant (HNP), Units 1 and 2, Appling County, Georgia

Date of amendment request: July 5, 2012.

Description of amendment request: The proposed amendments would revise Technical Specification (TS) Limiting Condition for Operation (LCO) for the plant service water (PSW) and ultimate heat sink (UHS). Specifically, the surveillance requirement (SR) for the minimum water level in each PSW pump well of the intake structure would be revised from the existing value to a lower value. This change is based on updated design basis analyses that demonstrate that at the new minimum level sufficient water inventory remains available from the Altamaha River for PSW and residual heat removal service water (RHRSW) to handle Loss of Coolant Accident (LOCA) cooling requirements for 30 days post-accident with no additional makeup water source available.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed TS change revises the minimum water level in the PSW pump well, as required by SR 3.7.2.1, from 60.7 [feet] ft [mean sea level] MSL to 60.5 ft MSL. TS SR 3.7.2.1 verifies that the UHS is OPERABLE by ensuring the water level in the PSW pump well of the intake structure is sufficient for the PSW, RHRSW and standby service water pumps to supply post-LOCA cooling requirements for 30 days. The safety function of the UHS is to mitigate the impact of an accident. The proposed TS change does not result in or require any physical changes to HNP systems, structures, and components, including those intended for the prevention of accidents. The potential impact of the lower PSW pump well minimum water level on pump operation requirements, supply of water for 30 days post-LOCA, and potential environmental impact have been evaluated and found to be acceptable.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed TS change revises the minimum water level in the PSW pump well, as required by SR 3.7.2.1, from 60.7 ft MSL to 60.5 ft MSL. TS SR 3.7.2.1 verifies that the UHS is OPERABLE by ensuring the water level in the PSW pump well of the intake structure is sufficient for the PSW, RHRSW and standby service water pumps to supply post-LOCA cooling requirements for 30 days. The proposed TS change does not result in or require any physical changes to HNP systems, structures, and components. The potential impact of the lower PSW pump well minimum water level on pump operation requirements, supply of water for 30 days post-LOCA, and potential environmental impact have been evaluated and found to be acceptable.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed TS change revises the minimum water level in the PSW pump well, as required by SR 3.7.2.1, from 60.7 1t MSL to 60.5 1t MSL. TS SR 3.7.2.1 verifies that the UHS is OPERABLE by ensuring the water level in the PSW pump well of the intake structure is sufficient for the PSW, RHRSW and standby service water pumps to supply post-LOCA cooling requirements for 30 days. The proposed TS change does not result in or require any physical changes to HNP systems, structures, and components. The potential impact of the lower PSW pump well minimum water level on pump operation requirements, supply of water for 30 days post-LOCA, and potential environmental impact have been evaluated and found to be acceptable.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street NW., Washington, DC 20037.

NRC Branch Chief: Nancy L. Salgado.

Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: May 2, 2012.

Description of amendment request: The amendment would revise Technical Specification (TS) 3.6.6, ''Containment Spray and Cooling Systems,'' to replace the 10-year surveillance frequency for testing the containment spray nozzles as required by TS Surveillance Requirement 3.6.6.8 with an event-based frequency.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The Containment Spray System and its spray nozzles are not accident initiators and therefore, the proposed change does not involve a significant increase in the probability of an accident. The revised surveillance requirement will require event-based Frequency verification in lieu of fixed Frequency verification. The proposed change does not have a detrimental impact on the integrity of any plant structure, system, or component that may initiate an analyzed event. The proposed change will not alter the operation or otherwise increase the failure probability of any plant equipment that can initiate an analyzed accident.

This change does not affect the plant design. There is no increase in the likelihood of formation of significant corrosion products. Due to their location at the top of the containment, introduction of foreign material into the spray headers is unlikely. Foreign material introduced during maintenance activities would be the most likely source for obstruction, and verification following such maintenance would confirm the nozzles remain unobstructed. Since the Containment Spray System will continue to be available to perform its accident mitigation function, the consequences of accidents previously evaluated are not significantly increased.

Therefore, the consequences of an accident previously evaluated are not significantly affected by the proposed change.

2. Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change will not physically alter the plant (no new or different type of equipment will be installed) or change the methods governing normal plant operation. The proposed change does not introduce new accident initiators or impact assumptions made in the safety analysis. Testing requirements continue to demonstrate that the Limiting Conditions for Operation are met and the system components are functional.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

Response: No.

The system is not susceptible to corrosion-induced obstruction or obstruction from sources external to the system. Maintenance activities that could introduce foreign material into the system would require subsequent verification to ensure there is no nozzle blockage. The spray header nozzles are expected to remain unblocked and available in the event that the safety function is required. Therefore, the capacity of the system would remain unaffected. The proposed change does not relax any criteria used to establish safety limits and will not relax any safety system settings. The safety analysis acceptance criteria are not affected by this change.

Therefore the proposed change does not involve a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jay Silberg, Esq., Pillsbury Winthrop Shaw Pittman LLP, 2300 N Street NW., Washington, DC 20037.

NRC Branch Chief: Michael T. Markley.

Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: April 26, 2012.

Description of amendment request: The amendment would revise the Technical Specifications (TSs) to adopt Technical Specification Task Force (TSTF) Change Traveler TSTF–510, Revision 2, ''Revision to Steam Generator Program Inspection Frequencies and Tube Sample Selection,'' using the consolidated line item improvement program (CLIIP). The NRC staff issued a notice of availability of the model for referencing in license amendment applications in the **Federal Register** on October 27, 2011 (76 FR 66763).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises the Steam Generator (SG) Program to modify the frequency of verification of SG tube integrity and SG tube sample selection. A steam generator tube rupture (SGTR) event is one of the design basis accidents that are analyzed as part of a plant's licensing basis. The proposed SG tube inspection frequency and sample selection criteria will continue to ensure that the SG tubes are inspected such that the probability of a SGTR is not increased. The consequences of a SGTR are bounded by the conservative assumptions in the design basis accident analysis. The proposed change will not cause the consequences of a SGTR to exceed those assumptions.

Therefore, it is concluded that this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes to the SG Program will not introduce any adverse changes to the plant design basis or postulated accidents resulting from potential tube degradation. The proposed change does not affect the design of the SGs or their method of operation. In addition, the proposed change does not impact any other plant system or component.

Therefore, it is concluded that this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The SG tubes in pressurized water reactors are an integral part of the reactor coolant pressure boundary and, as such, are relied upon to maintain the primary system's pressure and inventory. As part of the reactor coolant pressure boundary, the SG tubes are unique in that they are also relied upon as a heat transfer surface between the primary and secondary systems such that residual heat can be removed from the primary system. In addition, the SG tubes also isolate the radioactive fission products in the primary coolant from the secondary system. In summary, the safety function of a SG is maintained by ensuring the integrity of its tubes.

Steam generator tube integrity is a function of the design, environment, and the physical condition of the tube. The proposed change does not affect tube design or operating environment. The proposed change will continue to require monitoring of the physical condition of the SG tubes such that there will not be a reduction in the margin of safety compared to the current requirements.

Therefore, it is concluded that the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jay Silberg, Esq., Pillsbury Winthrop Shaw Pittman LLP, 2300 N. Street NW., Washington, DC 20037.

NRC Branch Chief: Michael T. Markley.

Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the NRC's Public Document Room (PDR), located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are accessible electronically through the Agencywide Documents Access and Management System (ADAMS) in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR's Reference staff at 1–800–397–4209, 301–415–4737 or by email to *pdr.resource@nrc.gov*.

Calvert Cliffs Nuclear Power Plant, LLC, Docket Nos. 50–317 and 50–318, Calvert Cliffs Nuclear Power Plant, Units 1 and 2, Calvert County, Maryland

Date of application for amendments: August 8, 2011, as supplemented by letters dated January 11, May 7, and July 18, 2012.

Brief description of amendments: The amendments would modify Technical Specification (TS) 3.8.1, ''AC Sources—Operating,'' Surveillance Requirement (SR) 3.8.1.11 by revising the required power factor value to be achieved by the diesel generators (DGs) during conduct of the surveillance test. The proposed change would also modify the existing note in SR 3.8.1.11 to allow the DG to not achieve the required power factor if the grid conditions do not permit and the test is performed with DG synchronized with offsite power.

Date of issuance: August 22, 2012.

Effective date: As of the date of issuance to be implemented within 90 days.

Amendment Nos.: 302 and 279.

Renewed Facility Operating License Nos. DPR–53 and DPR–69: Amendments revised the License and TSs.

Date of initial notice in **Federal Register**: November 29, 2011 (76 FR 73729).

The Commission's related evaluation of these amendments is contained in a Safety Evaluation dated August 22, 2012.

No significant hazards consideration comments received: No.

Dominion Nuclear Connecticut, Inc., Docket No. 50–336, Millstone Power Station, Unit 2, New London County, Connecticut

Date of application for amendment: July 17, 2011, as supplemented by two letters dated August 9, 2012.

Brief description of amendment: The amendment revises Final Safety Analysis Report (FSAR) Section 9.7.2.1.2, and Appendix B to provide additional operating margin for measurement of the Ultimate Heat Sink (UHS) temperature. The proposed change to Appendix B is to remove a license condition that is no longer needed.

Date of issuance: August 10, 2012.

Effective date: As of the date of issuance, and shall be implemented within 30 days.

Amendment No.: 311.

Renewed Facility Operating License No. DPR–65: Amendment revised the License and Appendix B.

Public comments requested as to proposed no significant hazards consideration (NSHC): No.

The Commission's related evaluation of the amendment, finding of emergency circumstances, and final determination of no significant hazards consideration are contained in a Safety Evaluation dated August 10, 2012.

Attorney for licensee: Lillian M. Cuoco, Senior Counsel, Dominion Resources Services, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.

NRC Branch Chief: George A. Wilson.

Entergy Nuclear Operations, Inc., Docket No. 50–293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts

Date of application for amendment: October 28, 2011, as supplemented on May 16, 2012.

Brief description of amendment: This amendment request would revise the Technical Specifications (TSs) to increase the condensate storage tank low water level setpoint for the interlock to the high pressure coolant injection pump suction valves. Additionally, the amendment would correct typographical errors in TS numbering and referencing made in prior license amendment nos. 223 and 228.

Date of issuance: August 7, 2012.

Effective date: As of the date of issuance, and shall be implemented within 60 days.

Amendment No.: 237.

Facility Operating License No. DPR–35: The amendment revised the License and Technical Specifications.

Date of initial notice in **Federal Register**: January 10, 2012 (77 FR 1517).

The supplemental letter dated May 16, 2012, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated August 7, 2012.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–424 and 50–425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of application for amendments: July 26, 2011.

Brief description of amendments: The amendments revised the Technical Specifications (TSs). Specifically, the change revised the minimum indicated nitrogen cover pressure specified for the accumulators in TS surveillance requirement (SR) 3.5.1.3 from 617 psig (pounds per square inch, gauge) to 626 psig. The amendments also correct a typographical error in the text associate with SR 3.6.2.1 changing the word ''rage'' to ''rate.''

Date of issuance: August 14, 2012.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment Nos.: Unit 1–166 and Unit 2–148.

Facility Operating License Nos. NPF–68 and NPF–81: Amendments revised the licenses and the technical specifications.

Date of initial notice in **Federal Register**: September 6, 2011.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 14, 2012.

No significant hazards consideration comments received: No.

STP Nuclear Operating Company, Docket Nos. 50–498 and 50–499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: August 23, 2011.

Brief description of amendments: The amendments revised the application of Risk-Managed Technical Specifications (RMTS) to Technical Specification (TS) 3.7.7, ''Control Room Makeup and Cleanup Filtration System.'' The amendments corrected a potential misapplication of the Configuration Risk Management Program (CRMP) that is currently allowed by the TSs.

Date of issuance: August 14, 2012.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: Unit 1–199; Unit 2–187.

Facility Operating License Nos. NPF–76 and NPF–80: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in **Federal Register**: November 1, 2011 (76 FR 67490).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 14, 2012.

No significant hazards consideration comments received: No.

Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing (Exigent Public Announcement or Emergency Circumstances)

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual notice of consideration of issuance of amendment, proposed no significant hazards consideration determination, and opportunity for a hearing.

For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its no significant hazards consideration determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the application for amendment, (2) the amendment to Facility Operating License or Combined License, as applicable, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items are available for public inspection at the NRC's Public Document Room (PDR), located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are accessible electronically through the Agencywide Documents Access and Management System (ADAMS) in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR's Reference staff at 1–800–397–4209, 301–415–4737 or by email to *pdr.resource@nrc.gov.*

The Commission is also offering an opportunity for a hearing with respect to the issuance of the amendment. Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852, and electronically on the Internet at the NRC's Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If there are problems in accessing the document, contact the PDR's Reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact.[1] Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Each contention shall be given a separate numeric or alpha designation within one of the following groups:

1. Technical—primarily concerns/issues relating to technical and/or health and safety matters discussed or referenced in the applications.

2. Environmental—primarily concerns/issues relating to matters discussed or referenced in the environmental analysis for the applications.

3. Miscellaneous—does not fall into one of the categories outlined above.

As specified in 10 CFR 2.309, if two or more petitioners/requestors seek to co-sponsor a contention, the petitioners/requestors shall jointly designate a representative who shall have the authority to act for the petitioners/requestors with respect to that contention. If a requestor/petitioner seeks to adopt the contention of another sponsoring requestor/petitioner, the requestor/petitioner who seeks to adopt the contention must either agree that the sponsoring requestor/petitioner shall act as the representative with respect to that contention, or jointly designate with the sponsoring requestor/petitioner a representative who shall have the authority to act for the petitioners/requestors with respect to that contention.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing. Since the Commission has made a final determination that the amendment involves no significant hazards consideration, if a hearing is requested, it will not stay the effectiveness of the amendment. Any hearing held would take place while the amendment is in effect.

All documents filed in the NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov*, or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not

[1] To the extent that the applications contain attachments and supporting documents that are not publicly available because they are asserted to contain safeguards or proprietary information, petitioners desiring access to this information should contact the applicant or applicant's counsel and discuss the need for a protective order.

support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html*.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html*. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html*, by email at MSHD.Resource@nrc.gov, or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/*, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Dated at Rockville, Maryland, this 24th day of August 2012.

For The Nuclear Regulatory Commission.

Michele G. Evans,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–21545 Filed 8–31–12; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Cancellation Notice—OPIC September 6, 2012 Public Hearing

OPIC's Sunshine Act notice of its Public Hearing in Conjunction with each Board meeting was published in the **Federal Register** (Volume 77, Number 159, Pages 49472 and 49473) on August 16, 2012. No requests were received to provide testimony or submit written statements for the record; therefore, OPIC's public hearing scheduled for 3 p.m., September 6, 2012 in conjunction with OPIC's September 13, 2012 Board of Directors meeting has been cancelled.

Contact Person For Information: Information on the hearing cancellation may be obtained from Connie M. Downs at (202) 336–8438, or via email at *Connie.Downs@opic.gov.*

Dated: August 30, 2012.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 2012–21794 Filed 8–30–12; 11:15 am]

BILLING CODE 3210–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Cancellation Notice—OPIC's September 6, 2012 Annual Public Hearing

OPIC's Sunshine Act notice of its Annual Public Hearing was published in the **Federal Register** (Volume 77, Number 143, Page 43618) on July 25, 2012. No requests were received to provide testimony or submit written statements for the record; therefore, OPIC's Annual Public Hearing scheduled for 2 p.m., September 6, 2012 has been cancelled.

CONTACT PERSON FOR INFORMATION: Information on the hearing cancellation may be obtained from Connie M. Downs at (202) 336–8438, via facsimile at (202) 218–0136, or via email at *Connie.Downs@opic.gov.*

Dated: August 30, 2012.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 2012–21795 Filed 8–30–12; 11:15 am]

BILLING CODE 3210–01–P

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

Board Votes To Close August 23, 2012, Meeting

By telephone vote on August 23, 2012, members of the Board of Governors of the United States Postal Service met and voted unanimously to close to public observation its meeting held in Washington, DC, via teleconference. The Board determined that no earlier public notice was possible.

ITEMS CONSIDERED:

1. Strategic Issues.
2. Financial Matters.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting was properly closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Requests for information about the meeting should be addressed to the Secretary of the Board, Julie S. Moore, at (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. 2012–21860 Filed 8–30–12; 4:15 pm]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and purpose of information collection Request for Medicare Payment; OMB 3220–0131 under Section 7(d) of the Railroad Retirement Act, the RRB administers the Medicare program for persons covered by the railroad retirement system. The collection obtains the information needed by Palmetto GBA, the Medicare carrier for railroad retirement beneficiaries, to pay claims for payments under Part B of the Medicare program. Authority for collecting the information is prescribed in 42 CFR 424.32.

The RRB currently utilizes Forms G–740S, Patient's Request for Medicare Payment, along with Centers for Medicare & Medicaid Services Form CMS–1500, to secure the information necessary to pay Part B Medicare Claims. One response is completed for each claim. Completion is required to obtain a benefit. The RRB proposes minor, non-burden impacting editorial and cosmetic changes to RRB Form G–740S.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

[The estimated annual respondent burden is as follows]

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–740S	100	15	25

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV*. Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or emailed to *Charles.Mierzwa@RRB.GOV*. Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2012–21697 Filed 8–31–12; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30183; 813–379]

Alvarez & Marsal, Inc., et al.; Notice of Application

August 28, 2012.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an order under sections 6(b) and 6(e) of the Investment Company Act of 1940 (''Act'') granting an exemption from all provisions of the Act, except sections 9, 17, 30, and 36 through 53, and the rules and regulations under the Act (the ''Rules and Regulations''). With respect to sections 17(a), (d), (f), (g), and (j) of the Act, sections 30(a), (b), (e), and (h) of the Act and the Rules and Regulations, and rule 38a–1 under the Act, applicants request a limited exemption as set forth in the application.

Summary of Application: Applicants request an order to exempt certain limited partnerships and other entities formed for the benefit of eligible employees of Alvarez & Marsal, Inc. and its affiliates from certain provisions of the Act. Each partnership will be an ''employees' securities company'' within the meaning of section 2(a)(13) of the Act.

Applicants: Alvarez & Marsal, Inc. (''A&M Inc.''), Alvarez & Marsal Capital, LLC (''A&M Capital''), A&M Capital-GP, LP (''A&M Capital-GP''), Alvarez & Marsal Partners Fund, LP, and Alvarez & Marsal Partners Buyout Fund, LP.

Filing Dates: The application was filed on August 13, 2010, and amended on February 11, 2011, and May 4, 2012.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests

should be received by the Commission by 5:30 p.m. on September 24, 2012, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Elizabeth M. Murphy, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: Alvarez & Marsal, Inc., 600 Lexington Avenue, 6th Floor, New York, NY 10022.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Senior Counsel, at (202) 551–6876, or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. A&M Inc. is a New York corporation that is privately held and controlled by Antonio C. Alvarez II and Bryan P. Marsal. A&M Inc. and its ''affiliates,'' as defined in rule 12b–2 under the Securities Exchange Act of 1934 (the ''Exchange Act''), other than Third Party Funds (as defined below), are referred to collectively as the ''A&M Group'' and individually as an ''A&M Group entity.'' The A&M Group is one of the world's leading global professional services firms, providing, as its principal business, comprehensive performance improvement, turnaround management, and business advisory services to clients ranging from global enterprises to middle market companies that are publicly held or privately owned.

2. Alvarez & Marsal Partners Fund, LP and Alvarez & Marsal Partners Buyout Fund, LP are each a Delaware limited partnership (together, the ''Initial Funds''). A&M Capital and A&M Capital-GP, each a Delaware limited liability company, and A&M Inc. organized the Initial Funds, and may in the future organize limited partnerships, limited liability companies, business trusts or other entities (each an ''Other Fund,'' and together with the Initial Funds, the ''Funds'').

3. The Funds will be established primarily for the benefit of key Professionals (as defined below) of the A&M Group, as part of a program designed to create capital building opportunities that are competitive with those at other global professional services firms and to facilitate the A&M Group's recruitment and retention of high caliber Professionals. These programs may be structured as different Funds, or as separate series within the same Fund. Each Fund will be an ''employees' securities company'' within the meaning of section 2(a)(13) of the Act. Each of the Funds will operate as a non-diversified, closed-end management company within the meaning of the Act. The A&M Group will control the Funds within the meaning of section 2(a)(9) of the Act.

4. Each Fund will have a manager that is an A&M Group entity (''Manager''). A&M Capital and A&M Capital-GP will serve as the Managers of the Initial Funds. The Manager will manage, operate and control each of the Funds. The Manager will be authorized to delegate to an A&M Group entity or to a committee of A&M Group employees such management responsibility provided that the ultimate responsibility for and control of each Fund remain with the Manager. The Manager will delegate management responsibility only to entities that control, are controlled by, or are under common control with A&M Inc. The Manager or the A&M Group entity acting as the investment adviser to a Fund will register as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act'') if required under applicable law. Applicants represent and concede that the Manager in managing a Fund is an ''investment adviser'' within the meaning of sections 9 and 36 of the Act and is subject to those sections.

5. A Fund may pay a management or an administrative fee to its Manager or an A&M Group entity. The Manager, the A&M Group, or any employees of the Manager or the A&M Group may be entitled to receive compensation or a performance-based fee (a ''carried interest'') [1] based on the gains and losses of the investment program or of the Fund's investment portfolio.

6. Interests in the Funds (''Interests'') will be offered without registration in reliance on section 4(2) of the Securities Act of 1933 (the ''Securities Act'') or Regulation D or Regulation S under the Securities Act, and will be sold only to the A&M Group, Eligible Employees and Eligible Consultants, and certain related persons of Eligible Employees and Eligible Consultants, each as defined below. Prior to offering an Interest to a natural person, the Manager must reasonably believe that the natural person is a sophisticated investor capable of understanding and evaluating the risks of participating in the Fund without the benefit of regulatory safeguards. Investment in the Funds will be voluntary.

7. Only those Professionals of the A&M Group who qualify as ''Eligible Employees'' will be able to participate in the Funds. In order to qualify as an ''Eligible Employee,'' an individual must (a) be a principal, partner (or equivalent), officer, director [2] or current or former employee (provided that such former employee was a current employee at the time of investment) of an A&M Group entity (each, a ''Professional'') and (b) meet the standards of an ''accredited investor'' as defined in rule 501(a)(5) or 501(a)(6) of Regulation D or be one of a maximum of 35 individuals who are either (i) ''knowledgeable employees,'' as defined in rule 3c–5(a)(4) under the Act of the Fund (with the Fund treated as though it were a ''covered company'' for purposes of the rule) or (ii) individuals who (1) have a graduate degree in business, law or accounting, (2) have a minimum of three years of consulting, investment management, investment banking, financial services, legal or similar business experience, and (3) will have had reportable income from all sources (including any profit shares or bonus) of $100,000 in each of the two most recent years immediately preceding such individual's admission as a partner or member of a Fund (''Member'') and will have a reasonable expectation of income from all sources of at least $140,000 in each year in which such individual invests in a Fund

[1] A ''carried interest'' is an allocation to the Manager based on the net gains of an investment program. A Manager that is registered as an investment adviser under the Advisers Act may charge a carried interest only if permitted by rule 205–3 under the Advisers Act. Any carried interest paid to a Manager that is not registered under the Advisers Act will be structured to comply with section 205(b)(3) of the Advisers Act as if a Fund were a business development company as defined in the Advisers Act.

[2] Certain entities of the A&M Group are structured as partnerships or LLCs. The principals and partners (or equivalent) of these entities are owners of the entities rather than employees. However, such principals and partners perform identical functions to those of an employee and therefore are treated as employees for purposes of section 2(a)(13) of the Act. In order to qualify as an Eligible Employee, any current or former officer or director must be an employee or former employee (or person on retainer) within the meaning of section 2(a)(13) of the Act.

(such individuals, ''Non-Accredited Investors''). Any Fund offering will be limited to no more than 35 Non-Accredited Investors. In addition, an Eligible Employee in category (ii) above must meet the requirements set forth in rule 506(b) of Regulation D and will not be permitted to invest in any year more than 10% of his or her income from all sources for the immediately preceding year in the aggregate in the Fund and in all other Funds in which that Eligible Employee has previously invested. It is anticipated that, in the discretion of the Manager, Eligible Consultants (as defined below) of the A&M Group may be offered the opportunity to participate in the Funds.[3]

8. In the discretion of the Manager of a Fund and at the request of an Eligible Employee or Eligible Consultant, Interests may be assigned by such Eligible Employee or Eligible Consultant, or sold directly by the Fund, to a Qualified Entity or Eligible Family Member (each as defined below and, collectively, ''Qualified Participants'') of such Eligible Employee or Eligible Consultant. A ''Qualified Entity'' is (a) a trust of which the trustee, grantor and/or beneficiary is an Eligible Employee or Eligible Consultant, (b) a partnership, limited liability company, corporation or other entity controlled by an Eligible Employee or Eligible Consultant, or (c) an individual retirement account, trust, or other entity established solely for the benefit of an Eligible Employee, Eligible Consultant, or Eligible Family Members. An ''Eligible Family Member'' is a parent, sibling, spouse, child, spouse of a child, or grandchild of an Eligible Employee or Eligible Consultant (including step and adoptive relationships). If an Eligible Family Member is purchasing an Interest, such Eligible Family Member must come within one of the categories of an ''accredited investor'' under rule 501(a) of Regulation D. An Eligible Employee, Eligible Consultant or Eligible Family Member may purchase an Interest through a Qualified Entity only if either (a) the investment vehicle is an ''accredited investor'' as defined in rule 501(a) of Regulation D or (b) the Eligible Employee, Eligible Consultant, or Eligible Family Member is the settlor[4] and principal investment decision-maker with respect to the investment vehicle.[5] Qualified Entities that are not accredited investors will be included toward the limit of 35 Non-Accredited Investors discussed above.

9. The terms of a Fund will be fully disclosed to each Eligible Employee and Eligible Consultant, and, if applicable, to a Qualified Participant, at the time they are invited to participate in the Fund. Each Eligible Employee and Eligible Consultant and their Qualified Participants will be furnished with a private placement memorandum or other offering document, including a copy of the operating agreement or other organizational documents (the ''Operating Agreement'') for the relevant Fund. The Funds will send the Members annual financial statements audited by independent public accountants as soon as practicable after the end of the fiscal year of each of the Funds.[6] The Manager of each Fund, within 120 days after the end of the fiscal year of such Fund, or as soon as practicable thereafter, will send a report to each person who was a Member of such Fund at any time during the fiscal year then ended, setting forth such tax information as shall be necessary for the preparation by the Member of his, her or its federal and state income tax returns and a report of the investment activities of such Fund during that year.

10. Interests in each Fund will be non-transferable except with the prior written consent of the Manager, and, in any event, no person or entity will be admitted into a Fund as a Member unless such person or entity is an Eligible Employee, Eligible Consultant, a Qualified Participant or an A&M Group entity. The Interests in the Funds will be sold without a sales load.

11. If an Eligible Employee's or Eligible Consultant's relationship with the A&M Group terminates for any reason, including death, disability, termination, retirement, or withdrawal, his/her Interest may be subject to repurchase, reallocation, redemption, mandatory transfer, or cancellation. In the case of Interests held by an Eligible Consultant or its Qualified Participants, if any, whose retainer has been terminated or has expired, such Interests will be subject to mandatory redemption or repurchases by an A&M Group entity, or the A&M Group entity may require the former Eligible Consultant, or its Qualified Participants, to sell such Interests to an Eligible Employee or Eligible Consultant. Pursuant to a formula set forth in a Fund's Operating Agreement, the Member will, at a minimum, receive an amount equal to or greater than the lesser of (a) the amount actually paid by the Member to acquire the Interest plus interest less prior distributions and (b) the fair market value of the Interest as determined in good faith at the time of repurchase or cancellation by the Manager. The terms of any such redemption or resale will apply equally to any Qualified Participant of an Eligible Employee or Eligible Consultant.

12. It is possible that an investment program may be structured in which a Fund will co-invest in a portfolio investment with an A&M Group entity or an investment fund or separate account, organized primarily for the benefit of investors who are not affiliated with the A&M Group, over which an A&M Group entity exercises investment discretion (a ''Third Party Fund''). Subject to the terms of the applicable Operating Agreement and the requested order, a Fund will be permitted to enter into transactions involving (a) an A&M Group entity, (b) a Fund investment, (c) any Member or person or entity affiliated with a Member, (d) a Third Party Fund, or (e) any partner or other investor of a Third Party Fund that is not affiliated with the A&M Group (''Third Party Investor'').

13. A Fund may borrow from an A&M Group entity. In such case, the Manager or another A&M Group entity may make loans to a Fund, which would bear interest at a rate no less favorable than the rate of interest that could be obtained on an arm's length basis from third party lenders. Any borrowing by a Fund will be non-recourse to the Members other than the Manager. A Fund will not borrow from any person if the borrowing would cause any person not named in section 2(a)(13) of the Act to own securities of the Fund (other than short-term paper).

14. A Fund will not acquire any security issued by a registered investment company if, immediately after such acquisition, the Fund will own more than 3% of the outstanding

[3] In order to participate in the Funds, consultants will be required to be natural persons or entities who (a) an A&M Group entity has engaged on retainer at the time of investment to provide services and professional expertise on an ongoing basis as regular consultants or business or legal advisors to such A&M Group entity and (b) are sophisticated investors who qualify as an ''accredited investor'' under rule 501(a)(5) or 501(a)(6), if the consultants are natural persons, or if entities, meet the standards of an ''accredited investor'' under rule 501(a) of Regulation D (''Eligible Consultants'').

[4] If such investment vehicle is an entity other than a trust, the term ''settlor'' means a person who created such vehicle, alone or together with others, and contributed funds to such vehicle.

[5] If an Eligible Consultant is an entity (such as a law firm or consulting firm), and the Eligible Consultant proposes to invest in the Fund through a Qualified Entity, the individual participants in such partnership, corporation or other entity will be limited to senior level employees, members or partners of the Eligible Consultant who are responsible for the activities of the Eligible Consultant and will be required to qualify as ''accredited investors'' under rule 501(a) of Regulation D.

[6] ''Audit'' will have the meaning defined in rule 1–02(d) of Regulation S–X.

voting stock of the registered investment company.

Applicants' Legal Analysis

1. Section 6(b) of the Act provides, in part, that the Commission will exempt employees' securities companies from the provisions of the Act to the extent that the exemption is consistent with the protection of investors. Section 6(b) provides that the Commission will consider, in determining the provisions of the Act from which the company should be exempt, the company's form of organization and capital structure, the persons owning and controlling its securities, the price of the company's securities and the amount of any sales load, how the company's funds are invested, and the relationship between the company and the issuers of the securities in which it invests. Section 2(a)(13) defines an employees' securities company, in relevant part, as any investment company all of whose securities (other than short-term paper) are beneficially owned (a) by current or former employees, or persons on retainer, of one or more affiliated employers, (b) by immediate family members of such persons, or (c) by such employer or employers together with any of the persons in (a) or (b).

2. Section 7 of the Act generally prohibits investment companies that are not registered under section 8 of the Act from selling or redeeming their securities. Section 6(e) of the Act provides that, in connection with any order exempting an investment company from any provision of section 7, certain provisions of the Act, as specified by the Commission, will be applicable to the company and other persons dealing with the company as though the company were registered under the Act. Applicants request an order under sections 6(b) and 6(e) of the Act exempting the Funds from all the provisions of the Act, except sections 9, 17, 30, 36 through 53, and the Rules and Regulations. With respect to sections 17(a), (d), (f), (g), and (j) and 30(a), (b), (e), and (h) of the Act and the Rules and Regulations thereunder, and rule 38a-1 under the Act, the exemption is limited as set forth in the application.

3. Section 17(a) generally prohibits any affiliated person of a registered investment company, or any affiliated person of an affiliated person, acting as principal, from knowingly selling or purchasing any security or other property to or from the company. Applicants request an exemption from section 17(a) of the Act to permit an A&M Group entity or a Third Party Fund (or any ''affiliated person,'' as defined in the Act, of any such entity or Third Party Fund), acting as principal, to purchase or sell securities or other property to or from any Fund or any company controlled by such Fund. Applicants state that the relief is requested to permit each Fund the flexibility to deal with its investments in the manner the Manager deems most advantageous to all Members other than the Manager (''Participants''), including borrowing funds from an A&M Group entity, pledging its assets, restructuring its investments, having its investments redeemed, tendering such Fund's securities or negotiating options or implementing exit strategies with respect to its investments. Applicants state the requested exemption is sought to ensure that a Third Party Fund or Third Party Investor will not directly or indirectly become subject to a burden, restriction, or other adverse effect by virtue of a Fund's participation in an investment opportunity.

4. Applicants believe an exemption from section 17(a) is consistent with the policy of each Fund and the protection of investors and necessary to promote the basic purpose of such Fund. Applicants state that the Participants in each Fund will have been fully informed of the possible extent of such Fund's dealings with the A&M Group, and, as experienced professionals in the restructuring, advisory, consulting or investment management businesses, will be able to understand and evaluate the attendant risks. Applicants assert that the community of interest among the Members in each Fund, on the one hand, and the A&M Group, on the other hand, is the best insurance against any risk of abuse. Applicants, on behalf of the Funds, represent that any transactions otherwise subject to section 17(a) of the Act, for which exemptive relief has not been requested, would require approval of the Commission.

5. Section 17(d) of the Act and rule 17d–1 under the Act prohibit any affiliated person of a registered investment company, or any affiliated person of such person, acting as principal, from participating in any joint arrangement with the company unless authorized by the Commission. Applicants request relief to permit affiliated persons of each Fund, or affiliated persons of any of these persons, to participate in, or effect any transaction in connection with, any joint enterprise or other joint arrangement or profit-sharing plan in which the Fund or a company controlled by the Fund is a participant. The exemption requested would permit, among other things, co-investments by each Fund and individual Members or other investors or Professionals of the A&M Group making their own individual investment decisions apart from the A&M Group.

6. Applicants assert that compliance with section 17(d) would cause a Fund to forego investment opportunities simply because a Participant in such Fund or other affiliated person of such Fund (or any affiliate of such a person) also had, or contemplated making, a similar investment. Applicants further assert that attractive investment opportunities of the types considered by a Fund often require each participant in the transaction to make funds available in an amount that may be substantially greater than may be available to such Fund alone. Applicants contend that, as a result, the only way in which a Fund may be able to participate in such opportunities may be to co-invest with other persons, including its affiliates. Applicants assert that the flexibility to structure co-investments and joint investments will not involve abuses of the type section 17(d) and rule 17d–1 were designed to prevent.

7. Applicants state that side-by-side investments held by a Third Party Fund, or by an A&M Group entity in a transaction in which the A&M Group investment was made pursuant to a contractual obligation to a Third Party Fund, will not be subject to condition 3 below. Applicants assert that in structuring a Third Party Fund, it is likely that the unaffiliated investors of such fund will require that an A&M Group entity invest its own capital in Third Party Fund investments, either through the Third Party Fund or on a side-by-side basis, and that A&M Group investments be subject to substantially the same terms as those applicable to the Third Party Fund's investments. Applicants state that it is important that the interests of the Third Party Fund take priority over the interests of the Funds, and that the activities of the Third Party Fund not be burdened or otherwise affected by activities of the Funds. Applicants also state that the relationship of a Fund to a Third Party Fund is fundamentally different from a Fund's relationship to the A&M Group. Applicants contend that the focus of, and the rationale for, the protections contained in the application are to protect the Funds from any overreaching by the A&M Group in the employer/employee context, whereas the same concerns are not present with respect to the Funds vis-à-vis the investors of a Third Party Fund.

8. Section 17(f) of the Act designates the entities that may act as investment company custodians, and rule 17f–2 under the Act specifies requirements that must be satisfied for a registered

management investment company to act as custodian of its own investments. Applicants request an exemption from section 17(f) of the Act and rule 17f–2 to permit the following exceptions from the requirements of rule 17f–2: (a) A Fund's investments may be kept in the locked files of an A&M Group entity for purposes of paragraph (b) of the rule; (b) for purposes of paragraph (d) of the rule, (i) employees of the A&M Group will be deemed to be employees of the Funds, (ii) partners, officers or managers of the Manager of a Fund will be deemed to be officers of the Fund, and (iii) the Manager of a Fund, its board of directors or managers, or a committee of A&M Group Professionals to whom the Manager may delegate its functions will be deemed to be the board of directors of such Fund; and (c) in place of the verification procedure under paragraph (f) of the rule, verification will be effected quarterly by two employees of the A&M Group, each of whom shall have sufficient knowledge, sophistication and experience in business matters to perform such examination. Applicants expect that many of the Funds' investments will be evidenced only by partnership agreements, participation agreements or similar documents, rather than by negotiable certificates that could be misappropriated. Applicants believe that these instruments are most suitably kept in the files of an A&M Group entity, where they can be referred to as necessary. Applicants will comply with all other provisions of rule 17f–2.

9. Section 17(g) of the Act and rule 17g–1 under the Act generally require the bonding of officers and employees of a registered investment company who have access to its securities or funds. Rule 17g-1 requires that a majority of directors who are not interested persons take certain actions and give certain approvals relating to fidelity bonding. The rule also requires that the board of directors of an investment company relying on the rule satisfy the fund governance standards, as defined in rule 0–1(a)(7). Applicants request relief to permit the Manager's board of managers or directors, who may be deemed interested persons, to take actions and determinations as set forth in the rule. Applicants state that, because all the members of the board of directors or managers of the Manager of each Fund will be interested persons of the Fund, the Fund could not comply with rule 17g–1 without the requested relief. Applicants state that each Fund will comply with rule 17g–1 by having a majority of the members of the board of managers or directors of the Manager take such actions and make approvals as are set forth in rule 17g–1. Applicants also request an exemption from the requirements of rule 17g–l(g) and (h) relating to the filing of copies of fidelity bonds and related information with the Commission and the provision of notices to the board of directors and an exemption from the requirements of rule 17g–1(j)(3) relating to compliance with the fund governance standards. Applicants state that the fidelity bond of the Funds will cover employees of the A&M Group who have access to the securities or funds of the Funds and that the Funds will comply with all other requirements of rule 17g–1.

10. Section 17(j) of the Act and paragraph (b) of rule 17j–1 under the Act make it unlawful for certain enumerated persons to engage in fraudulent or deceptive practices in connection with the purchase or sale of a security held or to be acquired by a registered investment company. Rule 17j–1 also requires that every registered investment company adopt a written code of ethics and that every access person of a registered investment company report personal securities transactions. Applicants request an exemption from the provisions of rule 17j–1, except for the anti-fraud provisions of paragraph (b), because they are burdensome and unnecessary as applied to the Funds.

11. Applicants request an exemption from the requirements in sections 30(a), 30(b), and 30(e) of the Act, and the rules under those sections, that registered investment companies prepare and file with the Commission and mail to their shareholders certain periodic reports and financial statements. Applicants contend that the forms prescribed by the Commission for periodic reports have little relevance to a Fund and would entail administrative and legal costs that outweigh any benefit to the Participants in such Fund. Applicants request relief to the extent necessary to permit each Fund to report annually to its Participants. Applicants also request relief from the requirements of section 30(h), to the extent necessary to exempt the Manager of each Fund, members of the Manager, or any board of managers or directors or committee of A&M Group Professionals to whom the Manager may delegate its functions, and any other persons who may be subject to section 30(h), from filing Forms 3, 4 and 5 under Section 16 of the Exchange Act with respect to their ownership of Interests in such Fund. Applicants believe that, because there will be no trading market and the transfers of Interests will be severely restricted, these filings are unnecessary for the protection of investors and burdensome to those required to make them.

12. Rule 38a–1 requires investment companies to adopt, implement and periodically review written policies reasonably designed to prevent violation of the federal securities laws and to appoint a chief compliance officer. Applicants state that each Fund will comply with rule 38a–1(a), (c) and (d), except that (a) since the Fund does not have a board of directors, the governing body of the Manager with respect to the Fund will fulfill the responsibilities assigned to the Fund's board of directors under the rule, (b) since the governing body of the Manager with respect to the Fund does not have any disinterested members, approval by a majority of the disinterested board members required by rule 38a–1 will not be obtained, and (c) since the governing body of the Manager does not have any disinterested members, the Funds will comply with the requirement in rule 38a–1(a)(4)(iv) that the chief compliance officer meet with the independent directors by having the chief compliance officer meet with the governing body of the Manager as constituted.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Each proposed transaction otherwise prohibited by section 17(a) or section 17(d) and rule 17d–1 to which a Fund is a party (the ''Section 17 Transactions'') will be effected only if the Manager determines that:

(a) The terms of the Section 17 Transaction, including the consideration to be paid or received, are fair and reasonable to the Members of such Fund and do not involve overreaching of such Fund or its Members on the part of any person concerned, and

(b) The Section 17 Transaction is consistent with the interests of the Members of such Fund, such Fund's organizational documents and such Fund's reports to its Members.

In addition, the Manager of each Fund will record and preserve a description of all Section 17 Transactions, the Manager's findings, the information or materials upon which the findings are based and the basis for the findings. All records will be maintained for the life of such Fund and for at least six years thereafter, and will be subject to examination by the Commission and its staff. Each Fund will preserve the accounts, books and other documents required to be maintained in an easily accessible place for the first two years.

2. The Manager of each Fund will adopt, and periodically review and update, procedures designed to ensure that reasonable inquiry is made, prior to the consummation of any Section 17 Transaction, with respect to the possible involvement in the transaction of any affiliated person or promoter of or principal underwriter for such Fund, or any affiliated person of such a person, promoter or principal underwriter.

3. The Manager of each Fund will not invest the funds of such Fund in any investment in which a ''Co-Investor'' (as defined below) has acquired or proposes to acquire the same class of securities of the same issuer and where the investment transaction involves a joint enterprise or other joint arrangement within the meaning of rule 17d–1 in which such Fund and the Co-Investor are participants, unless any such Co-Investor, prior to disposing of all or part of its investment, (a) gives such Manager sufficient, but not less than one day's, notice of its intent to dispose of its investment, and (b) refrains from disposing of its investment unless such Fund has the opportunity to dispose of such Fund's investment prior to or concurrently with, on the same terms as, and pro rata with, the Co-Investor. The term ''Co-Investor'' with respect to any Fund means any person, other than a Third Party Fund or an A&M Group entity in a transaction in which the A&M Group investment was made pursuant to a contractual obligation to a Third Party Fund, who is: (a) An ''affiliated person'' (as such term is defined in section 2(a)(3) of the Act) of such Fund; (b) an A&M Group entity; (c) an Eligible Employee; or (d) an entity in which an A&M Group entity acts as a manager or has a similar capacity to control the sale or disposition of the entity's securities. The restrictions contained in this condition shall not be deemed to limit or prevent the disposition of an investment by a Co-Investor: (a) To its direct or indirect wholly-owned subsidiary, to any company (a ''parent'') of which such Co-Investor is a direct or indirect wholly-owned subsidiary, or to a direct or indirect wholly-owned subsidiary of its parent; (b) to immediate family members of such Co-Investor or a trust or other investment vehicle established for any such immediate family member; or (c) when the investment is comprised of securities that are (i) listed on any exchange registered under section 6 of the Exchange Act; (ii) NMS stocks pursuant to section 11A(a)(2) of the Exchange Act and rule 600(b) of Regulation NMS thereunder; (iii) government securities as defined in section 2(a)(16) of the Act or other securities that meet the definition of ''Eligible Security'' in rule 2a–7 under the Act; or (iv) listed on or traded on any foreign securities exchange or board of trade that satisfies regulatory requirements under the law of the jurisdiction in which such foreign securities exchange or board of trade is organized similar to those that apply to a national securities exchange or a national market system for securities.

4. Each Fund will maintain and preserve, for the life of the Fund and for at least six years thereafter, the accounts, books, and other documents as constitute the record forming the basis for the audited financial statements and annual reports to be provided to the Participants in such Fund, and agree that all such records will be subject to examination by the Commission and its staff. Each Fund will preserve the accounts, books and other documents required to be maintained in an easily accessible place for the first two years.

5. The Manager of each Fund will send to each Participant in such Fund who had an interest in such Fund, at any time during the fiscal year then ended, Fund financial statements audited by such Fund's independent accountants. At the end of each fiscal year, the Manager will make a valuation or have a valuation made of all of the assets of the Fund as of such fiscal year end in a manner consistent with customary practice with respect to the valuation of assets of the kind held by the Fund. In addition, within 120 days after the end of each fiscal year of each Fund, or as soon as practicable after the end of each fiscal year of each Fund, the Manager of such Fund will send a report to each person who was a Participant in such Fund at any time during the fiscal year then ended, setting forth such tax information as shall be necessary for the preparation by the Participant of that Participant's federal and state income tax returns, and a report of the investment activities of the Fund during that fiscal year.

6. If a Fund makes purchases or sales from or to an entity affiliated with the Fund by reason of a Professional of the A&M Group (a) serving as an officer, director, general partner, manager or investment adviser of the entity, or (b) having a 5% or more investment in the entity, such individual will not participate in the Fund's determination of whether or not to effect the purchase or sale.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21636 Filed 8–31–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30184; 812–13954]

Emerging Global Advisors, LLC, *et al.;* Notice of Application

August 28, 2012.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and (B) of the Act.

APPLICANTS: Emerging Global Advisors, LLC (the ''Adviser''), EGA Emerging Global Shares Trust (the ''Trust'') and ALPS Distributors, Inc. (''ALPS Distributors'').

SUMMARY OF APPLICATION: Applicants request an order that permits: (a) Certain open-end management investment companies or series thereof to issue shares (''Shares'') redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Shares to occur at negotiated market prices; (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days from the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; and (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares.

FILING DATES: The application was filed on September 8, 2011, and amended on January 20, 2012, April 6, 2012, and August 27, 2012.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving

applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. September 24, 2012 and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants, Trust and Adviser, c/o Robert C. Holderith, 171 East Ridgewood Avenue, Ridgewood, NJ 07450. ALPS Distributors, 1290 Broadway, Suite 1100, Denver, CO 80203.

FOR FURTHER INFORMATION CONTACT: Marilyn Mann, Special Counsel, at (202) 551–6813 or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is registered as an open-end management investment company under the Act and organized as a Delaware statutory trust. Applicants request that the order apply to the series of the Trust described in Appendix B to the application (''Initial Funds'') and any future series of the Trust and any other open-end management companies or series thereof (''Future Funds'') that may track specified securities indexes (''Underlying Indexes'').[1] Any Future Fund will be (a) advised by the Adviser or an entity controlling, controlled by, or under common control with the Adviser, and (b) comply with the terms and conditions of the application. Each Underlying Index will be comprised solely of equity and/or fixed income securities. The Funds will be based on Underlying Indexes comprised of equity and/or fixed income securities that trade in U.S. markets (''Domestic Funds'') or securities that trade in non-U.S. markets (''Foreign Funds'') or Underlying Indexes comprised of a combination of domestic and foreign securities (''Global Funds''). The Initial Funds and all Future Funds, together, are the ''Funds.''

2. The Adviser is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act'') and currently serves as sub-adviser to the Initial Funds. The Adviser expects to serve as investment adviser to the Funds. The Adviser may enter into sub-advisory agreements with one or more investment advisers to act as sub-advisers to a particular Fund (each, a ''Sub-Adviser''). Each Sub-Adviser will be registered under the Advisers Act. The Trust will enter into a distribution agreement with one or more distributors that will be registered as a broker-dealer (''Broker'') under the Securities Exchange Act of 1934 (''Exchange Act'') and will serve as the principal underwriter and distributor (''Distributor'') for one or more Funds. The Distributor for the Initial Funds is ALPS Distributors. A Distributor may be an affiliated person of, or an affiliated person of such affiliated person of, the Adviser and/or Sub-Advisers within the meaning of section 2(a)(3) of the Act.

3. Each Fund will consist of a portfolio of securities (''Portfolio Securities'') selected to correspond generally to the performance of an Underlying Index. No entity that creates, compiles, sponsors or maintains an Underlying Index (''Index Provider'') is or will be an affiliated person, as defined in section 2(a)(3) of the Act, (''Affiliated Person'') or an affiliated person of an affiliated person (''Second-Tier Affiliate'') of the Trust, any Fund, the Adviser, any Sub-Adviser, or promoter of a Fund, or of any Distributor.

4. The investment objective of each Fund will be to provide investment returns that correspond, before fees and expenses, generally to the performance of its Underlying Index.[2] Each Fund will sell and redeem Creation Units on a ''Business Day,'' which is defined as any day that the NYSE, the relevant Listing Exchange (as defined below), the Trust and the custodian of the Funds are open for business and includes any day that a Fund is required to be open under section 22(e) of the Act. A Fund will utilize either a replication or representative sampling strategy to track its Underlying Index. A Fund using a replication strategy will invest in the Component Securities in its Underlying Index in the same approximate proportions as in such Underlying Index. A Fund using a representative sampling strategy will hold some, but not necessarily all, of the Component Securities of its Underlying Index. Applicants state that in using the representative sampling strategy, a Fund is not expected to track the performance of its Underlying Index with the same degree of accuracy as would an investment vehicle that invests in every Component Security of the Underlying Index with the same weighting as the Underlying Index. Applicants expect that each Fund will have an annual tracking error relative to the performance of its Underlying Index of less than 5 percent.

5. Creation Units will consist of specified large aggregations of Shares, *e.g.,* 25,000 or 100,000 Shares, and it is expected that the initial price of a Creation Unit will range from $1 million to $10 million. All orders to purchase Creation Units must be placed with the Distributor by or through a party that has entered into an agreement with the Distributor (''Authorized Participant''). The Distributor will be responsible for transmitting the orders to the Funds. An Authorized Participant must be either: (a) A Broker or other participant in the continuous net settlement system of the National Securities Clearing Corporation (''NSCC''), a clearing agency registered with the Commission, or (b) a participant in the Depository Trust Company (''DTC,'' and such participant, ''DTC Participant'').

6. The Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified below, purchasers will be required to purchase Creation Units by making an in-kind deposit of specified instruments (''Deposit Instruments''), and shareholders redeeming their Shares will receive an in-kind transfer of specified instruments (''Redemption Instruments'').[3] On any given Business

[1] All entities that currently intend to rely on the order are named as applicants. Any other existing or future entity that relies on the order will comply with the terms and conditions of the application. An Investing Fund (as defined below) may rely on the order only to invest in the Funds and not in any other registered investment company.

[2] Applicants represent that at least 80% of each Fund's total assets (excluding securities lending collateral) (''80% Basket'') will be invested in component securities that comprise its Underlying Index (''Component Securities'') or TBA Transactions (as defined below), or in the case of Foreign Funds and Global Funds, the 80% Basket requirement may also include Depositary Receipts (defined below) representing Component Securities. Each Fund may also invest up to 20% of its total assets in a broad variety of other instruments, including securities not included in its Underlying Index, which the Adviser and/or Sub-Adviser believes will help the Fund in tracking the performance of its Underlying Index.

[3] The Funds must comply with the federal securities laws in accepting Deposit Instruments

Day the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will be identical, unless the Fund is Rebalancing (as defined below). In addition, the Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in a Fund's portfolio (including cash positions),[4] except: (a) In the case of bonds, for minor differences when it is impossible to break up bonds beyond certain minimum sizes needed for transfer and settlement; (b) for minor differences when rounding is necessary to eliminate fractional shares or lots that are not tradeable round lots; [5] (c) ''to be announced'' transactions (''TBA Transactions''),[6] derivatives and other positions that cannot be transferred in kind [7] will be excluded from the Deposit Instruments and the Redemption Instruments; [8] (d) to the extent the Fund determines, on a given Business Day, to use a representative sampling of the Fund's portfolio; [9] or (e) for temporary periods, to effect changes in the Fund's portfolio as a result of the rebalancing of its Underlying Index (any such change, a ''Rebalancing''). If there is a difference between the net asset value (''NAV'') attributable to a Creation Unit and the aggregate market value of the Deposit Instruments or Redemption Instruments exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the ''Cash Amount'').

7. Purchases and redemptions of Creation Units may be made in whole or in part on a cash basis, rather than in kind, solely under the following circumstances: (a) To the extent there is a Cash Amount, as described above; (b) if, on a given Business Day, a Fund announces before the open of trading that all purchases, all redemptions or all purchases and redemptions on that day will be made entirely in cash; (c) if, upon receiving a purchase or redemption order from an Authorized Participant, a Fund determines to require the purchase or redemption, as applicable, to be made entirely in cash; [10] (d) if, on a given Business Day, a Fund requires all Authorized Participants purchasing or redeeming Shares on that day to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are not eligible for transfer through either the NSCC or DTC; or (ii) in the case of Foreign Funds and Global Funds, such instruments are not eligible for trading due to local trading restrictions, local restrictions on securities transfers or other similar circumstances; or (e) if a Fund permits an Authorized Participant to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are, in the case of the purchase of a Creation Unit, not available in sufficient quantity; (ii) such instruments are not eligible for trading by an Authorized Participant or the investor on whose behalf the Authorized Participant is acting; or (iii) a holder of Shares of a Foreign Fund or Global Fund would be subject to unfavorable income tax treatment if the holder receives redemption proceeds in kind.[11]

8. Each Business Day, before the open of trading on a national securities exchange, as defined in section 2(a)(26) of the Act (''Exchange'') on which Shares are listed (''Listing Exchange''), each Fund will cause to be published through the NSCC the names and quantities of the instruments comprising the Deposit Instruments and the Redemption Instruments, as well as the estimated Cash Amount (if any), for that day. The list of Deposit Instruments and the list of Redemption Instruments will apply until new lists are announced on the following Business Day, and there will be no intra-day changes to the lists except to correct errors in the published lists. Each Listing Exchange will disseminate, every 15 seconds during regular Exchange trading hours, through the facilities of the Consolidated Tape Association, an amount for each Fund stated on a per individual Share basis representing the sum of (i) the estimated Cash Amount and (ii) the current value of the Deposit Instruments.

9. An investor purchasing or redeeming a Creation Unit from a Fund will be charged a fee (''Transaction Fee'') to prevent the dilution of the interests of shareholders resulting from costs in connection with the purchase or redemption of Creation Units.[12] All orders to purchase Creation Units will be placed with the Distributor by or through an Authorized Participant, and it will be the Distributor's responsibility to transmit such orders to the Funds. The Distributor also will be responsible for delivering the Fund's prospectus to those persons purchasing Shares in Creation Units and for maintaining records of both the orders placed with it and the confirmations of acceptance furnished by it. In addition, the Distributor will maintain a record of the instructions given to the applicable Fund to implement the delivery of its Shares.

10. Shares of the Initial Funds will be listed on the NYSE Arca, Inc. Exchange (''NYSE Arca''). Shares of each Future Fund will be listed and traded individually on an Exchange. It is expected that one or more Exchange liquidity providers or market makers (''Market Makers'') will be assigned to Shares and maintain a market for Shares trading on the Listing Exchange. The

and satisfying redemptions with Redemption Instruments, including that the Deposit Instruments and Redemption Instruments are sold in transactions that would be exempt from registration under the Securities Act of 1933 (''Securities Act''). In accepting Deposit Instruments and satisfying redemptions with Redemption Instruments that are restricted securities eligible for resale pursuant to Rule 144A under the Securities Act, the Funds will comply with the conditions of Rule 144A.

[4] The portfolio used for this purpose will be the same portfolio used to calculate the Fund's NAV for that Business Day.

[5] A tradeable round lot for a security will be the standard unit of trading in that particular type of security in its primary market.

[6] A TBA Transaction is a method of trading mortgage-backed securities. In a TBA Transaction, the buyer and seller agree on general trade parameters such as agency, settlement date, par amount and price. The actual pools delivered generally are determined two days prior to the settlement date.

[7] This includes instruments that can be transferred in kind only with the consent of the original counterparty to the extent the Fund does not intend to seek such consents.

[8] Because these instruments will be excluded from the Deposit Instruments and the Redemption Instruments, their value will be reflected in the determination of the Cash Amount (defined below).

[9] A Fund may only use sampling for this purpose if the sample: (i) Is designed to generate performance that is highly correlated to the performance of the Fund's portfolio; (ii) consists entirely of instruments that are already included in the Fund's portfolio; and (iii) is the same for all Authorized Participants on a given Business Day.

[10] In determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in kind basis (whether for a given day or a given order), the key consideration will be the benefit that would accrue to the Fund and its investors. For instance, in bond transactions, the Adviser may be able to obtain better execution than Share purchasers because of the Adviser's or Sub-Adviser's size, experience and potentially stronger relationships in the fixed income markets. Purchases of Creation Units either on an all cash basis or in kind are expected to be neutral to the Funds from a tax perspective. In contrast, cash redemptions typically require selling portfolio holdings, which may result in adverse tax consequences for the remaining Fund shareholders that would not occur with an in kind redemption. As a result, tax considerations may warrant in kind redemptions.

[11] A ''custom order'' is any purchase or redemption of Shares made in whole or in part on a cash basis in reliance on clause (e)(i) or (e)(ii).

[12] Where a Fund permits an in-kind purchaser to substitute cash-in-lieu of depositing one or more of the requisite Deposit Instruments, the purchaser may be assessed a higher Transaction Fee to cover the cost of purchasing such Deposit Instruments.

price of Shares trading on an Exchange will be based on a current bid-offer market. Transactions involving the sale of Shares on an Exchange will be subject to customary brokerage commissions and charges.

11. Applicants expect that purchasers of Creation Units will include institutional investors and arbitrageurs. Market Makers also may purchase or redeem Creation Units in connection with their market making activities. Applicants expect that secondary market purchasers of Shares will include both institutional and retail investors.[13] The price at which Shares trade will be disciplined by arbitrage opportunities created by the option continually to purchase or redeem Shares in Creation Units, which should help to ensure that Shares will not trade at a material discount or premium in relation to their NAV per Share.

12. Shares will not be individually redeemable and owners of Shares may acquire those Shares from a Fund or tender such shares for redemption to the Fund, in Creation Units only. To redeem, an investor must accumulate enough Shares to constitute a Creation Unit. Redemption requests must be placed by or through an Authorized Participant. A redeeming investor may pay a Transaction Fee, imposed in the same manner as the Transaction Fee incurred in purchasing such Shares of Creation Units.

13. Neither the Trust nor any Fund will be advertised or marketed or otherwise held out as a traditional open-end investment company or ''mutual fund.'' Instead, each Fund will be marketed as an ''exchange-traded fund'' or an ''ETF''. All advertising materials that describe the features or method of obtaining, buying or selling Creation Units, or Shares traded on an Exchange, or refer to redeemability, will prominently disclose that Shares are not individually redeemable and that the owners of Shares may acquire or tender such Shares for redemption to the Fund in Creation Units only. The Funds will provide copies of their annual and semi-annual shareholder reports to DTC Participants for distribution to beneficial owners of Shares.

Applicants' Legal Analysis

1. Applicants request an order under section 6(c) of the Act granting an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act; and under sections 6(c) and 17(b) of the Act granting an exemption from sections 17(a)(1) and (2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and (B) of the Act.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an ''open-end company'' as a management investment company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the holder, upon its presentation to the issuer, is entitled to receive approximately a proportionate share of the issuer's current net assets, or the cash equivalent. Because Shares will not be individually redeemable, applicants request an order that would permit the Trust and each Fund to redeem Shares in Creation Units only. Applicants state that investors may purchase Shares in Creation Units from each Fund and redeem Creation Units according to the provisions of the Act. Applicants further state that because the market price of Shares will be disciplined by arbitrage opportunities, investors should be able to sell Shares in the secondary market at prices that do not vary materially from their NAV per Share.

Section 22(d) of the Act and Rule 22c–1 Under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security that is currently being offered to the public by or through an underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming, or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in Shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus and not at a price based on NAV. Thus, purchases and sales of Shares in the secondary market will not comply with section 22(d) of the Act and rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.

5. Applicants assert that the concerns sought to be addressed by section 22(d) of the Act and rule 22c–1 under the Act with respect to pricing are equally satisfied by the proposed method of pricing Shares. Applicants maintain that, while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been designed to (a) prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers, and (c) ensure an orderly distribution system of investment company shares by eliminating price competition from non-contract dealers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

6. Applicants believe that none of these purposes will be thwarted by permitting Shares to trade in the secondary market at negotiated prices. Applicants state that (a) secondary market trading in Shares does not involve the Funds as parties and cannot result in dilution of an investment in Shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in Shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants contend that the proposed distribution system will be orderly because arbitrage activity will ensure that the Shares do not trade at a material discount or premium in relation to their NAV.

[13] Shares will be registered in book-entry form only. DTC or its nominee will be the record or registered owner of all outstanding Shares. Beneficial ownership of Shares will be shown on the records of DTC or DTC Participants.

Section 22(e) of the Act

7. Section 22(e) of the Act generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants state that settlement of redemptions for Foreign Funds, including the Initial Funds, and Global Funds will be contingent not only on the settlement cycle of the U.S. securities markets but also on the delivery cycles in local markets for underlying foreign Portfolio Securities held by the Foreign Funds and Global Funds. Applicants state that current delivery cycles for transferring Redemption Instruments to redeeming investors, coupled with local market holiday schedules, in certain circumstances will require a delivery process for the Foreign Funds and Global Funds of up to 14 calendar days. Applicants request relief under section 6(c) of the Act from section 22(e) to allow Foreign Funds and Global Funds to pay redemption proceeds up to 14 calendar days after the tender of the Creation Units for redemption. Except as disclosed in the relevant Foreign Fund's or Global Fund's SAI, applicants expect that each Foreign Fund and Global Fund will be able to deliver redemption proceeds within seven days.[14]

8. Applicants state that Congress adopted section 22(e) to prevent unreasonable, undisclosed and unforeseen delays in the actual payment of redemption proceeds. Applicants state that allowing redemption payments for Creation Units of a Foreign Fund or Global Fund to be made within the number of days indicated above would not be inconsistent with the spirit and intent of section 22(e). Applicants state that the SAI will disclose those local holidays (over the period of at least one year following the date of the SAI), if any, that are expected to prevent the delivery of in kind redemption proceeds in seven calendar days, and the maximum number of days (up to fourteen calendar days) needed to deliver the proceeds for each affected Foreign Fund and Global Fund.

9. Applicants are not seeking relief from section 22(e) with respect to Foreign Funds or Global Funds that do not effect creations and redemptions of Creation Units in-kind.

Section 12(d)(1) of the Act

10. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring shares of an investment company if the securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter, or any other broker or dealer from selling the investment company's shares to another investment company if the sale would cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale would cause more than 10% of the acquired company's voting stock to be owned by investment companies generally.

11. Applicants request an exemption to permit management investment companies (''Investing Management Companies'') and unit investment trusts (''Investing Trusts'') registered under the Act that are not sponsored or advised by the Adviser or an entity controlling, controlled by, or under common control with the Adviser and are not part of the same ''group of investment companies,'' as defined in section 12(d)(1)(G)(ii) of the Act, as the Funds (collectively, ''Investing Funds'') to acquire Shares beyond the limits of section 12(d)(1)(A). In addition, applicants seek relief to permit a Fund, any Distributor, and/or any Broker to sell Shares to Investing Funds in excess of the limits of section 12(d)(1)(B).

12. Each Investing Management Company's investment adviser within the meaning of section 2(a)(20)(A) of the Act is the ''Investing Fund Adviser'' and each Investing Management Company's investment adviser within the meaning of section 2(a)(20)(B) of the Act is the ''Investing Fund Sub-Adviser''. Any investment adviser to an Investing Fund will be registered under the Advisers Act. Each Investing Trust's sponsor is the ''Sponsor.''

13. Applicants submit that the proposed conditions to the requested relief adequately address the concerns underlying the limits in section 12(d)(1)(A) and (B), which include concerns about undue influence by a fund of funds over underlying funds, excessive layering of fees and overly complex fund structures. Applicants believe that the requested exemption is consistent with the public interest and the protection of investors.

14. Applicants believe that neither an Investing Fund nor an Investing Funds Affiliate would be able to exert undue influence over a Fund.[15] To limit the control that an Investing Fund may have over a Fund, applicants propose a condition prohibiting the Investing Fund Adviser, Sponsor, any person controlling, controlled by, or under common control with the Investing Fund Adviser or Sponsor, and any investment company and any issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by the Investing Fund Adviser, the Sponsor, or any person controlling, controlled by, or under common control with the Investing Fund Adviser or Sponsor (''Investing Funds' Advisory Group'') from controlling (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any Investing Fund Sub-Adviser, any person controlling, controlled by or under common control with the Investing Fund Sub-Adviser, and any investment company or issuer that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Investing Fund Sub-Adviser or any person controlling, controlled by or under common control with the Investing Fund Sub-Adviser (''Investing Funds' Sub-Advisory Group''). Applicants propose other conditions to limit the potential for undue influence over the Funds, including that no Investing Fund or Investing Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in an offering of securities during the existence of an underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate (''Affiliated Underwriting''). An ''Underwriting Affiliate'' is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Investing Fund Adviser, Investing Fund Sub-Adviser, employee or Sponsor of the Investing Fund, or a person of which any such officer, director, member of an

[14] Rule 15c6–1 under the Exchange Act requires that most securities transactions be settled within three business days of the trade date. Applicants acknowledge that relief obtained from the requirements of section 22(e) will not affect any obligations that they have under rule 15c6–1.

[15] An ''Investing Funds Affiliate'' is any Investing Fund Adviser, Investing Fund Sub-Adviser, Sponsor, promoter or principal underwriter of an Investing Fund, and any person controlling, controlled by or under common control with any of those entities. ''Fund Affiliate'' is the Adviser, Sub-Adviser, promoter, or principal underwriter of a Fund or any person controlling, controlled by or under common control with any of these entities.

advisory board, Investing Fund Adviser, Investing Fund Sub-Adviser, employee or Sponsor is an affiliated person (except any person whose relationship to the Fund is covered by section 10(f) of the Act is not an Underwriting Affiliate).

15. Applicants do not believe that the proposed arrangement will involve excessive layering of fees. The board of directors or trustees of any Investing Management Company, including a majority of the directors or trustees who are not interested directors or trustees within the meaning of section 2(a)(19) of the Act (''disinterested directors or trustees''), will find that the advisory fees charged under the contract are based on services provided that will be in addition to, rather than duplicative of, services provided under the advisory contract of any Fund in which the Investing Management Company may invest. In addition, under condition 9, an Investing Fund Adviser, or Investing Trust's trustee (''Trustee'') or Sponsor, will waive fees otherwise payable to it by the Investing Fund in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund under rule 12b–1 under the Act) received from a Fund by the Investing Fund Adviser, Trustee or Sponsor or an affiliated person of the Investing Fund Adviser, Trustee or Sponsor, in connection with the investment by the Investing Fund in the Fund. Applicants also state that any sales charges and/or service fees charged with respect to shares of an Investing Fund will not exceed the limits applicable to a fund of funds as set forth in Conduct Rule 2830 of the NASD.[16]

16. Applicants submit that the proposed arrangement will not create an overly complex fund structure. Applicants note that a Fund will be prohibited from acquiring securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Fund to purchase shares for short-term cash management purposes. To ensure that an Investing Fund is aware of the terms and conditions of the requested order, the Investing Funds must enter into an agreement with the respective Funds (''Investing Fund Participation Agreement''). The Investing Fund Participation Agreement will include an acknowledgement from the Investing Fund that it may rely on the order only to invest in the Funds and not in any other investment company.

17. Applicants also note that a Fund may choose to reject a direct purchase of Shares in Creation Units by an Investing Fund. To the extent that an Investing Fund purchases Shares in the secondary market, a Fund would still retain its ability to reject initial purchases of Shares made in reliance on the requested order by declining to enter into the Investing Fund Participation Agreement prior to any investment by an Investing Fund in excess of the limits of section 12(d)(1)(A).

Section 17 of the Act

18. Section 17(a) of the Act generally prohibits an Affiliated Person or a Second-Tier Affiliate, from selling any security to or purchasing any security from a registered investment company. Section 2(a)(3) of the Act defines ''affiliated person'' of another person to include any person directly or indirectly owning, controlling, or holding with power to vote 5% or more of the outstanding voting securities of the other person and any person directly or indirectly controlling, controlled by, or under common control with, the other person. Section 2(a)(9) of the Act defines ''control'' as the power to exercise a controlling influence over the management or policies of a company, and provides that a control relationship will be presumed where one person owns more than 25% of a company's voting securities. The Funds may be deemed to be controlled by the Adviser or an entity controlling, controlled by or under common control with the Adviser and hence Affiliated Persons of each other. In addition, the Funds may be deemed to be under common control with any other registered investment company (or series thereof) advised by the Adviser or an entity controlling, controlled by or under common control with the Adviser (an ''Affiliated Fund''). Applicants also state that any investor, including Market Makers, owning 5% or holding in excess of 25% of the Trust or such Funds may be deemed affiliated persons of the Trust or such Funds. In addition, an investor could own 5% or more, or in excess of 25% of the outstanding shares of one or more Affiliated Funds making that investor a Second-Tier Affiliate of the Funds.

19. Applicants request an exemption under sections 6(c) and 17(b) of the Act from sections 17(a)(1) and 17(a)(2) of the Act in order to permit in-kind purchases and redemptions of Creation Units from the Funds by persons that are Affiliated Persons or Second-Tier Affiliates of the Funds solely by virtue of one or more of the following: (a) holding 5% or more, or more than 25%, of the Shares of the Trust or one or more Funds; (b) having an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25%, of the shares of one or more Affiliated Funds. Applicants also request an exemption in order to permit each Fund to sell Shares to and redeem Shares from, and engage in the in-kind transactions that would accompany such sales and redemptions with, any Investing Fund of which the Fund is an Affiliated Person or Second-Tier Affiliate.[17]

20. Applicants contend that no useful purpose would be served by prohibiting such affiliated persons from making in-kind purchases or in-kind redemptions of Shares of a Fund in Creation Units. Deposit Instruments and Redemption Instruments for each Fund will be valued in the same manner as the Portfolio Securities currently held by such Fund, and will be valued in this same manner, regardless of the identity of the purchaser or redeemer. Portfolio Securities, Deposit Instruments, Redemption Instruments, and applicable Cash Amounts (except for any permitted cash-in-lieu amounts) will be the same regardless of the identity of the purchaser or redeemer. Therefore, applicants state that in-kind purchases and redemptions will afford no opportunity for the specified affiliated persons of a Fund to effect a transaction detrimental to the other holders of Shares. Applicants also believe that in-kind purchases and redemptions will not result in abusive self-dealing or overreaching of the Fund. Applicants also submit that the sale of Shares to and redemption of Shares from an Investing Fund satisfies the standards for relief under sections 17(b) and 6(c) of the Act. Applicants note that any consideration paid for the purchase or redemption of Shares directly from a Fund will be based on the NAV of the Fund in accordance with policies and procedures set forth in the Fund's

[16] All references to Conduct Rule 2830 of the NASD include any successor or replacement rule that may be adopted by the Financial Industry Regulatory Authority.

[17] To the extent that purchases and sales of Shares of a Fund occur in the secondary market (and not through principal transactions directly between an Investing Fund and a Fund), relief from section 17(a) would not be necessary. The requested relief is intended to cover, however, transactions directly between Funds and Investing Funds. Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person or Second-Tier Affiliate of an Investing Fund because an investment adviser to the Fund or an entity controlling, controlled by or under common control with the investment adviser is also an investment adviser to the Investing Fund.

registration statement.[18] Applicants also state that the proposed transactions are consistent with the general purposes of the Act and appropriate in the public interest.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

ETF Relief

1. As long as a Fund operates in reliance on the requested order, the Shares of such Fund will be listed on an Exchange.

2. Neither the Trust nor any Fund will be advertised or marketed as an open-end investment company or a mutual fund. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that Shares are not individually redeemable and that owners of Shares may acquire those Shares from a Fund and tender those Shares for redemption to a Fund in Creation Units only.

3. The Web site maintained for each Fund, which is and will be publicly accessible at no charge, will contain, on a per Share basis for each Fund, the prior Business Day's NAV and the market closing price or the midpoint of the bid/ask spread at the time of the calculation of such NAV (''Bid/Ask Price''), and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV.

4. The requested relief to permit ETF operations will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of index-based exchange-traded funds.

Section 12(d)(1) Relief

5. The members of an Investing Funds' Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The members of an Investing Funds' Sub-Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding voting securities of a Fund, the Investing Funds' Advisory Group or the Investing Funds' Sub-Advisory Group, each in the aggregate, becomes a holder of more than 25% of the outstanding voting securities of a Fund, it will vote its Shares of the Fund in the same proportion as the vote of all other holders of the Fund's Shares. This condition does not apply to the Investing Funds' Sub-Advisory Group with respect to a Fund for which the Investing Fund Sub-Adviser or a person controlling, controlled by, or under common control with the Investing Fund Sub-Adviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

6. No Investing Fund or Investing Funds Affiliate will cause any existing or potential investment by the Investing Fund in a Fund to influence the terms of any services or transactions between the Investing Fund or an Investing Funds Affiliate and the Fund or a Fund Affiliate.

7. The board of directors or trustees of an Investing Management Company, including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to assure that the Investing Fund Adviser and any Investing Fund Sub-Adviser are conducting the investment program of the Investing Management Company without taking into account any consideration received by the Investing Management Company or an Investing Funds Affiliate from a Fund or a Fund Affiliate in connection with any services or transactions.

8. Once an investment by an Investing Fund in securities of a Fund exceeds the limit in section 12(d)(1)(A)(i) of the Act, the board of trustees of the Trust (''Board''), including a majority of the disinterested trustees, will determine that any consideration paid by the Fund to the Investing Fund or an Investing Funds Affiliate in connection with any services or transactions: (a) Is fair and reasonable in relation to the nature and quality of the services and benefits received by the Fund; (b) is within the range of consideration that the Fund would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (c) does not involve overreaching on the part of any person concerned. This condition does not apply with respect to any services or transactions between a Fund and its investment adviser(s), or any person controlling, controlled by, or under common control with such investment adviser(s).

9. The Investing Fund Adviser, Trustee or Sponsor, as applicable, will waive fees otherwise payable to it by the Investing Fund in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund under rule 12b–1 under the Act) received from a Fund by the Investing Fund Adviser, Trustee or Sponsor, or an affiliated person of the Investing Fund Adviser, Trustee or Sponsor, other than any advisory fees paid to the Investing Fund Adviser, Trustee, or Sponsor, or its affiliated person by the Fund, in connection with the investment by the Investing Fund in the Fund. Any Investing Fund Sub-Adviser will waive fees otherwise payable to the Investing Fund Sub-Adviser, directly or indirectly, by the Investing Management Company in an amount at least equal to any compensation received from a Fund by the Investing Fund Sub-Adviser, or an affiliated person of the Investing Fund Sub-Adviser, other than any advisory fees paid to the Investing Fund Sub-Adviser or its affiliated person by the Fund, in connection with any investment by the Investing Management Company in the Fund made at the direction of the Investing Fund Sub-Adviser. In the event that the Investing Fund Sub-Adviser waives fees, the benefit of the waiver will be passed through to the Investing Management Company.

10. No Investing Fund or Investing Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in an Affiliated Underwriting.

11. The Board, including a majority of the disinterested trustees, will adopt procedures reasonably designed to monitor any purchases of securities by a Fund in an Affiliated Underwriting, once an investment by an Investing Fund in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment by the Investing Fund in the Fund. The Board will consider, among other things: (a) Whether the purchases were consistent with the investment objectives and policies of the Fund; (b) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (c) whether the amount of securities purchased by the Fund in Affiliated

[18] Applicants acknowledge that the receipt of compensation by (a) an Affiliated Person of an Investing Fund, or a Second-Tier Affiliate, for the purchase by the Investing Funds of Shares of a Fund or (b) an Affiliated Person of a Fund, or a Second-Tier Affiliate, for the sale by the Fund of Shares to an Investing Fund, may be prohibited by section 17(e)(1) of the Act. The Investing Fund Participation Agreement also will include this acknowledgment.

Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to assure that purchases of securities in Affiliated Underwritings are in the best interest of shareholders of the Fund.

12. Each Fund will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings once an investment by an Investing Fund in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate's members, the terms of the purchase, and the information or materials upon which the Board's determinations were made.

13. Before investing in a Fund in excess of the limits in section 12(d)(1)(A), each Investing Fund and the Fund will execute an Investing Fund Participation Agreement stating, without limitation, that their respective boards of directors or trustees and their investment advisers, or Trustee and Sponsor, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in Shares of a Fund in excess of the limit in section 12(d)(1)(A)(i), an Investing Fund will notify the Fund of the investment. At such time, the Investing Fund will also transmit to the Fund a list of the names of each Investing Funds Affiliate and Underwriting Affiliate. The Investing Fund will notify the Fund of any changes to the list of names as soon as reasonably practicable after a change occurs. The Fund and the Investing Fund will maintain and preserve a copy of the order, the Investing Fund Participation Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

14. Before approving any advisory contract under section 15 of the Act, the board of directors or trustees of each Investing Management Company, including a majority of the disinterested directors or trustees, will find that the advisory fees charged under such contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract(s) of any Fund in which the Investing Management Company may invest. These findings and their basis will be recorded fully in the minute books of the appropriate Investing Management Company.

15. Any sales charges and/or service fees charged with respect to shares of an Investing Fund will not exceed the limits applicable to an Investing Fund as set forth in Conduct Rule 2830 of the NASD.

16. No Fund will acquire securities of an investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Fund to purchase shares of other investment companies for short-term cash management purposes.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21637 Filed 8–31–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: [77 FR 52079, August 28, 2012].

STATUS: Closed Meeting.

PLACE: 100 F Street, NE., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: August 30, 2012 at 2:00 p.m.

CHANGE IN THE MEETING: Additional Item.

The following matter will also be considered during the 2:00 p.m. Closed Meeting scheduled for Thursday, August 30, 2012:

A personnel matter.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions as set forth in 5 U.S.C. 552b(c)(2), (4) and (6) and 17 CFR 200.402(a)(2), (4) and (6), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Walter, as duty officer, voted to consider the item listed for the Closed Meeting in closed session, and determined that no earlier notice thereof was possible.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: August 30, 2012.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–21845 Filed 8–30–12; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67743; File No. SR–CME–2012–33]

Self-Regulatory Organizations; Chicago Mercantile Exchange Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fee Schedule Applicable to its OTC Interest Rate Swap Clearing Offering

August 28, 2012.

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 August 17, 2012, Chicago Mercantile Exchange Inc. (''CME'') 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 CME. CME filed the proposed rule change pursuant to Section 19(b)(3)(A) [3] of the Act and Rule 19b–4(f)(2) [4] thereunder, so that the proposed rule change was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of Terms of Substance of the Proposed Rule Change

CME is proposing to amend the fee schedule that currently applies to its OTC Interest Rate Swap clearing offering.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

II. Self-Regulatory Organization's Statement of Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CME included statements concerning the purpose 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. CME 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 Purpose of, and Statutory Basis for, the Proposed Rule Change

CME currently offers clearing for certain OTC Interest Rate Swap products. This filing proposes to amend the current fee schedule that applies to CME's OTC Interest Rate Swap (''IRS'') clearing offering. Specifically, CME will be adding; (i) An optional alternative fee schedule, (ii) progressive fee tiers for the standard fee schedule, and (iii) fee waivers for CME OTC IRS clearing member's back-loaded trades.

Under the new optional alternative fee schedule, house or customer accounts will be able to elect to be subject to an alternate transaction fee schedule for OTC IRS that includes certain per ticket transaction fee and certain monthly charges measured in basis points annualized on the client's initial margin requirement. Election of the alternative transaction fee schedule requires notice to CME which must be given (i) during the firm's onboarding process, or (ii) at least fifteen (15) days prior to a calendar quarter that the firm elects to receive the alternative fee schedule.

The second feature of the proposed changes relates to new progressive fee tiers. Under these changes, each calendar quarter, firms may qualify to receive a fixed discount applicable to base OTC IRS fees for the following calendar quarter on the basis of the USD equivalent base fees incurred during the current quarter. The discount applicable to the following calendar quarter will be calculated on a weighted average basis using the USD equivalent base fees for the current calendar quarter and certain discount percentages. Additionally, from September 1, 2012 to December 31, 2013, the proposed changes would provide for a one-time rebate on current calendar quarter activity during the first calendar quarter that its weighted average discount is equal to or greater than 15%.

Finally, for IRS Clearing Members, the proposed rule changes would provide for certain fee waivers for back-loaded trades. A backloaded trade is a trade accepted for clearing where the effective date for the trade is prior to the date the trade was accepted for clearing. The proposed changes are related to fees and therefore will become effective immediately. However, the proposed fee changes will become operative as of September 1, 2012. CME has also certified the proposed rule changes that are the subject of this filing to the Commodity Futures Trading Commission (''CFTC''), in CFTC Submission 12–254.

The proposed CME rule amendments establish or change a member due, fee or other charge imposed by CME under Section 19(b)(3)(A)(ii) [5] of the Act and Rule 19b–4(f)(2) [6] thereunder. CME believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder and, in particular, to Section 17A(b)(3)(D),[7] in that it provides for the equitable allocation of reasonable dues, fees and other charges among participants. The proposed changes apply to all IRS Clearing Members or customers, as applicable. The modifications should encourage firms to submit additional volume into the system which should help ensure readiness and also help build open interest ahead of a regulatory mandate. CME notes that it operates in a highly competitive market in which market participants can readily direct business to competing venues.

B. Self-Regulatory Organization's Statement on Burden on Competition

CME does not believe that the proposed rule change will have any impact, or impose any burden, on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

CME has not solicited, and does not intend to solicit, comments regarding this proposed rule change. CME has not received any unsolicited written comments from interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change was filed pursuant to Section 19(b)(3)(A) [8] of the Act and Rule 19b–4(f)(2) [9] thereunder and thus became effective upon filing because it effects a change in a due, fee, or other charge applicable only to a member. At any time within sixty days of the filing of such rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–CME–2012–33 on the subject line.

Paper Comments

- Send in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CME–2012–33. 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 will also be available for inspection and copying at the principal office of CME and on CME's Web site at *http://www.cmegroup.com/market-regulation/files/SEC_19B–4_12–33.pdf.* All comments received will be posted without change; the Commission does

[5] 15 U.S.C. 78s(b)(3)(A)(ii).
[6] 17 CFR 240.19b–4(f)(2).
[7] 15 U.S.C. 78q–1(b)(3)(D).
[8] 15 U.S.C. 78s(b)(3)(A).
[9] 17 CFR 240.19b–4(f)(2).

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–CME–2012–33 and should be submitted on or before September 25, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21634 Filed 8–31–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67741; File No. SR–EDGX–2012–36]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the EDGX Exchange, Inc. Fee Schedule

August 28, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 22, 2012 the EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its fees and rebates applicable to Members [3] and non-Members of the Exchange pursuant to EDGX Rule 15.1(a) and (c). All of the changes described herein are applicable to EDGX Members and non-Members. The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.directedge.com*, at the Exchange's principal office, and at the Public Reference Room of the Commission.

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange maintains logical ports for order entry (FIX, HP–API), drop copies (DROP), and market data (collectively, ''DIRECT Logical Ports'').[4] The Exchange proposes to reduce the quantity of free DIRECT Logical Ports from ten (10) sessions to five (5) sessions. Therefore, the Exchange will assess a monthly fee per logical port for Members and non-Members that maintain six or more DIRECT Logical Ports. Accordingly, the Exchange proposes to amend its fee schedule to reduce the quantity of free DIRECT Logical Ports from ten sessions to five sessions. In addition, the Exchange, pursuant to an information circular dated July 20, 2012, communicated to Members and non-Members that the Exchange would propose these changes in a subsequent filing with the Securities and Exchange Commission.[5]

The Exchange proposes to implement these amendments to its fee schedule on September 1, 2012.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with the objectives of Section 6 of the Act,[6] in general, and furthers the objectives of Section 6(b)(4),[7] in particular, as the proposed rule changes are designed to provide for the equitable allocation of reasonable dues, fees and other charges among Members and other persons using the Exchange's facilities.

The Exchange believes its proposal to amend its fee schedule to reduce the quantity of free DIRECT Logical Ports from ten sessions to five sessions represents an equitable allocation of reasonable dues, fees and other charges because the Exchange has implemented several infrastructure enhancements that increased the message throughput (efficiency) per port, thereby requiring fewer ports to communicate the same information. The Exchange also believes that reducing the quantity of free DIRECT Logical Ports to five sessions will promote efficient use of the ports by market participants, helping the Exchange to continue to maintain and improve its infrastructure, while also encouraging Members and non-Members to request and enable only the ports that are necessary for their operations related to the Exchange. In addition, the Exchange will use the revenue generated from its proposal to supplement its administrative and infrastructure costs associated with allowing Members and non-Members to establish logical ports to connect to the Exchange's systems and continue to maintain and improve its infrastructure, market technology, and services. The Exchange also notes that assessing charges for logical ports is reasonable because it is consistent with the practices of other exchanges, such as the BATS Exchange and the NASDAQ OMX Group, Inc. that charge customers for logical ports.[8] Lastly, the Exchange also believes that the proposed reduction in quantity of free ports is non-discriminatory because it applies uniformly to Members and non-Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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

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[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A Member is any registered broker or dealer, or any person associated with a registered broker or dealer, that has been admitted to membership in the Exchange.

[4] *See* Securities and Exchange Act Release No. 64963 (July 26, 2011), 76 FR 45895 (August 1, 2011) (SR–EDGX–2011–21) (discussing the Exchange's proposal to include logical ports that receive market data among the types of logical ports that the Exchange assesses a monthly fee to Members and non-Members).

[5] *See* Direct Edge Notice to Members # 12–28, Reduction in Number of Free Logical Ports Effective September 4, 2012, *http://www.directedge.com/About/Announcements/ViewNewsletterDetail.aspx?NewsletterID=751.*

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] *See* BATS BZX fee schedule at *http://batstrading.com/FeeSchedule/* (where BATS BZX charges its customers a monthly fee per logical port). *See also* NASDAQ Price List-Trading & Connectivity, *http://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2* (where NASDAQ charges its customers a monthly fee per logical port).

this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3) of the Act [9] and Rule 19b–4(f)(2) [10] thereunder. 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.

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–EDGX–2012–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGX–2012–36. 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGX–2012–36 and should be submitted on or before September 25, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21679 Filed 8–31–12; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 19b–4(f)(2) [sic].

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67742; File No. SR–EDGA–2012–37]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the EDGA Exchange, Inc. Fee Schedule

August 28, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 22, 2012 the EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its fees and rebates applicable to Members [3] and non-Members of the Exchange pursuant to EDGA Rule 15.1(a) and (c). All of the changes described herein are applicable to EDGA Members and non-Members. The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.directedge.com,* at the Exchange's principal office, and at the Public Reference Room of the Commission.

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange maintains logical ports for order entry (FIX, HP–API), drop copies (DROP), and market data (collectively, ''DIRECT Logical Ports'').[4] The Exchange proposes to reduce the quantity of free DIRECT Logical Ports from ten (10) sessions to five (5) sessions. Therefore, the Exchange will assess a monthly fee per logical port for Members and non-Members that maintain six or more DIRECT Logical Ports. Accordingly, the Exchange proposes to amend its fee schedule to reduce the quantity of free DIRECT Logical Ports from ten sessions to five sessions. In addition, the Exchange, pursuant to an information circular dated July 20, 2012, communicated to Members and non-Members that the Exchange would propose these changes in a subsequent filing with the Securities and Exchange Commission.[5]

The Exchange proposes to implement these amendments to its fee schedule on September 1, 2012.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A Member is any registered broker or dealer, or any person associated with a registered broker or dealer, that has been admitted to membership in the Exchange.

[4] *See* Securities and Exchange Act Release No. 64964 (July 26, 2011), 76 FR 45898 (August 1, 2011) (SR–EDGA–2011–22) (discussing the Exchange's proposal to include logical ports that receive market data among the types of logical ports that the Exchange assesses a monthly fee to Members and non-Members).

[5] *See* Direct Edge Notice to Members # 12–28, Reduction in Number of Free Logical Ports Effective September 4, 2012, *http://www.directedge.com/About/Announcements/ViewNewsletterDetail.aspx?NewsletterID=751.*

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with the objectives of Section 6 of the Act,[6] in general, and furthers the objectives of Section 6(b)(4),[7] in particular, as the proposed rule changes are designed to provide for the equitable allocation of reasonable dues, fees and other charges among Members and other persons using the Exchange's facilities.

The Exchange believes its proposal to amend its fee schedule to reduce the quantity of free DIRECT Logical Ports from ten sessions to five sessions represents an equitable allocation of reasonable dues, fees and other charges because the Exchange has implemented several infrastructure enhancements that increased the message throughput (efficiency) per port, thereby requiring fewer ports to communicate the same information. The Exchange also believes that reducing the quantity of free DIRECT Logical Ports to five sessions will promote efficient use of the ports by market participants, helping the Exchange to continue to maintain and improve its infrastructure, while also encouraging Members and non-Members to request and enable only the ports that are necessary for their operations related to the Exchange. In addition, the Exchange will use the revenue generated from its proposal to supplement its administrative and infrastructure costs associated with allowing Members and non-Members to establish logical ports to connect to the Exchange's systems and continue to maintain and improve its infrastructure, market technology, and services. The Exchange also notes that assessing charges for logical ports is reasonable because it is consistent with the practices of other exchanges, such as the BATS Exchange and the NASDAQ OMX Group, Inc. that charge customers for logical ports.[8] Lastly, the Exchange also believes that the proposed reduction in quantity of free ports is non-discriminatory because it applies uniformly to Members and non-Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3) of the Act[9] and Rule 19b–4(f)(2)[10] thereunder. 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.

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–EDGA–2012–37 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGA–2012–37. 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGA–2012–37 and should be submitted on or before September 25, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21680 Filed 8–31–12; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] *See* BATS BZX fee schedule at *http://batstrading.com/FeeSchedule/* (where BATS BZX charges its customers a monthly fee per logical port). *See also* NASDAQ Price List-Trading & Connectivity, *http://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2* (where NASDAQ charges its customers a monthly fee per logical port).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 19b–4(f)(2) [sic].

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67740; File No. SR–NYSEMKT–2012–37]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending NYSE MKT Rules 103B(IX)—Equities and 504—Equities To Provide That a Designated Market Maker Unit May Trade at the Same Panel Securities Traded on the Exchange and/or Securities Listed on the New York Stock Exchange LLC

August 28, 2012.

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 August 22, 2012, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE MKT Rules 103B(IX)—Equities and 504—Equities to provide that a Designated Market Maker (''DMM'') unit may trade at the same panel securities traded on the Exchange and/or securities listed on the New York Stock Exchange LLC (''NYSE''). The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

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

The Exchange proposes to amend NYSE MKT Rules 103B– Equities (''Rule 103B'') and 504—Equities (''Rule 504'') to provide that a DMM unit may trade at the same panel securities traded at the Exchange and/or securities listed on the NYSE.

Background

Rule 103B(IX) currently provides that securities listed on the Exchange or admitted to dealings on the Exchange pursuant to a grant of unlisted trading privileges, i.e., Nasdaq Securities,[3] (collectively, ''Exchange-traded securities'') shall be assigned for trading only at panels exclusively designated for trading securities on the Exchange. The rule further provides that ''DMM units may only trade securities listed on the Exchange or admitted to dealings on the Exchange pursuant to a grant of unlisted trading privileges at panels exclusively designated for trading securities on the Exchange.'' In practice, this means that a DMM panel designated for trading in Exchange-traded securities may not also be assigned securities listed on the New York Stock Exchange, LLC (''NYSE'').[4] This rule was adopted in 2008, when the Exchange moved from the 86 Trinity Place location and trading systems to 11 Wall Street and the NYSE trading systems,[5] and amended in 2010 when the Exchange began trading Nasdaq Securities.[6] At the time, the Exchange proposed that Exchange-traded Securities be traded at separate panels designated for trading in NYSE securities to prevent any potential confusion between Exchange and NYSE rules.

Rule 504(b)(6) further provides that DMM units registered on both the Exchange and the NYSE must commit staff, including DMMs and clerks, for the trading of NYSE-listed securities separate from that for the trading of Exchange-listed securities and/or Nasdaq Securities. The rule further provides that ''[i]ndividual DMMs and support staff will not be permitted to trade NYSE-listed securities together with Exchange-listed securities and/or Nasdaq Securities at the same time.'' Rule 504(d) also provides that, in accordance with Rule 103B(IX), Nasdaq Securities shall be allocated for trading only at panels exclusively designated for trading Nasdaq Securities and/or securities listed on the Exchange.

As a result of these rule requirements, DMM units that are registered in both Exchange-traded securities and NYSE-listed securities must maintain separate panels and staff for NYSE-listed securities. In addition, Exchange DMM units must maintain separate panels and staff for Nasdaq Securities, separate from Exchange-listed securities.

Proposed Amendments

The Exchange proposes to eliminate the restrictions on a DMM unit trading Exchange-listed, Nasdaq Securities, and NYSE-listed securities at the same panel. To effect this change, the Exchange proposes to amend Rule 103B(IX) to provide that Exchange-traded securities may be assigned to panels that also trade NYSE-listed securities, delete Rule 504(b)(6), and amend Rule 504(d) to provide that Nasdaq Securities may be allocated to DMM units for trading at panels that also trade Exchange-listed and/or NYSE-listed securities.

The Exchange notes that even if Exchange-traded securities and NYSE-listed securities are assigned to a single panel, the Exchange will keep them on separate Display Book systems. To the extent the rules applicable to a security differ between the Exchange and NYSE, the separate Display Book systems will operate in accordance with the separate rules. In addition, the individual DMMs and clerks will be able to sign into ID Track simultaneously for both Exchange-traded and NYSE-listed securities so that the Exchange can continue to track which securities a DMM and Floor clerk is operating in for a particular day.[7]

The Exchange proposes these changes to reflect the changes in the trading environment, as compared to 2010, when Rule 504 was adopted and Rule 103B(IX) was last amended. In particular, the Exchange believes the changes are warranted because they reflect the changing landscape for DMM units. In 2010, when the rules relating to trading Nasdaq Securities were adopted, only one of the DMM units registered to trade on the Exchange was also registered to trade securities listed on the NYSE. Now, all DMM units registered to trade on the Exchange are also registered to trade securities listed on the NYSE. In addition, former NYSE-only DMM units are now all either registered, or in the process of registering, to trade Exchange-traded securities. Accordingly, all but one DMM units that operate on the Trading Floor are now dually-registered for Exchange-traded and NYSE-listed securities.

The Exchange notes that the rationale provided in 2010 to maintain separate panels was to reduce confusion between Exchange and NYSE rules. However, the Exchange believes that now that DMM units and Floor broker firms have had two years' experience managing Exchange-traded and NYSE-listed securities on the Trading Floor, the risk of confusion among trading rules has been obviated through experience. Accordingly, the stated need in 2010 to maintain separate panels is no longer necessary, and is outweighed by the inefficiencies in DMM unit operations that maintaining separate panels entails.

The Exchange further notes that the Exchange and NYSE already operate in an integrated manner on a single physical Trading Floor, and the proposed change is minimally

[3] *See* Exchange Rule 501(c)—Equities.

[4] The restriction on trading Exchange-traded securities and NYSE-listed securities at the same panel is only in Exchange rules; NYSE rules do not have a counterpart.

[5] *See* Securities Exchange Act Release No. 58705 (Oct 1, 2008), 73 FR 58995 (Oct. 8. 2008) (SR–Amex–2008–63).

[6] *See* Securities Exchange Act Release No. 62479 (July 9, 2010), 75 FR 41264 (July 15, 2010) (SR–NYSEAmex–2010–31) (Amending Rule 103B to permit trading of Exchange-traded securities on posts throughout the Trading Floor).

[7] *See* Exchange Rule 103.11—Equities.

incremental. For example, in 2008, when the Exchange moved to its current location, it adopted a rule that made clear that Exchange-traded equity securities would be traded on the systems and facilities of NYSE Market, Inc., which are located at 11 Wall Street and are the same systems and facilities where NYSE-listed securities trade.[8] In recognition of the fact that the Exchange-traded and NYSE-listed securities would be trading on the same physical space, in 2008, the Exchange adopted Exchange Rule 2.10—Equities, which provides that any registered broker dealer that is approved or deemed approved as a member organization of the NYSE shall be approved as an Exchange member organization. Similarly, pursuant to Exchange Rule 2.20—Equities, all natural persons who were approved or deemed approved as a member of the NYSE, i.e., all NYSE DMMs and Floor brokers, were similarly deemed approved as members of the Exchange.[9] Accordingly, as part of the move of the Exchange to the NYSE facilities, all Floor brokers and DMMs were approved as member organizations of both the Exchange and the NYSE. As a practical matter, this meant that Floor brokers were approved to operate from their Trading Floor booth premises to trade both Exchange-traded and NYSE-listed securities.

With respect to the physical location of DMM units assigned to Exchange-listed securities, the Exchange notes that in 2008, Exchange-listed securities were physically located at DMM posts in the ''Garage'' room of the Trading Floor. However, in 2010, when the Exchange adopted its pilot program to trade Nasdaq Securities, the Exchange further integrated Exchange-listed securities and Nasdaq Securities at DMM posts throughout the Trading Floor, which had the practical effect of moving Exchange-traded securities from the posts located in the Garage and having them assigned to posts in both the Main Room and the Garage, at panels that were contiguous with panels that traded NYSE-listed securities.[10] The Exchange believes that the current proposal to permit Exchange-traded and NYSE-listed securities to trade at a single panel within a post is an incremental change from the existing physical integration between Exchange and NYSE trading that raises no new or novel regulatory issues.

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 applicable to a national securities exchange. In particular, the Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposal promotes just and equitable principles of trade because it will remove a restriction that is applicable only to DMM units. Off-Floor market makers, and Exchange supplemental liquidity provides [sic], do not have similar restrictions, and may assign personnel to trade in equity securities regardless of the listing venue. The Exchange therefore believes that the proposed rule change would eliminate a restriction that places DMMs at a competitive disadvantage as compared to off-Floor market participants. The Exchange further believes that the proposed rule change removes impediments to and perfects the mechanism of a free and open market because it would eliminate rule-based requirements that impose unnecessary restrictions on DMM units that in today's market environment, serve only to force DMM units to operate in an inefficient manner, and at a competitive disadvantage to off-Floor market participants. Rather, the proposed rule change will perfect the mechanism of a free and open market by assuring that DMM units staff the securities registered with that DMM unit based on the needs of the market, rather than on artificial constraints imposed by rule.

Finally, the Exchange believes that the proposal to further integrate trading of Exchange-traded and NYSE-listed securities at a single panel of a DMM post is consistent with the Act because the Commission has already approved the existing integration to permit Exchange-traded and NYSE-listed securities to trade at the same DMM post. The Exchange believes that permitting the securities to trade at a single panel is an incremental change because currently, Exchange-traded and NYSE-listed securities can trade at contiguous panels at the same post. Therefore, the proposed change does not raise any new or novel regulatory issues.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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

Because the foregoing proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule

[8] *See* Exchanges [sic] Rule 0(b) and 0—Equities. In addition, the Exchange's Equities Trading Floor is defined as the physical locations commonly known as the ''Main Room'' and the ''Garage'', which is the same definition of Trading Floor for the NYSE. *See* Exchange Rule 6A—Equities and NYSE Rule 6A.

[9] NYSE adopted similar rules pursuant to which Exchange member organizations and members were deemed approved as NYSE member organizations and members. *See* NYSE Rules 2.10 and 2.20.

[10] *See supra* footnote 6. In the approval order, the Commission noted that the integration of Exchange-traded and NYSE-listed securities trading at the same post was reasonable and consistent with the Act.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2012–37 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2012–37. 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2012–37 and should be submitted on or before September 25, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21678 Filed 8–31–12; 8:45 am]

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[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67737; File No. SR–NYSEArca–2012–93]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Deleting NYSE Arca Equities Rule 4.3(c) and Adopting New Rules 2262 and 2269 To Harmonize With the Rules of New York Stock Exchange LLC, NYSE MKT LLC, and Financial Industry Regulatory Authority, Inc.

August 28, 2012.

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 August 16, 2012, 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. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete NYSE Arca Equities Rule 4.3(c) and adopt new Rules 2262 and 2269 to harmonize with the rules of New York Stock Exchange LLC (''NYSE''), NYSE MKT LLC (''NYSE MKT''), and Financial Industry Regulatory Authority, Inc. (''FINRA''). The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

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, Proposed Rule Change

1. Purpose

The Exchange proposes to delete NYSE Arca Equities Rule 4.3(c) and to adopt new Rules 2262 and 2269 to harmonize with the rules of New York Stock Exchange LLC (''NYSE''), NYSE MKT LLC (''NYSE MKT''), and Financial Industry Regulatory Authority, Inc. (''FINRA'').[4] To harmonize the Exchange Rules with the rules of NYSE, NYSE MKT, and FINRA, the Exchange correspondingly proposes to delete NYSE Arca Equities Rule 4.3(c) and replace it with proposed NYSE Arca Equities Rules 2262 and 2269. As proposed, NYSE Arca Equities Rules 2262 and 2269 adopt the same language as FINRA Rules 2262 and 2269, except for substituting for or adding to, as needed, the term ''ETP Holder'' for the term ''member'', and making corresponding technical changes.[5]

Current NYSE Arca Equities Rule 4.3(c) states that an ETP Holder shall not trade in (except on an unsolicited basis) or make recommendations with respect to its own securities or those of its parents or affiliates (other than registered investment companies) and any parents or affiliates of an ETP Holder shall not trade in (except on an unsolicited basis) or make recommendations with respect to its own securities or those of its affiliates, or those of the ETP Holder (other than registered investment companies). While the current NYSE Arca Equities Rule 4.3(c) restricts the trading and recommendation activities of the ETP Holder with respect to its own securities or those of its parents or affiliates, the rule does not cover transactions beyond those involving securities of parent or affiliate and does not contain a written disclosure requirement that is consistent with Rules 15c1–5 and 15c1–6 of the Act.[6]

In 2009, FINRA adopted NASD Rules 2240 (Disclosure of Control Relationship

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* NYSE Rules 2262, 2269; NYSE MKT Rules 2262—Equities, 2269—Equities; and FINRA Rules 2262, 2269. *See also* Securities Exchange Act Release Nos. 60659 (September 11, 2009), 74 FR 48117 (September 21, 2009) (order approving SR–FINRA–2009–44); 61176 (December 16, 2009), 74 FR 68442 (December 24, 2009) (SR–NYSE–2009–125); and 61179 (December 16, 2009), 74 FR 68440 (December 24, 2009) (SR–NYSEAmex–2009–89).

[5] These changes to FINRA Rules 2262, 2269 are consistent with the changes done by NYSE and NYSE MKT. *See supra* note 4.

[6] *See* 17 CFR 240.15c1–5 and 17 CFR 240.15c1–6.

with Issuer) and 2250 (Disclosure of Participation or Interest in Primary or Secondary Distribution) as consolidated FINRA Rules 2262 and 2269, respectively.[7] FINRA Rule 2262 requires that a FINRA member with a control relationship with the issuer of any security provide disclosure of such control before entering into any contract with or for a customer for the purchase or sale of a security of the issuer. FINRA Rule 2269 requires that a FINRA member that is participating in a primary or secondary distribution or otherwise is financially interested, provide notification to a customer for which it is acting as a broker or dealer with respect to such securities of the existence of such participation or interest. In its filing, FINRA noted that the requirements of FINRA Rules 2262 and 2269 are almost identical to Rules 15c1–5 and 15c1–6 under the Act, respectively. FINRA further noted that FINRA Rules 2262 and 2269 would operate to protect customers without regard as to whether or not a member makes a recommendation on a security to a customer. In addition, FINRA noted that FINRA Rules 2262 and 2269 require disclosure in transactions involving securities beyond those issued by a subsidiary of the member.

As proposed, because NYSE Arca Equities Rule 4.3(c) covers the same topic as FINRA Rules 2262 and 2269, the Exchange would delete NYSE Arca Equities Rule 4.3(c) and replace it with new Rules 2262 and 2269.[8] As such, the Exchange would replace the existing restrictions with a written disclosure requirement applicable to a broader range of transactions that allows customers to make informed decisions on whether to trade the securities. By adopting new Rules 2262 and 2269, the proposal would also extend the written disclosure requirement to securities transactions currently not covered by NYSE Arca Equities Rule 4.3(c). In contrast to NYSE Arca Equities Rule 4.3(c), the proposed changes will impose disclosure requirements in situations where there is either a control relationship or where the ETP Holder has an interest or participation in a distribution.[9] Thus, the new language will broaden the protection of the Exchange Rules through both additional written disclosure requirements and extension to securities transactions not currently covered by current Rule 4.3(c).

The Exchange believes that proposed NYSE Arca Equities Rules 2262 and 2269 would broaden protection of its Rules in a manner that will better protect customers through the additional disclosure requirements that the new proposed rules prescribe. In addition, by harmonizing the rules with FINRA, ETP Holders that are also members of FINRA will be subject to a single standard with respect to disclosure of trading or recommending securities in which an ETP Holder has an interest.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule changes also support the principles of Section 11A(a)(1)[12] of the Act in that they seek to ensure the economically efficient execution of securities transactions and fair competition among brokers and dealers and among exchange markets.

The proposed changes are designed to protect investors and the public interest by broadening the protection of its Rules in a manner that will better protect customers whether or not a member or member organization makes a recommendation on a security for a customer and providing additional disclosures of potential conflicts of interest in transactions on the Exchange. With the additional disclosures of potential conflicts of interest in transactions where an ETP Holder is involved, the Exchange believes that investors will be better protected by being able to make more informed investment decisions and thus promote just and equitable principles of trade on the Exchange.

In addition, the Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization among Exchange Rules and the rules of NYSE, NYSE MKT, and FINRA of similar purpose, resulting in less burdensome and more efficient regulatory compliance for Dual Members. To the extent the Exchange has proposed changes that differ from the FINRA version of the Rules, such changes are technical in nature and do not change the substance of the proposed NYSE Rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[15] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

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.

[7] *See* Securities Exchange Act Release No. 60659 (September 11, 2009), 74 FR 48117 (September 21, 2009) (SR–FINRA–2009–044).

[8] Neither FINRA, NYSE, NYSE MKT or any other exchange has a rule based on the language of NYSE Arca Equities Rule 4.3(c).

[9] The proposal has no impact on the other requirements in Exchange Rules that apply to ETP Holders, including NYSE Arca Equities Rule 6.3. *See* NYSE Arca Equities Rule 6.3.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78k–1(a)(1).

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2012–93 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR–NYSEArca–2012–93. 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of NYSE Arca. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2012–93 and should be submitted on or before September 25, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21635 Filed 8–31–12; 8:45 am]

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[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67738; File No. SR–NASDAQ–2012–100]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Direct Registration Requirements under Rule 5210(c)

August 28, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on August 24, 2012, The NASDAQ Stock Market LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I and II below, which items have been prepared primarily by Nasdaq. Nasdaq filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder so that the proposed rule change was effective upon filing with the Commission.[2] The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

Nasdaq proposes to modify Rule 5210(c) related to the Direct Registration System (''DRS'') to reconcile a discrepancy between the initial and continued listing requirements. Nasdaq will implement the proposed change immediately. The text of the proposed rule change is available on Nasdaq's Web site at *http://www.nasdaq.cchwallstreet.com*, at *http://www.sec.gov*, at the principal office of Nasdaq, 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, Nasdaq 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. Nasdaq has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[3]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

Nasdaq proposes to modify Rule 5210(c) related to DRS to reconcile a discrepancy between the initial and continued listing requirements. As currently drafted, Rule 5210(c) provides that the DRS requirement does not apply to additional classes of securities of companies which already have securities listed on Nasdaq and companies which immediately prior to such listing had securities listed on another registered securities exchange in the U.S.

This language is now outdated. Specifically, when Nasdaq introduced the DRS, it applied the rule to most new listings, but created a phase-in period for already listed companies, including companies listing additional classes of securities and companies switching from other exchanges.[4] This phase-in period has now ended[5] and all listed companies are required by Rule 5255 to comply with the DRS requirement, however, the language allowing an exemption from the DRS initial listing requirement for these companies remains in Rule 5210(c). Thus, as currently written, a company could qualify to list on Nasdaq pursuant to one of these exceptions in Rule 5210(c), but immediately be out of compliance with the continued listing requirements in Rule 5255. The purpose of the proposed rule change is to remove these exceptions from the initial listing requirement, and thereby clarify and conform to these rules.

Additionally, the proposed rule change corrects a second inconsistency between the initial listings rules and continued listings rules regarding securities which are book-entry-only.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78s(b)(3)(A) and 17 CFR 240.19b–4(f)(6).

[3] The Commission has modified the text of the summaries prepared by Nasdaq.

[4] Securities Exchange Act Release No. 54288 (August 8, 2006), 71 FR 47276 (August 16, 2006) (Order Granting Approval of SR–NASDAQ–2006–008).

[5] The phase in period ended on March 31, 2008. *See* Securities Exchange Act Release No. 57062 (December 28, 2007), 73 FR 900 (January 4, 2008) (Order Granting Approval of SR–NASDAQ–2007–101).

The continued listing requirement in Rule 5255 excludes securities that are book-entry-only because ownership of such securities is already recorded only on the books and records of the company and is not held in certificated form. As such, these securities already enjoy many of the advantages that DRS is designed to promote. The comparable exception in the initial listing requirement contained in Rule 5210(c), however, only excludes ''non-equity securities that are book-entry-only.'' While similar language previously existed limiting the exception from the continued listing requirement to non-equity securities, Nasdaq expanded that exception to include all securities that are book-entry-only.[6] As with the other correction herein, this creates an inconsistency between the initial and continued listings requirements. Nasdaq now proposes to expand the exception in Rule 5210(c) relating to initial listings to exclude all securities that are book-entry-only to clarify and conform these rules. If a security ceases to be book-entry-only, that security would then be required to be eligible to participate in DRS.

(2) Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[7] in general, and with section 6(b)(5) of the Act,[8] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination in persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed rule change will remove inconsistent rule language, thereby clarifying Nasdaq's rules, and help assure that the benefits of DRS are available for securities that do not otherwise enjoy those benefits, which should in turn help promote the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq 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, as amended.

(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 Nasdaq. Nasdaq will notify the Commission of any written comments received by Nasdaq.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is effective upon filing pursuant to Section 19(b)(3)(A) of the Act and paragraph (f)(6) of Rule 19b–4 thereunder, in that the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. On August 10, 2012, Nasdaq gave the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change.

Nasdaq believes that the proposed rule change does not significantly affect the protection of investors or the public interest because it conforms the initial listing standard contained in Rule 5210 to the existing continued listing standard contained in Rule 5255 by eliminating exceptions to the rule that are no longer applicable and providing that the rule is not applicable to any security which is book-entry only, since such securities already enjoy the benefits of a direct registration program.

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. Nasdaq has provided the Commission of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

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–NASDAQ–2012–100 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2012–100. 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 Section, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filings will also be available for inspection and copying at the principal office of Nasdaq and on Nasdaq's Web site at *http://www.nasdaq.cchwallstreet.com*. 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–NASDAQ–2012–100 and should be submitted on or before September 25, 2012.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–21677 Filed 8–31–12; 8:45 am]

BILLING CODE 8011–01–P

[6] *See* Securities Exchange Act Release No. 58125 (July 9, 2008), 73 FR 42389 (July 21, 2008) (Order Granting Approval of SR–NASDAQ–2008–31).

[7] 15 U.S.C 78f.

[8] 15 U.S.C 78f(b)(5).

DEPARTMENT OF STATE

[Public Notice 8007]

Culturally Significant Object Imported for Exhibition Determinations: ''Pedimental Relief''

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, and 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 object to be included in the exhibition ''Pedimental Relief,'' imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at the Metropolitan Museum of Art, New York, New York, from on or about October 1, 2012, until on or about October 1, 2022, 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 description of the exhibit object, contact Paul W. Manning, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6469). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: August 27, 2012.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2012–21710 Filed 8–31–12; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8009]

Culturally Significant Object Imported for Exhibition Determinations: ''Dancing Into Dreams, Maya Vases From the IK'Kingdom''

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 object to be included in the exhibition ''Dancing Into Dreams, Maya Vases from the IK'Kingdom,'' imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at the Princeton University Art Museum, Princeton, NJ, from on or about October 6, 2012, until on or about February 17, 2013, 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 exhibit object, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: August 28, 2012.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2012–21707 Filed 8–31–12; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8008]

Culturally Significant Objects Imported for Exhibition Determinations: ''Roads of Arabia: Archaeology and the History of the Kingdom of Saudi Arabia''

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, and 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 ''Roads of Arabia: Archaeology and the History of the Kingdom of Saudi Arabia,'' 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 Arthur M. Sackler Gallery, Smithsonian Institution in Washington, DC from on or about November 17, 2012, until on or about February 24, 2013; the Museum of Fine Arts, Houston in Houston, Texas from on or about November 15, 2013 until on or about February 1, 2014 (dates still being finalized); and possibly also The Field Museum in Chicago, Illinois from on or about March 1, 2014 until on or about June 30, 2014; and/or the San Francisco Asian Art Museum in San Francisco, California from on or about July 30, 2014 until on or about September 30, 2014 (venues and dates still being finalized); 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 exhibit objects, contact Ona M. Hahs, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6473). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: August 27, 2012.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2012–21705 Filed 8–31–12; 8:45 am]

BILLING CODE 4710–05–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Dispute No. WT/DS444]

WTO Dispute Settlement Proceeding Regarding Argentina—Measures Affecting the Importation of Goods

AGENCY: Office of the United States Trade Representative.

ACTION: Notice; request for comments.

SUMMARY: The Office of the United States Trade Representative (''USTR'') is providing notice that on August 21, 2012, the United States requested consultations with the Government of Argentina (''Argentina'') under the

Marrakesh Agreement Establishing the World Trade Organization (''WTO Agreement'') concerning certain measures imposed by Argentina on the importation of goods. That request may be found at *www.wto.org*, contained in a document designated as WT/DS444/1. USTR invites written comments from the public concerning the issues raised in this dispute.

DATES: Although USTR will accept any comments received during the course of the dispute settlement proceedings, comments should be submitted on or before September 28, 2012 to assure timely consideration by USTR.

ADDRESSES: Public comments should be submitted electronically at *www.regulations.gov,* docket number USTR–2012–0023. If you are unable to provide submissions at *www.regulations.gov* , please contact Sandy McKinzy at (202) 395–9483 to arrange for an alternative method of transmission.

If (as explained below) the comment contains confidential information, then the comment should be submitted by fax only to Sandy McKinzy at (202) 395–3640.

FOR FURTHER INFORMATION CONTACT: Greta Milligan, Assistant General Counsel, Office of the United States Trade Representative, (202) 395–3150.

SUPPLEMENTARY INFORMATION: USTR is providing notice that consultations have been requested pursuant to the WTO *Understanding on Rules and Procedures Governing the Settlement of Disputes* (''DSU''). If such consultations should fail to resolve the matter and a dispute settlement panel is established pursuant to the DSU, such a panel, which would hold its meetings in Geneva, Switzerland, would be expected to issue a report on its findings and recommendations within nine months after it is established.

Major Issues Raised by the United States

On August 21, 2012, the United States requested consultations concerning certain measures imposed by Argentina on the importation of goods into Argentina. In particular, Argentina subjects the importation of all goods to approval of a non-automatic import license through the *Declaración Jurada Anticipada de Importación* (''DJAI'') system. In addition, Argentina subjects the importation of certain goods into Argentina to other product-specific non-automatic import licenses, or *Licencias No Automáticas de Importación* in the form of *Certificados de Importación* (''CIs''). The legal instruments through which Argentina maintains these measures are set out in the annexes to the request for consultations. The issuance of CIs and approval of DJAIs are systematically delayed or denied by Argentine authorities on non-transparent grounds.

In addition, Argentina often requires imports to undertake certain commitments including to limit imports, to balance imports with exports, to make or increase investments in production facilities in Argentina, to increase the local content of products manufactured in Argentina (and thereby discriminate against imported products), to refrain from transferring revenue or other funds abroad and/or to control the price of imported goods. The Argentine authorities often make the issuance of CIs and the approval of DJAIs conditional upon the importers undertaking to comply with the above-mentioned trade-restrictive commitments.

Through these measures, Argentina appears to have acted inconsistently with its obligations under the *General Agreement on Tariffs and Trade* (''GATT 1994''), the *Agreement on Import Licensing Procedures* (''Import Licensing Agreement''), the *Agreement on Trade-Related Investment Measures* (''TRIMS Agreement''), and the *Agreement on Safeguards* (''Safeguards Agreement'').

Specifically, the United States asserts in the request for consultations that Argentina's measures appear to be inconsistent with the following provisions of the GATT 1994, the TRIMs Agreement, the Import Licensing Agreement, and the Safeguards Agreement:

1. Articles III:4, X:1, X:2, X:3(a) and XI:1 of the GATT 1994;
2. Article 2 of the TRIMs Agreement;
3. Articles 1.2, 1.3, 1.4, 3.2, 3.3, 3.4, 3.5, 5.1, 5.2, 5.3 and 5.4 of the Import Licensing Agreement; and
4. Article 11 of the Safeguards Agreement

Public Comment: Requirements for Submissions

Interested persons are invited to submit written comments concerning the issues raised in this dispute. Persons may submit public comments electronically to *www.regulations.gov*, docket number USTR–2012–0023. If you are unable to provide submissions by *www.regulations.gov,* please contact Sandy McKinzy at (202) 395–9483 to arrange for an alternative method of transmission.

To submit comments via *www.regulations.gov,* enter docket number USTR–2012–0023 on the home page and click ''search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting ''Notice'' under ''Document Type'' on the left side of the search-results page, and click on the link entitled ''Submit a Comment'' (For further information on using the *www.regulations.gov* Web site, please consult the resources provided on the Web site by clicking on ''How to Use This Site'' on the left side of the home page).

The *www.regulations.gov* Web site allows users to provide comments by filling in a ''Type Comments'' field, or by attaching a document using an ''Upload File'' field. It is expected that most comments will be provided in an attached document. If a document is attached, it is sufficient to type ''See attached'' in the ''Type Comments'' field.

A person requesting that information, contained in a comment that he submitted, be treated as confidential business information must certify that such information is business confidential and would not customarily be released to the public by the submitter. Confidential business information must be clearly designated as such and the submission must be marked ''BUSINESS CONFIDENTIAL'' at the top and bottom of the cover page and each succeeding page. Any comment containing business confidential information must be submitted by fax to

Sandy McKinzy at (202) 395–3640. A non-confidential summary of the confidential information must be submitted at *www.regulations.gov.* The non-confidential summary will be placed in the docket and will be open to public inspection.

USTR may determine that information or advice contained in a comment submitted, other than business confidential information, is confidential in accordance with section 135(g)(2) of the Trade Act of 1974 (19 U.S.C. 2155(g)(2)). If the submitter believes that information or advice may qualify as such, the submitter—

(1) Must clearly so designate the information or advice;

(2) Must clearly mark the material as ''SUBMITTED IN CONFIDENCE'' at the top and bottom of the cover page and each succeeding page; and

(3) Must provide a non-confidential summary of the information or advice.

Any comment containing confidential information must be submitted by fax. A non-confidential summary of the confidential information must be submitted at *www.regulations.gov.* The non-confidential summary will be

placed in the docket and will be open to public inspection.

Pursuant to section 127(e) of the Uruguay Round Agreements Act (19 U.S.C. 3537(e)), USTR will maintain a docket on this dispute settlement proceeding, docket number USTR–2012–0023, accessible to the public at *www.regulations.gov*.

The public file will include non-confidential comments received by USTR from the public regarding the dispute. If a dispute settlement panel is convened, or in the event of an appeal from such a panel, the following documents will be made available to the public at *www.ustr.gov:* the United States' submissions, any non-confidential submissions received from other participants in the dispute, and any non-confidential summaries of submissions received from other participants in the dispute. In the event that a dispute settlement panel is convened, or in the event of an appeal from such a panel, the report of the panel, and, if applicable, the report of the Appellate Body, will also be available on the Web site of the World Trade Organization at *www.wto.org.* Comments open to public inspection may be viewed at *www.regulations.gov.*

Bradford L. Ward,

Assistant United States Trade Representative for Monitoring and Enforcement.

[FR Doc. 2012–21729 Filed 8–31–12; 8:45 am]

BILLING CODE 3290–F2–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2012–0087]

Advisory Committee for Aviation Consumer Protection

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of third meeting of advisory committee.

SUMMARY: This notice announces the third meeting of the Advisory Committee for Aviation Consumer Protection.

DATES: The third meeting of the advisory committee is scheduled for October 2, 2012, from 9:00 a.m. to 5:00 p.m., Eastern Time.

ADDRESSES: The meeting will be held in the Oklahoma City Room (located on the lobby level of the West Building with capacity for approximately 100 attendees) at the U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC. Attendance is open to the public up to the room's capacity; however, since access to the U.S. DOT headquarters building is controlled for security purposes, any member of the general public who plans to attend this meeting must notify the Department contact noted below at least five (5) calendar days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: To register to attend the meeting, please contact Amanda Stokes, Associate Research Analyst, Centra Technology, Inc., *stokesa@centratechnology.com;* 703–894–6529. For other information please contact Nicholas Lowry, Senior Attorney, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, *nick.lowry@dot.gov;* U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590; 202–366–9342 (phone), 202–366–7152 (fax).

SUPPLEMENTARY INFORMATION: On May 24, 2012, the Secretary, as mandated by Section 411 of the FAA Modernization and Reform Act of 2012 (Pub. L. 112–95, 126 Stat. 11 (2012)), established the Advisory Committee on Aviation Consumer Protection and announced those persons appointed as members. Two earlier meetings of the committee were held on June 28 and August 7 of this year. The committee's charter, drafted in accordance with the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2, sets forth policies for the operation of the advisory committee and is available on the Department's Web site at *http://www.dot.gov/affairs/2012/dot5912.html.*

The third meeting of the committee is scheduled for October 2, 2012, from 9:00 a.m. to 5:00 p.m. Eastern Time in the Oklahoma City Room at the Department's headquarters, 1200 New Jersey Ave. SE., Washington, DC 20590. The agenda for that meeting will consist of a discussion by committee members of recommendations for proposed initiatives to be presented to the Secretary of Transportation. The charter provides that the committee present its recommendations to the Secretary by October 15, 2012, and every effort will be made to submit the Committee's recommendations by that date.

As announced in the notices of previous meetings of the committee, the meeting will be open to the public, and, time permitting, comments by members of the public are invited. Since access to the U.S. DOT headquarters building is controlled for security purposes, we ask that any member of the general public who plans to attend the third meeting notify the Department contact noted above no later than five (5) calendar days prior to the meeting. Attendance will be necessarily limited by the size of the meeting room.

Members of the public may present written comments at any time. The docket number referenced above (OST–2012–0087, available at *https://www.regulations.gov*) has been established for committee documents including any written comments that may be filed. At the discretion of the Chairperson and time permitting, after completion of the planned agenda, individual members of the public may provide oral comments. Any oral comments presented must be limited to the objectives of the committee and will be limited to five (5) minutes per person. Individual members of the public who wish to present oral comments must notify the Department contact noted above via email that they wish to attend and present oral comments at least five (5) calendar days prior to the meeting. This meeting, however, will be primarily devoted to discussion among committee members of possible initial recommendations to the Secretary which are due on October 15, 2012. In light of this agenda and the time constraints imposed by the committee's charter, we anticipate that the time available for oral presentations and comments by the general public will be significantly more limited than in prior meetings.

Persons with a disability who plan to attend the meeting and require special accommodations, such as an interpreter for the hearing impaired, should notify the Department contact noted above at least seven (7) calendar days prior to the meeting. Persons attending with a service animal should also advise us of that fact so that it can be taken into account in connection with space and possible allergy issues.

Notice of this meeting is being provided in accordance with the FACA and the General Services Administration regulations covering management of Federal advisory committees. (41 CFR part 102–3.)

Issued in Washington, DC, on August 28, 2012.

Samuel Podberesky,

Assistant General Counsel for Aviation Enforcement & Proceedings, U.S. Department of Transportation.

[FR Doc. 2012–21616 Filed 8–31–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Technical Standard Order (TSO)–C65a, Airborne Doppler Radar Ground Speed and/or Drift Angle Measuring Equipment (For Air Carrier Aircraft)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of cancellation of Technical Standard Order (TSO)–C65a, Airborne Doppler Radar Ground Speed and/or Drift Angle Measuring Equipment (For Air Carrier Aircraft).

SUMMARY: This notice announces the FAA's cancellation of TSO–C65a. The effect of the cancelled TSO will result in no new TSO–C65a design or production approvals. However, cancellation will not affect current production of articles with an existing TSO authorization (TSOA). Articles produced under an existing TSOA can still be installed per the existing airworthiness approvals.

FOR FURTHER INFORMATION CONTACT: Mr. Albert Sayadian, AIR–130, Federal Aviation Administration, 470 L'Enfant Plaza, Suite 4102, Washington, DC 20024. Telephone (202) 385–4652, fax (202) 385–4651, email to: *albert.sayadian@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Doppler radar ground speed and/or drift angle measuring equipment described by this TSO was used to provide inputs to semiautomatic self-contained dead reckoning navigation systems which were not continuously dependent on information derived from ground based or external navigation aids. The system employed radar signals to detect and measure ground speed and drift angle, using the aircraft compass system as its directional reference. This approach is less accurate than Inertial Navigation Systems (INS), and the use of an external reference is required for periodic updates if acceptable position accuracy is to be achieved on long range flights. Use of INS and Global Positioning System (GPS) has rendered TSO–C65a Doppler sensor equipment that provides inputs to dead reckoning navigation systems obsolete.

On August 18, 1983, the FAA published TSO–C65a. The FAA has no record of any TSO–C65a applications dating back to 1990. Our research indicates there are no new TSO–C65a applications in progress, and there are no authorized manufacturers manufacturing, advertising, or selling TSO–C65a compliant equipment. Given the obsolescence of the equipment, and the lack of industry interest in new TSO–C65a product design, the FAA is cancelling TSO–C65a.

Comments

Request for comments of our proposed cancellation of TSO–C65a as published in 77 FR 37470, June 21, 2012, produced no comments.

Conclusion

TSO–C65a is cancelled effective February 1, 2013.

Issued in Washington, DC, on August 28, 2012.

Susan J.M. Cabler,

Assistant Manager, Aircraft Engineering Division, Aircraft Certification Service.

[FR Doc. 2012–21632 Filed 8–31–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Technical Standard Order (TSO)–C68a, Airborne Automatic Dead Reckoning Computer Equipment Utilizing Aircraft Heading and Doppler Ground Speed and Drift Angle Data (for Air Carrier Aircraft)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of cancellation of Technical Standard Order (TSO)–C68a, Airborne Automatic Dead Reckoning Computer Equipment Utilizing Aircraft Heading and Doppler Ground Speed and Drift Angle Data (for Air Carrier Aircraft).

SUMMARY: This notice announces the FAA's cancellation of TSO–C68a. The effect of the cancelled TSO–C68a will result in no new TSO–C68a design or production approvals.

FOR FURTHER INFORMATION CONTACT: Mr. Albert Sayadian, AIR–130, Federal Aviation Administration, 470 L'Enfant Plaza, Suite 4102, Washington, DC 20024. Telephone (202) 385–4652, fax (202) 385–4651, email to: *albert.sayadian@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Doppler radar is a semiautomatic self-contained dead reckoning navigation system (radar sensor plus computer) which is not continuously dependent on information derived from ground based or external aids. The system employs radar signals to detect and measure ground speed and drift angle, using the aircraft compass system as its directional reference. Doppler is less accurate than Inertial Navigation System (INS), and the use of an external reference is required for periodic updates if acceptable position accuracy is to be achieved on long range flights. Use of INS and Global Positioning System (GPS) has rendered TSO–C68a systems obsolete. The FAA has no record of any applications for TSO–C68a since it was published in 1983. Given the obsolescence of the equipment, and the lack of industry interest in TSO–C68a product designs, the FAA is cancelling TSO–C68a.

Comments

Request for comments of our proposed cancellation of TSO–C68a as published in 77 FR 37733, June 22, 2012, produced no comments.

Conclusion

TSO–C68a is cancelled effective February 1, 2013.

Issued in Washington, DC, on August 28, 2012.

Susan J. M. Cabler,

Assistant Manager, Aircraft Engineering Division, Aircraft Certification Service.

[FR Doc. 2012–21633 Filed 8–31–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Reports, Forms and Recordkeeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and approval. The nature of the information collection is described as well as its expected burden. The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 8, 2012, and comments were due by August 7, 2012. No comments were received.

DATES: Comments should be submitted on or before October 4, 2012.

FOR FURTHER INFORMATION CONTACT: Dennis Brennan, Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Telephone: 202–366–1029; or email: *dennis.brennan@dot.gov.* Copies of this

collection also can be obtained from that office.

SUPPLEMENTARY INFORMATION: Maritime Administration (MARAD).

Title: Monthly Report of Ocean Shipments Moving under Export-Import Bank Financing (Ocean Shipments Moving under Export-Import Bank Financing).

OMB Control Number: 2133–0013.

Type of Request: Revision of a currently approved collection.

Affected Public: Shippers subject to Export-Import Bank Financing.

Form Number(s): MA–518.

Abstract: In accordance with 46 U.S.C. 55304 (PR 17), certain shippers receiving Export-Import Bank financing must transport items that move by sea on U.S.-flag registered vessels unless they receive a Certification of Non-Availability from MARAD. MARAD will use the information collected to assist shippers with obtaining carriage on U.S.-flag registered vessels and to make determinations of vessel availability. MARAD will also use the information collected to monitor compliance with the U.S.-flag shipping requirements as required by 46 U.S.C. 55305(d)(2).

Annual Estimated Burden Hours: 196 hours.

Addresses: Send comments regarding these information collections to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 Seventeenth Street NW., Washington, DC, 20503, Attention: MARAD Desk Officer. Alternatively, comments may be sent via email to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, at the following address: *oira.submissions@omb.eop.gov.*

Comments Are Invited On: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will 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 collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is best assured of having its full effect if OMB receives it receives it within 30 days of publication.

Authority: 49 CFR 1.66.

Issued in Washington, DC on August 27, 2012.

Christine Gurland,

Acting Secretary, Maritime Administration.

[FR Doc. 2012–21721 Filed 8–31–12; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2012–0085]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ZINGARA; 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 October 4, 2012.

ADDRESSES: Comments should refer to docket number MARAD–2012–0085. 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 ZINGARA is:

INTENDED COMMERCIAL USE OF VESSEL: ''Carrying passengers for sailing, sightseeing, sunset cruises.''

GEOGRAPHIC REGION: Florida.

The complete application is given in DOT docket MARAD–2012–0085 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: August 27, 2012.

Christine Gurland,

Acting Secretary, Maritime Administration.

[FR Doc. 2012–21725 Filed 8–31–12; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Voluntary Intermodal Sealift Agreement (VISA)

AGENCY: Maritime Administration, DOT.

ACTION: Notice of open season for enrollment in the VISA program.

Introduction

The VISA program was established pursuant to section 708 of the Defense Production Act of 1950, as amended (DPA), which provides for voluntary agreements for emergency preparedness programs. VISA was approved for a two year term on January 30, 1997, and published in the **Federal Register** on February 13, 1997, (62 FR 6837).

Effective September 30, 2009, the DPA for voluntary agreements and plans of action for preparedness programs was amended to note that each voluntary agreement expires five (5) years after the date it becomes effective. Therefore, approval of the VISA as published in the **Federal Register** on March 24, 2010 (75 FR 14245) is currently extended until October 1, 2014.

As implemented, the VISA program is open to U.S.-flag vessel operators of oceangoing militarily useful vessels, to include tugs and barges. An operator is defined as an owner or bareboat charterer of a vessel. Tug enrollment alone does not satisfy VISA eligibility. Operators include vessel owners and bareboat charter operators if satisfactory signed agreements are in place committing the assets of the owner to the bareboat charterer for purposes of VISA. Voyage and space charterers are not considered U.S.-flag vessel operators for purposes of VISA eligibility.

VISA Concept

The mission of VISA is to provide commercial sealift and intermodal shipping services and systems, including vessels, vessel space, intermodal systems and equipment, terminal facilities, and related management services, to the Department of Defense (DOD), as necessary, to meet national defense contingency requirements or national emergencies.

VISA provides for the staged, time-phased availability of participants' shipping services/systems to meet contingency requirements through prenegotiated contracts between the Government and participants. Such arrangements are jointly planned with the Maritime Administration, U.S. Transportation Command (USTRANSCOM), and participants in peacetime to allow effective and best valued use of commercial sealift capacity, to provide DOD assured contingency access, and to minimize commercial disruption, whenever possible.

There are three time-phased stages in the event of VISA activation. VISA Stages I and II provide for prenegotiated contracts between DOD and participants to provide sealift capacity to meet all projected DOD contingency requirements. These contracts are executed in accordance with approved DOD contracting methodologies. VISA Stage III will provide for additional capacity to DOD when Stages I and II commitments or volunteered capacity are insufficient to meet contingency requirements, and adequate shipping services from non-participants are not available through established DOD contracting practices or U.S. Government treaty agreements.

VISA Annual Enrollment Open Season

The purpose of this notice is to invite interested, qualified U.S.-flag vessel operators that are not currently enrolled in the VISA program to participate. The annual enrollment is intended to link the VISA enrollment cycle with DOD's peacetime cargo contracting to ensure eligible participants priority consideration for DOD awards of cargo.

Alignment of VISA enrollment and eligibility for VISA priority will solidify the linkage between commitment of contingency assets by VISA participants and receiving VISA priority consideration for the award of DOD peacetime cargo. This is the only planned enrollment period for carriers to join the VISA program and derive benefits for DOD peacetime contracts during the time frame of October 1, 2012 through September 30, 2013. The only exception to this open season period for VISA enrollment will be for a non-VISA carrier that reflags a vessel into U.S. registry. That carrier may submit an application to participate in the VISA program at any time upon completion of reflagging.

Advantages of Peacetime Participation

Carriers enrolled in the VISA program provides DOD with assured access to sealift services during contingencies based on a level of commitment, as well as a mechanism for joint planning. In return for their VISA commitment, DOD awards peacetime cargo contracts to VISA participants on a priority basis. Award of DOD cargoes to meet DOD peacetime and contingency requirements is made on the basis of the following priorities:

- U.S.-flag vessel capacity operated by VISA participants and U.S.-flag Vessel Sharing Agreement (VSA) capacity held by VISA participants.
- U.S.-flag vessel capacity operated by non-participants.
- Combination U.S.-flag/foreign-flag vessel capacity operated by VISA participants, and combination U.S.-flag/foreign-flag VSA capacity held by VISA participants.
- Combination U.S.-flag/foreign-flag vessel capacity operated by non-participants.
- U.S.-owned or operated foreign-flag vessel capacity and VSA capacity held by VISA participants.
- U.S.-owned or operated foreign-flag vessel capacity and VSA capacity held by non-participants.
- Foreign-owned or operated foreign-flag vessel capacity of non-participants.

Participation

Any U.S.-flag vessel operator organized under the laws of a state of the United States, or the District of Columbia, who is able and willing to commit militarily useful sealift assets and assume the related consequential risks of commercial disruption, may be eligible to participate in the VISA program. The term ''operator'' is defined in the VISA document as ''an ocean common carrier or contract carrier that owns, controls or manages vessels by which ocean transportation is provided.'' Applicants wishing to become participants must provide satisfactory evidence that the vessels being committed to the VISA program are operational and that vessels are intended to be operated by the applicant in the carriage of commercial or government preference cargoes. While vessel brokers, freight forwarders and agents play an important role as a conduit to locate and secure appropriate vessels for the carriage of DOD cargo, they may not become participants in the VISA program due to lack of requisite vessel ownership or operation. However, brokers, freight forwarders and agents should encourage the carriers they represent to join the program.

Commitment

Any U.S.-flag vessel operator desiring to receive priority consideration in the award of DOD peacetime contracts must commit no less than 50 percent of its total U.S.-flag militarily useful capacity in Stage III of the VISA program. Participants operating vessels in international trade may receive top tier consideration in the award of DOD peacetime contracts by committing the minimum percentages of capacity to all three stages of VISA or bottom tier consideration by committing the minimum percentage of capacity to only Stage III of VISA. USTRANSCOM and the Maritime Administration will coordinate to ensure that the amount of sealift assets committed to Stages I and II will not have an adverse national economic impact. To minimize domestic commercial disruption, participants operating vessels exclusively in the domestic Jones Act trades are not required to commit the capacity of those U.S. domestic trading vessels to VISA Stages I and II. Overall VISA commitment requirements are based on annual enrollment.

In order to protect a U.S.-flag vessel operator's market share during contingency activation, VISA allows participants to join with other vessel operators in Carrier Coordination

Agreements (CCAs) to satisfy commercial or DOD requirements. VISA provides a defense against antitrust laws in accordance with the DPA. CCAs must be submitted to the Maritime Administration for coordination with the Department of Justice for approval, before they can be utilized.

Vessel Position Reporting

If VISA applicants have the capability to track their vessels, they must state which system is used in their VISA application and will be required to provide the Maritime Administration with access to their vessel tracking systems upon approval of their VISA application. If VISA applicants do not have a tracking system, they must indicate this in their VISA application. The VISA program requires enrolled ships to comply with 46 CFR Part 307, Establishment of Mandatory Position Reporting System for Vessels.

Compensation

In addition to receiving priority in the award of DOD peacetime cargo, a participant will receive compensation during contingency activation for that capacity activated under Stage I, II and III. The amount of compensation will depend on the Stage at which capacity is activated. During enrollment, each participant must select one of several compensation methodologies. The compensation methodology selection will be completed with the appropriate DOD agency, resulting in prices in contingency contracts between DOD and the participant.

Application for VISA Participation

New applicants may apply to participate by obtaining a VISA application package (Form MA–1020 (OMB Approval No. 2133–0532)) from the Director, Office of Sealift Support, at the address indicated below. Form MA–1020 includes instructions for completing and submitting the application, blank VISA Application forms and a request for information regarding the operations and U.S. citizenship of the applicant company. A copy of the VISA document as published in the **Federal Register** on March 24, 2010, will also be provided with the package. This information is needed in order to assist the Maritime Administration in making a determination of the applicant's eligibility. An applicant company must provide an affidavit that demonstrates that the company is qualified to document a vessel under 46 U.S.C. 12103, and that it owns, or bareboat charters and controls, oceangoing, militarily useful vessel(s) for purposes of committing assets to the VISA program.

New VISA applicants are required to submit their applications for the VISA program as described in this Notice no later than 30 days after the date of publication of this **Federal Register** notice. Applicants must provide the following:

- U.S. citizenship documentation;
- Copy of their Articles of Incorporation and/or By Laws;
- Copies of loadline documents from a recognized classification society to validate oceangoing vessel capability;
- U.S. Coast Guard Certificates of Documentation for all vessels in their fleet;
- Copy of Bareboat Charters, if applicable, valid through the period of enrollment, which state that the owner will not interfere with the charterer's obligation to commit chartered vessel(s) to the VISA program for the duration of the charter; and
- Copy of Time Charters, valid through the period of enrollment, for tug services to barge operators, if sufficient tug service is not owned or bareboat chartered by the VISA applicant. Barge operators must provide evidence to MARAD that tug service of sufficient horsepower will be available for all barges enrolled in the VISA program.

Approved VISA participants will be responsible for ensuring that information submitted with their application remains up to date beyond the approval process. Any changes to VISA commitments must be reported to the Maritime Administration and USTRANSCOM not later than seven days after the change. If charter agreements are due to expire, participants must provide the Maritime Administration with charters that extend the charter duration for another 12 months or longer.

Once the Maritime Administration has reviewed the application and determined VISA eligibility, the Maritime Administration will sign the VISA application document which completes the eligibility phase of the VISA enrollment process.

After VISA eligibility is approved by the Maritime Administration, approved applicants are required to execute a VISA Enrollment Contract (VEC) with DOD [USTRANSCOM]. USTRANSCOM will specify the participant's Stage III commitment, and appropriate Stage I and/or II commitments for the period October 1, 2012 through September 30, 2013. Once the VEC is completed, the applicant completes the DOD contracting process with USTRANSCOM by executing a Drytime Contingency Contract (DCC), if applicable, and for Liner Operators, a VISA Contingency Contract (VCC). The Maritime Administration reserves the right to revalidate all eligibility requirements without notice.

FOR ADDITIONAL INFORMATION AND APPLICATIONS CONTACT: Jerome D. Davis, Director, Office of Sealift Support, U.S. Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone (202) 366–0688; Fax (202) 366–5904. Other information about the VISA can be found on the Maritime Administration's Internet Web Page at *http://www.marad.dot.gov*.

Authority: 49 CFR 1.66.

By Order of the Maritime Administrator.

Dated: August 27, 2012.

Christine Gurland,

Acting Secretary, Maritime Administration.

[FR Doc. 2012–21727 Filed 8–31–12; 8:45 am]

BILLING CODE 4910–81–P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Notice of Open Meetings To Prepare and Release 2012 Annual Report to Congress

Advisory Committee: U.S.-China Economic and Security Review Commission.

ACTION: Notice of open meetings to be held in Washington, DC as follows: (1) Review-Edit 2012 Annual Report to Congress—August 1–2, September 12–13, October 11–12, and October 23–24, and (2) Official Public Release of Commission's Annual Report—November 14, 2012.

SUMMARY: Notice is hereby given of meetings of the U.S.-China Economic and Security Review Commission.

Name: Dennis C. Shea, Chairman of the U.S.-China Economic and Security Review Commission.

The Commission is mandated by Congress to investigate, assess, evaluate and report to Congress annually on the U.S.-China economic and security relationship. The mandate specifically charges the Commission to prepare a report to Congress ''regarding the national security implications and impact of the bilateral trade and economic relationship between the United States and the People's Republic of China [that] shall include a full analysis, along with conclusions and recommendations for legislative and administrative actions * * *''

Purpose of Meetings

Pursuant to this mandate, the Commission will meet in Washington,

DC on August 1–2, September 12–13, October 11–12, and October 23–24, 2012 to consider drafts of material for its 2012 Annual Report to Congress that have been prepared for its consideration by the Commission staff, and to make modifications to those drafts that Commission members believe are needed; and release the final Annual Report to the public on November 14, 2012.

The report review-editing sessions are for members of the Commission to review and edit staff drafts of sections of the Commission's 2012 Annual Report for submission to Congress. The Commission is subject to the Federal Advisory Committee Act (FACA) with the enactment of the Science, State, Justice, Commerce and Related Agencies Appropriations Act, 2006 that was signed into law on November 22, 2005 (Pub. L. 109–108). In accord with FACA's requirement, meetings of the Commission to make decisions concerning the substance and recommendations of its 2012 Annual Report to Congress are open to the public.

Topics To Be Discussed

The Commissioners will be considering draft report sections addressing the following topics:

- The United States-China trade and economic relationship, including its bilateral investment and the role of state-owned enterprises, intellectual property protection and its 5-year plan, technology transfers, and outsourcing.
- China's activities directly affecting U.S. national security interests, including its area control military strategy, space developments, and intelligence activities and capabilities.
- China's foreign and regional activities and relationships, including those pertaining to Taiwan and Hong Kong.
- China's foreign and national security policies.

Dates, Times, and Room Locations (Eastern Daylight Time)

- Wednesday, August 1, 2012 (10 a.m. to 5 p.m.)—Room 231
- Thursday, August 2, 2012 (9 a.m. to 5 p.m.)—Room 231
- Wednesday and Thursday, September 12–13, 2012 (9 a.m. to 5 p.m.)—Room 233
- Thursday and Friday, October 11–12, 2012 (9 a.m. to 5 p.m.)—Room 231
- Tuesday and Wednesday, October 23–24, 2012 (9 a.m. to 5 p.m.)—Room 231
- Wednesday, November 14, 2012—Official Press Conference to Release Final Report to the Public—Date, Time and Location will be announced in October on the Commission's Web site at *www.uscc.gov.*

ADDRESSES: All report review-editing sessions will be held in The Hall of the States (North Bldg., 2nd Floor), located at 444 North Capitol Street NW., Washington, DC 20001. The location for the Official Press Conference to release the final Annual Report to the public will be announced on the Commission's Web site at *www.uscc.gov* in October 2012.

Public seating is limited and will be available on a ''first-come, first-served'' basis. Advanced reservations are not required. All participants must register at the front desk of the lobby.

Required Accessibility Statement

The entirety of these Commission editorial and drafting meetings will be open to the public. The Commission may recess the public editorial/drafting sessions to address administrative issues in closed session.

The open meetings will also be adjourned in the noon vicinity for a lunch break. At the beginning of the lunch break, the Chairman will announce the reconvening time for the Annual Report review and editing session so members of the public will know when they may return if they wish to do so.

FOR FURTHER INFORMATION CONTACT: Gavin Williams, USCC Staff Assistant, U.S.-China Economic and Security Review Commission, 444 North Capitol Street NW., Suite 602, Washington, DC 20001; Phone: (202) 624–1407; Email: *gwilliams@uscc.gov*

Authority

Congress created the U.S.-China Economic and Security Review Commission in 2000 in the National Defense Authorization Act (Pub. L. 106–398), as amended by Division P of the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7), as amended by Public Law 109–108 (November 22, 2005).

Date: August 29, 2012.

Michael Danis,

Executive Director, U.S.-China Economic and Security Review Commission.

[FR Doc. 2012–21702 Filed 8–31–12; 8:45 am]

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FEDERAL REGISTER

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No. 171 September 4, 2012

Part II

Department of Health and Human Services

45 CFR Part 170

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 495

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2; 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; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 495

[CMS–0044–F]

RIN 0938–AQ84

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2

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

ACTION: Final rule.

SUMMARY: This final rule specifies the Stage 2 criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and/or Medicaid electronic health record (EHR) incentive payments. In addition, it specifies payment adjustments under Medicare for covered professional services and hospital services provided by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of certified EHR technology (CEHRT) and other program participation requirements. This final rule revises certain Stage 1 criteria, as finalized in the July 28, 2010 final rule, as well as criteria that apply regardless of Stage.

DATES: *Effective dates:* This final rule is effective on November 5, 2012, with the exception of the definition of ''meaningful EHR user'' in § 495.4 and the provisions in § 495.6(f), § 495.6(g), § 495.8, § 495.102(c), and part 495 subpart D, which are effective September 4, 2012.

Applicability dates: Sections 495.302, 495.304, and 495.306 are applicable beginning payment year 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth Holland, (410) 786–1309, or Robert Anthony, (410) 786–6183, EHR Incentive Program issues or Administrative appeals process issues. David Koppel, (410) 786–3255, for Medicaid Incentive Program issues. Frank Szeflinski, (303) 844–7119, for Medicare Advantage issues. Travis Broome, (214) 767–4450, Medicare payment adjustment issues. Douglas Brown, (410) 786–0028, or Maria Michaels, (410) 786–2809 for Clinical quality measures issues.

SUPPLEMENTARY INFORMATION:

Acronyms

ARRA American Recovery and Reinvestment Act of 2009
AAC Average Allowable Cost (of CEHRT)
ACO Accountable Care Organization
AIU Adopt, Implement, Upgrade (CEHRT)
CAH Critical Access Hospital
CAHPS Consumer Assessment of Healthcare Providers and Systems
CCN CMS Certification Number
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
CPOE Computerized Provider Order Entry
CQM Clinical Quality Measure
CY Calendar Year
EHR Electronic Health Record
EP Eligible Professional
EPO Exclusive Provider Organization
FACA Federal Advisory Committee Act
FFP Federal Financial Participation
FFY Federal Fiscal Year
FFS Fee-For-Service
FQHC Federally Qualified Health Center
FTE Full-Time Equivalent
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
HITPC Health Information Technology Policy Committee
HIPAA Health Insurance Portability and Accountability Act of 1996
HITECH Health Information Technology for Economic and Clinical Health Act
HMO Health Maintenance Organization
HOS Health Outcomes Survey
HPSA Health Professional Shortage Area
HRSA Health Resource and Services Administration
IAPD Implementation Advance Planning Document
ICR Information Collection Requirement
IHS Indian Health Service
IPA Independent Practice Association
IT Information Technology
LOINC Logical Observation Identifiers and Codes System
MA Medicare Advantage
MAC Medicare Administrative Contractor
MAO Medicare Advantage Organization
MCO Managed Care Organization
MITA Medicaid Information Technology Architecture
MMIS Medicaid Management Information Systems
MSA Medical Savings Account
NAAC Net Average Allowable Cost (of CEHRT)
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NPI National Provider Identifier
NPRM Notice of Proposed Rulemaking
ONC Office of the National Coordinator for Health Information Technology
PAHP Prepaid Ambulatory Health Plan
PAPD Planning Advance Planning Document
PCP Primary Care Provider
PECOS Provider Enrollment, Chain, and Ownership System
PFFS Private Fee-For-Service
PHO Physician Hospital Organization
PHR Personal Health Record
PHS Public Health Service
PHSA Public Health Service Act
PIHP Prepaid Inpatient Health Plan
POS Place of Service
PPO Preferred Provider Organization
PQRS Physician Quality Reporting System
PSO Provider Sponsored Organization
RHC Rural Health Clinic
RPPO Regional Preferred Provider Organization
SAMHSA Substance Abuse and Mental Health Services Administration
SMHP State Medicaid Health Information Technology Plan
TIN Tax Identification Number

Table of Contents

I. Executive Summary and Overview
A. Executive Summary
1. Purpose of Regulatory Action
a. Need for the Regulatory Action
b. Legal Authority for the Regulatory Action
2. Summary of Major Provisions
a. Stage 2 Meaningful Use Objectives and Measures
b. Reporting on Clinical Quality Measures (CQMs)
c. Payment Adjustments and Exceptions
d. Modifications to Medicaid EHR Incentive Program
e. Stage 2 Timeline Delay
3. Summary of Costs and Benefits
B. Overview of the HITECH Programs Created by the American Recovery and Reinvestment Act of 2009
II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments
A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs
1. Uniform Definitions
2. Meaningful EHR User
3. Definition of Meaningful Use
a. Considerations in Defining Meaningful Use
b. Changes to Stage 1 Criteria for Meaningful Use
c. State Flexibility for Stage 2 of Meaningful Use
d. Stage 2 Criteria for Meaningful Use (Core Set and Menu Set)
(1) Discussion of Whether Certain EPs, Eligible Hospitals or CAHs can meet all Stage 2 Meaningful Use Objectives Given Established Scopes of Practice
(2) EPs Practicing in Multiple Practices/Locations
(3) Discussion of the Reporting Requirements of the Measures Associated with the Stage 2 Meaningful Use Objectives
B. Reporting on Clinical Quality Measures Using Certified EHRs Technology by Eligible Professionals, Eligible Hospitals, and Critical Access Hospitals
1. Time Periods for Reporting Clinical Quality Measures
2. Certification Requirements for Clinical Quality Measures

3. Criteria for Selecting Clinical Quality Measures
4. Clinical Quality Measures for Eligible Professionals
a. Statutory and Other Considerations
b. Clinical Quality Measures for Eligible Professionals for CY 2013
c. Clinical Quality Measures for Eligible Professionals Beginning With CY 2014
5. Reporting Methods for Clinical Quality Measures for Eligible Professionals
a. Reporting Methods for Medicaid EPs
b. Reporting Methods for Medicare EPs in CY 2013
c. Reporting Methods for Medicare EPs Beginning With CY 2014
d. Group Reporting Option for Medicare and Medicaid Eligible Professionals Beginning With CY 2014
6. Clinical Quality Measures for Eligible Hospitals and Critical Access Hospitals
a. Statutory and Other Considerations
b. Clinical Quality Measures for Eligible Hospitals and CAHs for FY 2013
7. Reporting Methods for Eligible Hospitals and Critical Access Hospitals
a. Reporting Methods in FY 2013
b. Reporting Methods Beginning With FY 2014
c. Electronic Reporting of Clinical Quality Measures for Medicaid Eligible Hospitals
C. Demonstration of Meaningful Use and Other Issues
1. Demonstration of Meaningful Use
a. Common Methods of Demonstration in Medicare and Medicaid
b. Methods for Demonstration of the Stage 2 Criteria of Meaningful Use
c. Group Reporting Option of Meaningful Use Core and Menu Objectives and Associated Measures for Medicare and Medicaid EPs Beginning With CY 2014
2. Data Collection for Online Posting, Program Coordination, and Accurate Payments
3. Hospital-Based Eligible Professionals
4. Interaction With Other Programs
D. Medicare Fee-for-Service
1. General Background and Statutory Basis
2. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs Who Are Not Meaningful Users of CEHRT for an Applicable Reporting Period
a. Applicable Payment Adjustments in CY 2015 and Subsequent Calendar Years for EPs Who Are Not Meaningful Users of CEHRT
b. EHR Reporting Period for Determining Whether an EP Is Subject to the Payment Adjustment for CY 2015 and Subsequent Calendar Years
c. Exception to the Application of the Payment Adjustment to EPs in CY 2015 and Subsequent Calendar Years
d. HPSA Bonus Technical Change
e. Payment Adjustment Not Applicable to Hospital-Based EPs
3. Incentive Market Basket Adjustment Effective in FY 2015 and Subsequent Years for Eligible Hospitals That Are Not Meaningful EHR Users for an Applicable Reporting Period
a. Applicable Market Basket Adjustment for Eligible Hospitals Who Are Not Meaningful EHR Users for FY 2015 and Subsequent FYs
b. EHR Reporting Period for Determining Whether a Hospital is Subject to the Market Basket Adjustment for FY 2015 and Subsequent FYs
c. Exception to the Application of the Market Adjustment to Hospitals in FY 2015 and Subsequent FYs
d. Application of Market Basket Adjustment in FY 2015 and Subsequent FYs to a State Operating Under a Payment Waiver Provided by Section 1814(B)(3) of the Act
4. Reduction of Reasonable Cost Reimbursement in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users
a. Applicable Reduction of Reasonable Cost Payment Reduction in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users
b. EHR Reporting Period for Determining Whether a CAH Is Subject to the Applicable Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years
c. Exception to the Application of Reasonable Cost Payment Reductions to CAHs in FY 2015 and Subsequent FYs
5. Administrative Review Process of Certain Electronic Health Record Incentive Program Determinations
E. Medicare Advantage Organization Incentive Payments
1. Definition (§ 495.200)
2. Identification of Qualifying MA Organizations, MA–EPs and MA-Affiliated Eligible Hospitals (§ 495.202)
3. Incentive Payments to Qualifying MA Organizations for Qualifying MA EPs and Qualifying MA-Affiliated Eligible Hospitals (§ 495.204)
a. Amount Payable to a Qualifying MA Organization for Its Qualifying MA EPs
b. Increase in Incentive Payment for MA EPs Who Predominantly Furnish Services in a Geographic Health Professional Shortage Area (HPSA)
4. Avoiding Duplicate Payments
5. Payment Adjustments Effective in 2015 and Subsequent MA Payment Adjustment Years (§ 495.211).
6. Reconsideration Process for MA Organizations
F. Revisions and Clarifications to the Medicaid EHR Incentive Program
1. Net Average Allowable Costs
2. Eligibility Requirements for Children's Hospitals
3. Medicaid Professionals Program Eligibility
a. Calculating Patient Volume Requirements
b. Practices Predominately
4. Medicaid Hospital Incentive Payment Calculation
a. Discharge Related Amount
b. Acute Care Inpatient Bed Days and Discharges for the Medicaid Share and Discharge- Related Amount
c. Hospitals Switching States
5. Hospital Demonstrations of Meaningful Use—Auditing and Appeals
6. State Flexibility for Stage 2 of Meaningful Use
7. State Medicaid Health Information Technology Plan (SMHP) and Implementation Advance Planning Document (IAPD)
a. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates
b. Requirements of States Transitioning From HIT Planning Advanced Planning Documents (P–APDs) to HIT IAPDs
III. Waiver of Delay in Effective Date
IV. Collection of Information Requirements
A. ICR Regarding Demonstration of Meaningful Use Criteria (§ 495.6 and § 495.8)
B. ICRs Regarding Qualifying MA Organizations (§ 495.210)
C. ICRs Regarding State Medicaid Agency and Medicaid EP and Hospital Activities (§ 495.332 Through § 495.344)
V. Regulatory Impact Analysis
A. Statement of Need
B. Overall Impact
C. Anticipated Effects
1. Overall Effects
a. Regulatory Flexibility Analysis and Small Entities
(1) Number of Small Entities
(2) Conclusion
b. Small Rural Hospitals
c. Unfunded Mandates Reform Act
d. Federalism
2. Effects on Eligible Professionals, Eligible Hospitals, and CAHs
a. Background and Assumptions
b. Industry Costs and Adoption Rates
c. Costs of EHR Adoption for EPs
d. Costs of EHR Adoption for Eligible Hospitals
3. Medicare Incentive Program Costs
a. Medicare Eligible Professionals (EPs)
b. Medicare Eligible Hospitals and CAHs
c. Critical Access Hospitals (CAHs)
4. Medicaid Incentive Program Costs
a. Medicaid EPs
b. Medicaid Hospitals
5. Benefits For All EPs and All Eligible Hospitals
6. Benefits to Society
7. General Considerations
8. Summary
9. Explanation of Benefits and Savings Calculations
D. Accounting Statement
E. Conclusion

Regulations Text

I. Executive Summary and Overview

A. Executive Summary

1. Purpose of Regulatory Action

a. Rationale for the Regulatory Action

In this final rule the Secretary of the Department of Health and Human Services (the Secretary) will specify Stage 2 criteria beginning in 2014 that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for an incentive payment, as well as introduce changes to the program timeline and detail Medicare payment adjustments. Recommendations on Stage 2 criteria from the Health IT

Policy Committee (HITPC), a Federal Advisory Committee that coordinates industry and provider input regarding the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs were substantially adopted, with consideration of current program data for the Medicare and Medicaid EHR Incentive Programs. Our current program data is derived from two sources. First, data elements from the registration and attestation process of those providers who have already registered and attested to Stage 1 of meaningful use. This includes demographic information about the provider, the Certified EHR Technology (CEHRT) used by the provider and their performance on the meaningful use objectives and measures. Second, we have information from thousands of questions providers submitted about the EHR Incentive Programs. These questions provide insights into the difficulties faced by providers and also into the areas of the EHR Incentive Programs that warrant additional clarification.

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, and 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, Medicare Advantage (MA) organizations (for certain qualifying EPs and hospitals that meaningfully use CEHRT), subsection (d) hospitals and critical access hospitals (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 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 Stage 1 final rule (75 FR 44316 through 44317).

2. Summary of Major Provisions

a. Stage 2 Meaningful Use Objectives and Measures

In the Stage 1 final rule we outlined Stage 1 meaningful use criteria, we finalized a separate set of core objectives and menu objectives for EPs, eligible hospitals and CAHs. EPs and hospitals must meet the measure or qualify for an exclusion to all 15 core objectives and 5 out of the 10 menu objectives in order to qualify for an EHR incentive payment. In this final rule, we maintain the same core-menu structure for the program for Stage 2. We are finalizing that EPs must meet the measure or qualify for an exclusion to 17 core objectives and 3 of 6 menu objectives. We are finalizing that eligible hospitals and CAHs must meet the measure or qualify for an exclusion to 16 core objectives and 3 of 6 menu objectives. Nearly all of the Stage 1 core and menu objectives are retained for Stage 2. The ''exchange of key clinical information'' core objective from Stage 1 was re-evaluated in favor of a more robust ''transitions of care'' core objective in Stage 2, and the ''Provide patients with an electronic copy of their health information'' objective was removed because it was replaced by a ''view online, download, and transmit'' core objective. There are also multiple Stage 1 objectives that were combined into more unified Stage 2 objectives, with a subsequent rise in the measure threshold that providers must achieve for each objective that has been retained from Stage 1.

b. Reporting on Clinical Quality Measures (CQMs)

EPs, eligible hospitals, and CAHs are required to report on specified clinical quality measures in order to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs. This final rule outlines a process by which EPs, eligible hospitals, and CAHs will submit CQM data electronically, reducing the associated burden of reporting on quality measures for providers. EPs will submit 9 CQMs from at least 3 of the National Quality Strategy domains out of a potential list of 64 CQMs across 6 domains. We are recommending a core set of 9 CQMs focusing on adult populations with a particular focus on controlling blood pressure. We are also recommending a core set of 9 CQMs for pediatric populations. EPs should report on these recommended CQMs if they are representative of their clinical practice and patient population. Eligible hospitals and CAHs will submit 16 CQMs from at least 3 of the National Quality Strategy domains out of a potential list of 29 CQMs across 6 domains. For the Medicare EHR Incentive Program, EPs, eligible hospitals, and CAHs in their first year of demonstrating meaningful use must submit their CQM data via attestation, and those beyond their first year must submit their CQM data electronically via a CMS-designated transmission method. For EPs, this includes an aggregate electronic submission or a patient-level electronic submission through the method specified by the Physician Quality Reporting System (PQRS) that would provide one submission for credit in both the PQRS and Medicare EHR Incentive Program. For eligible hospitals and CAHs, this includes an aggregate electronic submission or a patient-level data submission through the method similar to the Medicare EHR Incentive Program Electronic Reporting Pilot, which is proposed for extension in the CY 2013 Hospital Outpatient Prospective Payment System (OPPS) proposed rule (July 30, 2012, 77 FR 45188). For electronic submissions, patient-level data must be submitted using the Quality Reporting Data Architecture (QRDA) Category I format, and aggregate-level data must be submitted using the QRDA Category III format.

c. Payment Adjustments and Exceptions

Medicare payment adjustments are required by statute to take effect in 2015. We are finalizing a process by which payment adjustments will be determined by a prior reporting period. Therefore, we specify that EPs and eligible hospitals that are meaningful EHR users in 2013 will avoid payment adjustment in 2015. Also, if such providers first meet meaningful use in 2014, they will avoid the 2015 payment adjustment, if they are able to demonstrate meaningful use at least 3 months prior to the end of the calendar (for EPs) or fiscal year (for eligible hospitals) and meet the registration and attestation requirement by July 1, 2014 (for eligible hospitals) or October 1, 2014 (for EPs).

We also are finalizing exceptions to these payment adjustments. This final rule outlines four categories of exceptions based on (1) the lack of availability of internet access or barriers to obtaining IT infrastructure; (2) a time-limited exception for newly practicing EPs or new hospitals that will not otherwise be able to avoid payment adjustments; (3) unforeseen circumstances such as natural disasters that will be handled on a case-by-case basis; and (4) (EP only) exceptions due to a combination of clinical features

limiting a provider's interaction with patients or, if the EP practices at multiple locations, lack of control over the availability of CEHRT at practice locations constituting 50 percent or more of their encounters.

d. Modifications to Medicaid EHR Incentive Program

We are expanding the definition of what constitutes a Medicaid patient encounter, which is a required eligibility threshold for the Medicaid EHR Incentive Programs. We include encounters for individuals enrolled in a Medicaid program, including Title XXI-funded Medicaid expansion encounters (but not separate Children's Health Insurance Programs (CHIPs)). We also specify flexibility in the lookback period for patient volume to be over the 12 months preceding attestation, not tied to the prior calendar year.

We are also making eligible approximately 12 additional children's hospitals that have not been able to participate to date, despite meeting all other eligibility criteria, because they do not have a CMS Certification Number since they do not bill Medicare.

These changes would take effect beginning with payment year 2013.

e. Stage 2 Timeline Delay

Lastly, we are finalizing a delay in the implementation of the onset of Stage 2 criteria. In the Stage 1 final rule, we established that any provider who first attested to Stage 1 criteria in 2011 would begin using Stage 2 criteria in 2013. This final rule delays the onset of those Stage 2 criteria until 2014, which we believe provides the needed time for vendors to develop CEHRT. We are also introducing a special 3-month EHR reporting period, rather than a full year of reporting, for providers attesting to either Stage 1 or Stage 2 in 2014 in order to allow time for providers to implement newly certified CEHRT. In future years, providers who are not in their initial year of demonstrating meaningful use must meet criteria for 12-month reporting periods. The 3-month reporting period allows providers flexibility in their first year of meeting Stage 2 without warranting any delay for Stage 3. This policy is consistent with CMS's commitment to ensure that Stage 3 occurs on schedule (implemented by 2016).

3. Summary of Costs and Benefits

This final rule 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 that to the best of our ability presents the costs and benefits of the final rule. The total Federal cost of the Medicare and Medicaid EHR Incentive Programs between 2014 and 2019 is estimated to be $15.4 billion (these estimates include net payment adjustments for Medicare providers who do not achieve meaningful use in 2015 and subsequent years in the amount of $2.1 billion). In this final rule we have not quantified the overall benefits to the industry, nor to EPs, eligible hospitals, or CAHs participating in the Medicare and Medicaid EHR Incentive Programs. Information on the costs and benefits of adopting systems specifically meeting the requirements for the EHR Incentive Programs has not yet been collected and information on costs and benefits overall is limited. Nonetheless, we believe there are substantial benefits that can be obtained by eligible hospitals and EPs, including reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, increased patient safety, and reduced medical errors. There is evidence to support the cost-saving benefits anticipated from wider adoption of EHRs.

TABLE 1—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	
2014	$2.1	$1.9	$0.6	$0.5	$5.10
2015	1.8	1.9	0.4	0.8	4.90
2016	1.2	0.6	0.5	0.8	3.10
2017	0.2	0.1	0.5	0.7	1.50
2018	−0.1	−0.2	0.1	0.7	0.50
2019	0.0	−0.2	0.0	0.5	0.30

B. Overview of the HITECH Programs Created by the American Recovery and Reinvestment Act of 2009

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, and CAHs, and Medicare Advantage (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 entitled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program,'' that specified the Stage 1 criteria that 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 (hereinafter referred to as the Stage 1 final rule). (For a full explanation of the amendments made by ARRA, see the Stage 1 final rule (75 FR 44316).) In that final rule, we also detailed that the Medicare and Medicaid EHR Incentive Programs will consist of 3 different stages of meaningful use requirements.

For Stage 1, CMS and the Office of the National Coordinator for Health Information Technology (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 part 170.

For Stage 2, CMS and ONC again worked together to align our regulations.

In the March 7, 2012 **Federal Register** (77 FR 13698), we published a proposed rule that specified the potential Stage 2 criteria that EPs, eligible hospitals, and CAHs would have to meet in order to qualify for Medicare and/or Medicaid EHR incentive payments (hereinafter referred to as the Stage 2 proposed rule). In addition, the proposed rule —(1) proposed payment adjustments under Medicare for covered professional services and hospital services provided

by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of CEHRT and other program participation requirements; and (2) proposed the revision of certain Stage 1 criteria, as well as criteria that apply regardless of stage.

In the April 18, 2012 **Federal Register** (77 FR 23193), we published a document that corrected typographical and technical errors in the March 7, 2012 Stage 2 proposed rule.

Simultaneously in the March 7, 2012 **Federal Register** (77 FR 13832), ONC published its notice of proposed rulemaking 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. The notice of proposed rulemaking proposed revisions to the initial set of standards, implementation specifications, and certification criteria in ONC's July 28, 2010 final rule as well as the adoption of new standards, implementation specifications, and certification criteria.

We urge those interested in this final rule to also review the ONC final rule on standards and implementation specifications for CEHRT. Readers may also visit *http://www.cms.hhs.gov/EHRincentiveprograms* and *http://healthit.hhs.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

We received approximately 6,100 items of timely correspondence in response to our Stage 2 proposed rule published in the March 7, 2012 **Federal Register**. We received some comments that were outside the scope of the proposed rule and therefore are not addressed in this final rule. Summaries of the timely public comments that are within the scope of the Stage 2 proposed rule and our responses to those comments are set forth in the various sections of this final rule under the appropriate headings. We have generally organized those sections by stating our proposals, summarizing and responding to the timely public comments received, and describing our final policy.

A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs

1. Uniform Definitions

As discussed in the proposed rule, in the Stage 1 final rule, we finalized many uniform definitions for the Medicare FFS, Medicare Advantage (MA), and Medicaid EHR incentive programs. These definitions are set forth in part 495 subpart A of the regulations, and we proposed to maintain most of these definitions, including, for example, ''Certified EHR Technology (CEHRT),'' ''Qualified EHR,'' ''Payment Year,'' and ''First, Second, Third, Fourth, Fifth, and Sixth Payment Year.'' We noted in the Stage 2 proposed rule that our definitions of ''CEHRT'' and ''Qualified EHR'' incorporate the definitions adopted by ONC, and to the extent that ONC's definitions are revised, our definitions would also incorporate those changes. For these definitions, we refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register**.

We did not receive any comments on our proposal and will continue to use the existing definitions in part 495 subpart A, except where stated otherwise in this final rule.

We stated that we would revise the descriptions of the EHR reporting period to clarify that providers who are demonstrating meaningful use for the first time would have an EHR reporting period of 90 days regardless of payment year. We proposed to add definitions for the applicable EHR reporting period that would be used in determining the payment adjustments, as well as a definition of a payment adjustment year.

A summary of the comments pertaining to the EHR reporting period, the applicable EHR reporting period for determining the payment adjustments, and the definition of a payment adjustment year, as well as our responses to those comments, can be found in sections II.A.3.a and II.D.2 of this final rule.

2. Meaningful EHR User

We proposed to include clinical quality measure reporting as part of the definition of ''meaningful EHR user'' under § 495.4 instead of as a separate meaningful use objective under § 495.6.

Comment: A few commenters suggested that this change would create confusion, but the majority supported this change to alleviate confusion caused by the current situation. Many comments discussed the specifics of clinical quality measures.

Response: We appreciate the support expressed for the proposal. We continue to believe that separating clinical quality measures from the meaningful use objectives and measures in § 495.6 will reduce confusion and finalize the change as proposed. We address comments on the specifics of clinical quality measures in section II.B of this final rule. While clinical quality measure reporting will no longer be listed as a separate objective and measure in § 495.6, as it is now incorporated in the definition of meaningful EHR user in § 495.4, it remains a condition for demonstrating meaningful use.

We proposed to revise the third paragraph of the definition of meaningful EHR user at § 495.4 to refer specifically to the payment adjustments and read as follows: ''(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during an EHR reporting period for a payment year (or during an applicable EHR reporting period for a payment adjustment year) must occur at a practice/location or practices/locations equipped with CEHRT.'' We did not receive any comments on this revision and we are finalizing it as proposed.

3. Definition of Meaningful Use

a. Considerations in Defining Meaningful Use

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, the Congress identified the broad goal of expanding the use of EHRs through the concept of meaningful use. Section 1903(t)(6)(C) of the Act also requires that Medicaid providers adopt, implement, upgrade or meaningfully use CEHRT if they are to receive incentives under Title XIX. CEHRT used in a meaningful way is one piece of the broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. This vision of reforming the health care system and improving health care quality, efficiency, and patient safety should inform the definition of meaningful use.

As we explained in our Stage 1 meaningful use rule and again in our Stage 2 proposed rule, we seek to balance the sometimes competing considerations of health system advancement (for example, improving health care quality, encouraging widespread EHR adoption, promoting innovation) and minimizing burdens on health care providers given the short timeframe available under the HITECH Act.

Based on public and stakeholder input received during our Stage 1 rule, we laid out a phased approach to meaningful use. Such a phased approach encompasses reasonable criteria for meaningful use based on currently available technology capabilities and provider practice experience, and builds up to a more robust definition of meaningful use as technology and capabilities evolve. The HITECH Act acknowledges the need for this balance by granting the Secretary the discretion to require more stringent measures of meaningful use over time. Ultimately, consistent with other provisions of law, meaningful use of CEHRT should result in health care that is patient centered, evidence-based, prevention-oriented, efficient, and equitable.

Under this phased approach to meaningful use, we update the criteria of meaningful use through staggered rulemaking. We published the Stage 1 final rule (75 FR 44314) on July 28, 2010, and this rule finalizes the criteria and other requirements for Stage 2. We currently are planning at least one additional update, and anticipate finalizing the Stage 3 criteria through additional rulemaking in early 2014 with Stage 3 starting in 2016. The stages represent an initial graduated approach to arriving at the ultimate goal.

- The Stage 1 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, focused on electronically capturing health information in a structured format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); implementing clinical decision support tools to facilitate disease and medication management; using EHRs to engage patients and families and reporting clinical quality measures and public health information. Stage 1 focused heavily on establishing the functionalities in CEHRT that will allow for continuous quality improvement and ease of information exchange. By having these functionalities in CEHRT at the onset of the program and requiring that the EP, eligible hospital or CAH become familiar with them through the varying levels of engagement required by Stage 1, we believe we created a strong foundation to build on in later years. Though some functionalities were optional in Stage 1, all of the functionalities are considered crucial to maximize the value to the health care system provided by CEHRT. We encouraged all EPs, eligible hospitals and CAHs to be proactive in implementing all of the functionalities of Stage 1 in order to prepare for later stages of meaningful use, particularly functionalities that improve patient care, the efficiency of the health care system and public and population health. The specific criteria for Stage 1 of meaningful use are discussed in the Stage 1 final rule, published on July 28, 2010 (75 FR 44314 through 44588). We are finalizing certain changes to the Stage 1 criteria in section II.A.3.b. of this final rule.
- Stage 2: We stated in the Stage 2 proposed rule that our Stage 2 goals, consistent with other provisions of Medicare and Medicaid law, would expand upon the Stage 1 criteria with a focus on ensuring that the meaningful use of EHRs supports the aims and priorities of the National Quality Strategy. Specifically, Stage 2 meaningful use criteria would encourage the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible. Our proposed Stage 2 meaningful use requirements included rigorous expectations for health information exchange including: more demanding requirements for e-prescribing; incorporating structured laboratory results; and the expectation that providers will electronically transmit patient care summaries with each other and with the patient to support transitions in care. Increasingly robust expectations for health information exchange in Stage 2 and Stage 3 would support the goal that information follows the patient. In addition, as we forecasted in the Stage 1 final rule, we proposed that nearly every objective that was optional for Stage 1 would be part of the core for Stage 2.
- Stage 3: We anticipate that Stage 3 meaningful use criteria will focus on: promoting improvements in quality, safety and efficiency leading to improved health outcomes; focusing on decision support for national high priority conditions; patient access to self-management tools; access to comprehensive patient data through robust, secure, patient-centered health information exchange; and improving population health. For Stage 3, we currently intend to propose higher standards for meeting meaningful use. For example, we intend to propose that every objective in the menu set for Stage 2 be included in Stage 3 as part of the core set. While the use of a menu set allows providers flexibility in setting priorities for EHR implementation and takes into account their unique circumstances, we maintain that all of the objectives are crucial to building a strong foundation for health IT and to meeting the objectives of the HITECH Act. In addition, as the capabilities of HIT infrastructure increase, we may raise the thresholds for these objectives in both Stage 2 and Stage 3.

In the Stage 1 final rule (75 FR 44323), we published the following Table 2 with our expected timeline for the stages of meaningful use.

TABLE 2—STAGE OF MEANINGFUL USE CRITERIA BY PAYMENT YEAR AS FINALIZED IN 2010

First payment year	Payment year				
	2011	2012	2013	2014	2015
2011	Stage 1	Stage 1	Stage 2	Stage 2	TBD
2012		Stage 1	Stage 1	Stage 2	TBD
2013			Stage 1	Stage 1	TBD
2014				Stage 1	TBD

We proposed changes to this timeline as well as its extension beyond 2014. As we explained in the Stage 2 proposed rule, under the timeline used in Table 2, an EP, eligible hospital, or CAH that became a meaningful EHR user for the first time in 2011 would need to begin their EHR reporting period for Stage 2 on January 1, 2013 (EP) or October 1, 2012 (eligible hospital or CAH). The HITPC recommended we delay by 1 year the start of Stage 2 for providers who became meaningful EHR users in 2011. We stated in the proposed rule that Stage 2 of meaningful use would require changes to both technology and workflow that cannot reasonably be expected to be completed in the time

between the publication of the final rule and the start of the EHR reporting periods as listed in Table 2. We noted the similar concerns we have heard from other stakeholders and agreed that, based on our proposed definition of meaningful use for Stage 2, providers could have difficulty implementing these changes in time. Therefore, we proposed a 1-year extension of Stage 1 of meaningful use for providers who successfully demonstrated meaningful use for 2011. Our proposed timeline through 2021, which we finalize in this rule with a notation of the special EHR reporting period in 2014, is displayed in Table 3. We refer readers to section II.D.2 of this final rule for a discussion of the applicable EHR reporting period that will be used to determine whether providers are subject to payment adjustments.

TABLE 3—STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR

First payment year	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	*2	2	3	3	TBD	TBD	TBD	TBD
2012	.....	1	1	*2	2	3	3	TBD	TBD	TBD	TBD
2013	.....	.....	1	*1	2	2	3	3	TBD	TBD	TBD
2014	.....	.....	.....	*1	1	2	2	3	3	TBD	TBD
2015	.....	.....	.....	.....	1	1	2	2	3	3	TBD
2016	.....	.....	.....	.....	.....	1	1	2	2	3	3
2017	.....	.....	.....	.....	.....	.....	1	1	2	2	3

*3-month quarter EHR reporting period for Medicare and continuous 90-day EHR reporting period (or 3 months at state option) for Medicaid EPs. All providers in their first year in 2014 use any continuous 90-day EHR reporting period.

We explained in the proposed rule that the Medicare EHR incentive program and the Medicaid EHR incentive program have different rules regarding the number of payment years available, the last year for which incentives may be received, and the last payment year for initiating the program. The last year for which an EP and an eligible hospital or CAH can begin receiving Medicare incentive payments is 2014 and 2015 respectively. These providers would begin in Stage 1 of meaningful use. Medicaid EPs and eligible hospitals can receive a Medicaid EHR incentive payment for ''adopting, implementing, and upgrading'' (AIU) to CEHRT for their first payment year, which is not reflected in Table 3. For example, a Medicaid EP who earns an incentive payment for AIU in 2013 would have to meet Stage 1 of meaningful use in his or her next 2 payment years (2014 and 2015). The applicable payment years and the incentive payments available for each program are discussed in the Stage 1 final rule.

If we anticipate future criteria beyond Stage 3 of meaningful use, we expect to update Table 3 in the rulemaking for Stage 3, which remains on schedule for implementation in 2016.

Comment: We received numerous comments, which represented a significant majority of all comments received, on the timing of the stages of meaningful use. Commenters asserted that the timeline is too aggressive and will result in many providers being unable to meet Stage 2 of meaningful use, particularly those who first attested in 2011 and 2012. The most common justification for this claim was the lack of sufficient time between the publication of this final rule and the time when a provider who first attested to meaningful use in 2011 or 2012 would have to begin Stage 2 of meaningful use. Some commenters suggested that the time was insufficient regardless of resource constraints, while others suggested that currently vendors of CEHRT lack the necessary capacity to make the necessary upgrades to their CEHRT products and implement them for their customers in time. Commenters also pointed to competing priorities and demands on provider time and resources, such as the transition to ICD–10, the various programs and policies under the Affordable Care Act and other priorities that diminish the time and resources that can be devoted to reaching Stage 2 of meaningful use. Commenters offered several suggestions on how to increase the time available between publication of this final rule and the EHR reporting periods in 2014. The suggestions included using a shorter than full year EHR reporting period in 2014, delaying the start of Stage 2 until 2015 and using a shorter than full year EHR reporting period in 2015, and delaying the start of Stage 2 until 2015 with a full year EHR reporting period. Several commenters suggested a minimum of 18 months is needed, while others suggested longer periods.

Response: While our proposal would provide more than a year between the publication of this final rule and the first day any provider would start their EHR reporting period in 2014 for any stage of meaningful use, we agree that additional time to demonstrate meaningful use in 2014 would be helpful to providers, many of whom will need to upgrade to new technology as well as ensure they are able to meet all of the objectives and measures for Stage 2. In considering what would be an appropriate length of time between publication of this final rule and the start of the EHR reporting periods for providers in 2014 for either Stage 2 or Stage 1, we weighed two primary factors against the comments calling for a delay. The first is that by delaying Stage 2 until 2015, the movement towards improved outcomes that is the main goal of meaningful use would be put off by a full year. This full-year delay would have a ripple effect through the timeline of the stages as providers move along their own timelines across the stages of meaningful use. For this reason, we will not delay Stage 2 until 2015, but instead we are using a 3-month EHR reporting period in 2014 as the first year any provider would attest to Stage 2. The second consideration is the data integrity of meaningful use attestations and clinical quality measure submissions, especially as it relates to our efforts towards alignment with other programs such as PQRS, Medicare Shared Savings Program (SSP), and potentially others. The more robust data set provided by a full year reporting period offers more opportunity for alignment than the data set provided by a shorter reporting period, especially compared across years. By altering the reporting period from year to year the data is less comparable from year to year. However, we agree with commenters that the use of a shorter EHR reporting period in 2014 is necessary to allow sufficient time for vendors to upgrade their CEHRT and for

providers to implement it. In an effort to preserve some data validity with similar Medicare quality measurement programs, we are finalizing 3-month quarter EHR reporting periods in 2014 for certain providers that are beyond their first year of meaningful use, rather than any continuous 90-day period within the year as for first-time meaningful users. For more information on alignment with other programs, we refer readers to our discussion on clinical quality measures (see section II.B.1. of this final rule).

While commenters generally suggested a shorter EHR reporting period for the start of Stage 2 in any year rather than just Stage 2 in 2014, we believe that most of the reasons for a shorter period are due to the time constraints for vendor certification, upgrades and provider implementation between publication of this final rule and the beginning of Stage 2 in 2014. Any provider starting Stage 2 after 2014 will have more time and therefore most of the constraints are lifted. We acknowledge that not all constraints go away, but we believe that the balance is sufficiently shifted such that the concerns of data validity and program alignment outweigh the few remaining concerns with a full year EHR reporting period for the provider's first year of Stage 2 if it is after 2014. In addition, since ONC's 2014 Edition certification is for all EHR systems, regardless of the stage of meaningful use the provider using that system is in, there are far fewer implementation concerns after 2014. For example, if a provider begins Stage 2 in 2015, that provider would have been required to use CEHRT (that was certified to the 2014 Edition EHR certification criteria) for the previous year (2014) for Stage 1.

Finally, we considered that for the Medicaid EHR incentive program, EPs work exclusively with the states as they must choose between either the Medicare or Medicaid EHR incentive program. We do not know whether shifting from an EHR reporting period of any continuous 90 days to a 3-month quarter will provide any alignment benefits for Medicaid EPs, and it could introduce system complexity for Medicaid agencies. Therefore, we are maintaining flexibility for states to allow Medicaid EPs to select any continuous 90-day EHR reporting period during 2014 as defined by the state Medicaid program, or, if the state so chooses, any 3-month calendar quarter in 2014. As nearly all hospitals participate in both Medicare and Medicaid, we are using the 3-month quarter EHR reporting period for all hospitals to align both programs.

After consideration of the public comments received, we are modifying our proposal with regard to the EHR reporting periods for EPs, eligible hospitals and CAHs that attest to meaningful use for 2014 for their first year of Stage 2 or their second year of Stage 1. Our final policy is as follows: For 2014, Medicare EPs will attest using an EHR reporting period of January 1, 2014 through March 31, 2014; April 1, 2014 through June 30, 2014; July 1, 2014 through September 30, 2014; or October 1, 2014 through December 31, 2014. For 2014, Medicare and Medicaid eligible hospitals and CAHs will attest using an EHR reporting period of October 1, 2013 through December 31, 2013; January 1, 2014 through March 31, 2014; April 1, 2014 through June 30, 2014; or July 1, 2014 through September 30, 2014. Medicaid EPs will attest using an EHR reporting period of any continuous 90-day period between January 1, 2014 and December 1, 2014 as defined by the state Medicaid program, or, if the state so chooses, any 3-month calendar quarter in 2014.

b. Changes to Stage 1 Criteria for Meaningful Use

We proposed the following changes to the objectives and associated measures for Stage 1:

• Computerized Provider Order Entry (CPOE)—In 2013 (CY for EPs, FY for eligible hospitals/CAHs), we proposed that providers in Stage 1 could use the alternative denominator of the number of medication orders created by the EP or in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period (for further explanation of this alternative denominator, see the discussion of the CPOE objective in the Stage 2 criteria section at II.A.3.d. of this final rule).

A provider seeking to meet Stage 1 in 2013 can use either the denominator defined in the Stage 1 final rule or the alternative denominator to calculate the percentage for the CPOE measure. We also proposed to require the alternative denominator for Stage 1 beginning in 2014.

Comment: Commenters both supported and opposed the new denominator for CPOE. Those supporting the proposed denominator did so for its simplicity and greater accuracy for measuring actual CPOE usage. Those opposing the proposed denominator did so either because they were concerned with the burden associated with counting paper or other orders that are never entered into the EHR or because of the potential higher performance required by the proposed denominator.

Response: We proposed the alternative denominator to alleviate the burden associated with measurement, not to create a higher performance threshold. As we stated in the proposed rule, feedback from many providers indicated that the alternative denominator was more easily measurable. In response to concerns from commenters, we are finalizing the alternative denominator for this measure and specify that providers at any year in Stage 1 may elect to use either the denominator defined in the Stage 1 final rule or the alternative denominator to calculate the percentage for the CPOE measure. In response to comments, we are not requiring that the alternative denominator be used beginning in 2014, which will give providers who may find it difficult to measure the flexibility to continue to use the denominator defined in the Stage 1 final rule.

• Vital Signs—For the objective of record and chart changes in vital signs, the proposed Stage 2 measure would allow an EP to split the exclusion and exclude blood pressure only or height/weight only (for more detail, see the discussion of this objective in the Stage 2 criteria section at II.A.3.d. of the final rule). We proposed an identical change to the Stage 1 exclusion as well, starting in CY 2013. We also proposed changing the age limitations on vital signs for Stage 2 (for more detail, see the discussion of this objective in the Stage 2 criteria section). We proposed an identical change to the age limitations on vital signs for Stage 1, starting in 2013 (CY for EPs, FY for eligible hospitals/CAHs). These changes to the exclusion and age limitations were proposed as an alternative in 2013 to the current Stage 1 requirements but required for Stage 1 beginning in 2014.

Comment: While some commenters suggested that these changes would be confusing, most commenters supported the changes and indicated that they would provide added flexibility for providers who seek to incorporate the recording of this data into their clinical workflow. These commenters also noted that the age change reflects best clinical practices. Some commenters suggested removing BMI and growth charts from the measure since there are no best practices on BMI for patients under 3 years of age and since providers who would not record height and weight would not be able to provide BMI or growth charts.

Response: We appreciate the support for these changes and finalize them as proposed. We also note that BMI and

growth charts are not required to meet this measure but are instead a capability provided by CEHRT. Providers who claim the exclusion for height and weight will not have data for CEHRT to create either BMI or growth charts and this will not affect their ability to meet the measure of this objective.

Comment: Some commenters requested clarification on whether providers who provide ancillary services and do not normally record any of these elements as part of their regular scope of practice can claim the exclusion.

Response: If a provider believes that height and weight and/or blood pressure are relevant to their scope of practice, they must record those data elements and cannot qualify for the exclusion. We believe that most providers who provide ancillary services can meet the measure of this objective by obtaining this information from a referring provider and recording the necessary data in their CEHRT.

Comment: Some providers asked for clarification on whether providers who only occasionally record height and weight and/or blood pressure are still permitted to claim the exclusions for this measure.

Response: We recognize that there are situations in which certain providers may only record height and weight and/or blood pressure for a very limited number of patients (for example, high-risk surgical patients or patients on certain types of medication) but do not normally regard these data as relevant to their scope of practice. When a provider does not believe that height and weight and/or blood pressure are typically relevant to their scope of practice but still records these vital signs only in exceptional circumstances, the provider is permitted to claim the exclusions for this measure.

After consideration of the public comments received, we are finalizing the changes to vital signs as proposed. We are making technical corrections to the regulation text at § 495.6(d)(8) and § 495.6(f)(7) to clarify these are alternatives in 2013 and required beginning in 2014.

• Exchange Key Clinical Information—As noted in the proposed rule, the objective of ''capability to exchange key clinical information'' has been surprisingly difficult for providers to understand, which has made the objective difficult for most providers to achieve. We solicited comment on several options for this objective that we believed would reduce or eliminate the burden associated with this objective or increase the value of the objective. The first option we considered was removal of this objective. The second option was to require that the test be successful. The third option was to eliminate the objective, but require that providers select either the Stage 1 medication reconciliation objective or the Stage 1 summary of care at transitions of care and referrals objective from the menu set. The fourth option was to move from a test to one case of actual electronic transmission of a summary of care document for a real patient either to another provider of care at a transition or referral or to a patient authorized entity. We proposed the first option to remove this objective and measure from the Stage 1 core set beginning in 2013 (CY for EPs, FY for eligible hospitals/CAHs), but we also stated we would evaluate all four options in light of the public comments we received.

Comment: While we received feedback and support from commenters on all of the proposed options, the majority of commenters supported the elimination of this objective for Stage 1. Some commenters instead supported a more exact definition of data exchange for this measure, and other commenters supported additional elements or additional requirements for exchange to be included as part of the measure. Other proposals included implementing a system that would allow case-by-case reporting of data exchange that would allow CMS to measure successes and failures by provider, vendor, and other elements.

Response: We appreciate the many suggestions from commenters on clarifying data exchange and/or adding requirements to the measure. We also appreciate the suggestion of a case-by-case reporting system for data exchange. However, we are concerned that all of these options would not alleviate but actually increase the burden of this measure for providers by requiring them to document and submit substantially greater information than is currently required by attestation. While such a burden may be justified, we do not believe it is in this case because the Stage 2 requirements for actual electronic exchange of summary of care records create sufficient incentive to begin testing in Stage 1 without there being an explicit meaningful use requirement to do so. Because of these concerns and in reaction to the opinion of most commenters, we are finalizing the removal of this objective and measure for Stage 1 beginning in 2013. Although some commenters suggested removing this objective earlier, we do not believe the timing of publication of this final rule would allow us to implement such a change and allow consistent reporting for all providers in 2012. Therefore, this objective and measure will be removed from the Stage 1 criteria beginning in 2013 (CY for EPs, FY for eligible hospitals and CAHs).

• View Online, Download, and Transmit—We proposed for Stage 2 a new method for making patient information available electronically, which would enable patients to view online, download, and transmit their health information and hospital admission information. We discuss in the Stage 2 criteria section at II.A.3.d the ''view online, download, and transmit'' objectives for EPs and hospitals. We noted in the proposed rule that starting in 2014, CEHRT would no longer be certified to the Stage 1 EP and hospital core objectives of providing patients with electronic copies of their health information (§ 495.6(d)(12) and (f)(11)) or the Stage 1 hospital core objective of providing patients with electronic copies of their discharge instructions upon request (§ 495.6(f)(12)), nor would it support the Stage 1 EP menu objective of providing patients with timely electronic access to their health information (§ 495.6(e)(5)). Therefore starting in 2014, for Stage 1, we proposed to replace these objectives with the new ''view online, download and transmit'' objectives.

Comment: There were a number of commenters who asked for clarifications regarding the requirements of these objectives. Other commenters raised concerns regarding the implementation of these objectives in both Stage 1 and Stage 2.

Response: We discuss the clarifications and concerns raised by commenters in our Stage 2 criteria at II.A.3.d regarding these objectives. Please refer to those discussions for additional information.

Comment: Some commenters supported this change while other commenters disagreed with it. Those who disagreed with the proposed change indicated that providers would not be ready to implement online access to health information in Stage 1, and that it was unlikely that providers could convince more than 50 percent of patients to sign up for online access within the Stage 1 reporting period. These commenters suggested eliminating all of the Stage 1 objectives for providing electronic copies of health information or discharge summaries and not replacing these objectives with the ''view, download, and transmit'' objectives.

Response: We disagree that the Stage 1 objectives for providing patients with electronic copies of their health information and discharge instructions should be eliminated without replacing

these objectives with the ''view online, download, and transmit'' objectives. We believe patient access to their health information is an important aspect of patient care and engagement, and we further believe that the capabilities of CEHRT in 2014 and beyond will enable providers to make this information available online in a way that does not impose a significant burden on providers.

We note that only the first measure of the ''view online, download, and transmit'' objectives would be required for Stage 1. This means that providers would only have to make information available online to view online, download, and transmit for more than 50 percent of all unique patients during the EHR reporting period in order to meet the measure. We further clarify that providers are only required to make this information available online to view online, download, and transmit and that patients who do not access the information or would not affect whether or not the provider is able to meet the measure. For Stage 1, providers are not required to meet the second measure of more than 5 percent of patients view online, download, or transmit to a third party their health or hospital admission information. Providers are only required to meet the second measure of the objectives in Stage 2. However, the exclusions for these objectives are available for providers in Stage 1. Therefore, we are finalizing our proposal to replace the existing Stage 1 EP and hospital objectives listed above with the ''view online, download, and transmit'' objectives beginning in 2014 for Stage 1. We are making a technical correction to the regulations text to clarify that the existing Stage 1 objective at § 495.6(f)(11) is being replaced. We clarify in Table 4 the four existing Stage 1 objectives that are being replaced. We are also making a technical correction to the regulation text to remove the existing exclusion for the objective at § 495.6(f)(12)(iii) beginning in 2014 because the objective that this exclusion applies to is being replaced.

• Removing CQM Reporting from Stage 1 Objectives—We proposed a revised definition of a meaningful EHR user at § 495.4 which would incorporate the requirement to submit clinical quality measures, as discussed in section II.A.2 of this final rule. We also proposed to remove the objective to submit clinical quality measures from § 495.6 beginning in 2013 for Stage 1 to conform with this change in the definition of a meaningful EHR user.

Comment: While some commenters indicated that this change would be confusing, most commenters supported this change.

Response: We appreciate the support of commenters and believe that removing the objective will actually alleviate confusion. Therefore, as discussed earlier in II.A.2. of this final rule, we are finalizing as proposed, the revised definition of a meaningful EHR user at § 495.4 to include clinical quality measure submission, as well as the removal of this objective from § 495.6 beginning in 2013.

• Public Health Objectives—For the Stage 1 public health objectives, beginning in 2013, we proposed to add ''except where prohibited'' to the regulation text in order to encourage all EPs, eligible hospitals, and CAHs to submit electronic immunization data, even when not required by state/local law. Therefore, if they are authorized to submit the data, they should do so even if it is not required by either law or practice. There are a few instances where some EPs, eligible hospitals, and CAHs are prohibited from submitting to a state/local immunization registry. For example, in sovereign tribal areas that do not permit transmission to an immunization registry or when the immunization registry only accepts data from certain age groups (for example, adults).

Comment: Some commenters supported this change while others disagreed with it. A number of commenters interpreted the proposed addition of language as a change to either the measure of the objectives or the exclusions that are currently in place.

Response: As noted in the proposed rule, the addition of this language was intended to ensure that providers who are not required by law or practice to submit data would do so and to make it clear that EPs, eligible hospitals, and CAHs that are prohibited from submitting data would not be required to submit such data. Immunizations was used as a descriptive example in the proposed rule, but this change applies to all Stage 1 public health objectives. The exclusions provided for these objectives in Stage 1 are not affected by the addition of this language and remain in place for all providers. Therefore, we are finalizing the addition of this language as proposed.

• Menu Set Exclusions Policy—We proposed to change the policy on menu set exclusions for Stage 1 beginning in 2014. Please see section II.A.3.d. of this final rule for a discussion of the proposal and our final policy.

• Electronic Prescribing

Comment: We received comments pointing out that we proposed a new exclusion for electronic prescribing objective for Stage 2 regarding the availability of pharmacies that can accept electronic prescriptions. These commenters noted that if this exclusion was not also made available for Stage 1 then it would create a strange scenario where an EP might have to electronically prescribe during their 2 years of Stage 1 and then meet an exclusion in Stage 2.

Response: We agree that it makes no sense to apply this exclusion to e-prescribing in Stage 2, but not in Stage 1. We consider it an oversight of our proposed rule that we did not include that exclusion in our proposed changes to the Stage 1 criteria. We are finalizing an exclusion for the e-prescribing objective in Stage 2 for any EP who 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/her EHR reporting period. We are also finalizing the addition of this exclusion to Stage 1 starting in CY 2013.

TABLE 4—STAGE 1 CHANGES

Stage 1 objective	Final changes	Effective year (CY/FY)
Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	Change: Addition of an alternative measure More than 30 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.	2013 - Onward (Optional).

TABLE 4—STAGE 1 CHANGES—Continued

Stage 1 objective	Final changes	Effective year (CY/FY)
Generate and transmit permissible prescriptions electronically (eRx).	Change: Addition of an additional exclusion Any EP who: 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/her EHR reporting period.	2013—Onward (Required).
Record and chart changes in vital signs.	Change: Addition of alternative age limitations More than 50 percent of all unique patients 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 blood pressure (for patients age 3 and over only) and height and weight (for all ages) recorded as structured data.	2013 Only (Optional).
Record and chart changes in vital signs.	Change: Addition of alternative exclusions ..... Any EP who (*1*) Sees no patients 3 years or older is excluded from recording blood pressure; (*2*) Believes that all three vital signs of height, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them; (*3*) Believes that height and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or (*4*) Believes that blood pressure is relevant to their scope of practice, but height and weight are not, is excluded from recording height and weight.	2013 Only (Optional).
Record and chart changes in vital signs.	Change: Age limitations on height, weight and blood pressure ..... More than 50 percent of all unique patients 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 blood pressure (for patients age 3 and over only) and height and weight (for all ages) recorded as structured data.	2014—Onward (Required).
Record and chart changes in vital signs.	Change: Changing the age and splitting the EP exclusion ..... Any EP who (*1*) Sees no patients 3 years or older is excluded from recording blood pressure; (*2*) Believes that all three vital signs of height, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them; (*3*) Believes that height and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or (*4*) Believes that blood pressure is relevant to their scope of practice, but height and weight are not, is excluded from recording height and weight.	2014—Onward (Required).
Capability to exchange key clinical information (for example, problem list, medication list, medication allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.	Change: Objective is no longer required	2013—Onward (Required).
Report ambulatory (hospital) clinical quality measures to CMS or the states.	Change: Objective is incorporated directly into the definition of a meaningful EHR user and eliminated as an objective under § 495.6.	2013—Onward (Required).
EP and Hospital Objectives: Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies, discharge summary, procedures) upon request.	Change: Replace these four objectives with the Stage 2 objective and one of the two Stage 2 measures.. 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: 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.	2014—Onward (Required).

TABLE 4—STAGE 1 CHANGES—Continued

Stage 1 objective	Final changes	Effective year (CY/FY)
Hospital Objective: Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request.	Hospital Objective: Provide patients the ability to view online, download, and transmit information about a hospital admission.	
EP Objective: Provide patients with timely electronic access to their health information (including lab results, problem list, medicatiion lists, and allergies) within 4 business days of the information being available to the EP..	Hospital Measure: 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.	
Public Health Objectives:	Change: Addition of ''except where prohibited'' to the objective regulation text for the public health objectives under § 495.6.	2013—Onward (Required).
Stage 1 Policy Changes		
Meeting an exclusion for a menu set objective counts towards the number of menu set objectives that must be satisfied to meet meaningful use.	Meeting an exclusion for a menu set objective does not count towards the number of menu set objectives that must be satisfied to meet meaningful use..	2014—Onward (Required).

c. State Flexibility for Stage 2 of Meaningful Use

We proposed to offer states flexibility under the Medicaid incentive program with the public health measures in Stage 2, similar to that of Stage 1, subject to the same conditions and standards as the Stage 1 flexibility policy. This applies to the public health measures as well as the measure to generate lists of specific conditions to use for quality improvement, reduction of disparities, research or outreach. We clarify that our proposal included the existing public health measures from Stage 1 as well as the new public health measures proposed for Stage 2.

In addition, we stated that whether a state moved an objective to the core or left it in the menu, states may also 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 2014 ONC EHR certification criteria.

We solicited comments on extending state flexibility as described for Stage 2 of meaningful use and whether this remains a useful tool for state Medicaid agencies.

Comment: Commenters requested clarification of the requirement that states cannot require EHR functionality above and beyond that which is included in the 2014 ONC EHR certification criteria. These commenters point out that the Stage 2 public health measures require capabilities beyond that which is included in the 2014 ONC EHR certification criteria already.

Response: We assume commenters are referring to transmission methods which are not included in 2014 Edition EHR certification criteria adopted by ONC for public health objectives (immunizations, electronically reportable lab results, syndromic surveillance, cancer registries and specialized registries). This limitation applies only to those capabilities and standards included in 2014 ONC EHR certification criteria for a given public health objective. For example, a state could not require a different standard than the one included in 2014 ONC EHR certification criteria. 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.

Comment: Several commenters supported extending state flexibility with meaningful use for Stage 2, but requested that CMS provide a clearer definition of state flexibility. Commenters suggested that it would be helpful to EPs and eligible hospitals if states follow a common timeline for establishing state-specific requirements.

Response: We appreciate these comments and would like to clarify that the state flexibility for Stage 2 remains defined the same way as it is defined in Stage 1 at § 495.316 (d)(2) and § 495.322 (f)(2). Given that states are launching their programs at different times and are therefore at different stages in the program lifecycle and process, at this time we do not support the development of a common timeline for establishing state-specific requirements. The parameters remain the same as for Stage 1 and providers are subject to the requirements found in § 495.332. CMS approval of states' requests will include a review of the outlined elements.

After consideration of the public comments received, we are finalizing these provisions as proposed.

d. Stage 2 Criteria for Meaningful Use (Core Set and Menu Set)

We proposed to continue the Stage 1 concept of a core set of objectives and a menu set of objectives for Stage 2. In the Stage 1 final rule (75 FR 44322), we indicated that for Stage 2, we expected to include the Stage 1 menu set objectives in the core set. We proposed to follow that approach for our Stage 2 core set with two exceptions. We proposed to keep the objective of ''capability to submit electronic syndromic surveillance data to public health agencies'' in the menu set for EPs. Our experience with Stage 1 is that very few public health agencies have the ability to accept non-emergency or non urgent care ambulatory syndromic surveillance data electronically and those that do are less likely to support EPs than hospitals; therefore we do not believe that current infrastructure supports moving this objective to the core set for EPs. We also proposed to keep the objective of ''record advance directives'' in the menu set for eligible hospitals and CAHs. As we stated in our Stage 1 final rule (75 FR 44345), we have continuing concerns that there are potential conflicts between storing advance directives and existing state laws.

We proposed new objectives for Stage 2, some of which would be part of the

Stage 2 core set and others would make up the Stage 2 menu set, as discussed below with each objective. We proposed to eliminate certain Stage 1 objectives for Stage 2, such as the objective for testing the capability to exchange key clinical information. We proposed to combine some of the Stage 1 objectives for Stage 2. For example, the objectives of maintaining an up-to-date problem list, active medication list, and active medication allergy list would not be separate objectives for Stage 2. Instead, we proposed to combine these objectives with the objective of providing a summary of care record for each transition of care or referral by including them as required fields in the summary of care.

We proposed a total of 17 core objectives and 5 menu objectives for EPs. We proposed that an EP must meet the criteria or an exclusion for all of the core objectives and the criteria for 3 of the 5 menu objectives. This is a change from our current Stage 1 policy where an EP could reduce the number of menu set objectives that the EP would otherwise need to meet by the number of menu set objectives that the EP could exclude. We noted the feedback we received on Stage 1 from providers and health care associations leads us to believe that most EPs had difficulty understanding the concept of deferral of a menu objective in Stage 1. Therefore, we proposed this change for Stage 2, as well as for Stage 1 beginning in 2014, to make the selection of menu objectives easier for EPs. We also proposed this change because we are concerned that under the current Stage 1 requirements some EPs could select and exclude menu objectives when there are other menu objectives they can legitimately meet, thereby making it easier for them to demonstrate meaningful use than EPs who attempt to legitimately meet the full complement of menu objectives. Although we provided the ability to do this in the selection of Stage 1 menu objectives through 2013, we stated that EPs participating in Stage 1 and Stage 2 starting in 2014 should focus solely on those objectives they can meet rather than those for which they have an exclusion. In addition, we noted the exclusions for the Stage 2 menu objectives that we believe would accommodate EPs who are unable to meet certain objectives because of scope of practice. However, just as we signaled in our Stage 1 regulation, we stated our intent to propose in our next rulemaking that every objective in the menu set for Stage 2 (as described later in this section) be included in Stage 3 as part of the core set.

We explained that in the case where an EP meets the criteria for the exclusions for 3 or more of the Stage 2 menu objectives, the EP would have more exclusions than the allowed deferrals. EPs in this situation would attest to an exclusion for 1 or more menu objectives in his or her attestation to meaningful use. In doing so, the EP would be attesting that he or she also meets the exclusion criteria for all of the menu objectives that he or she did not choose. We stated that the same policy would also apply for the Stage 1 menu objectives for EPs beginning in 2014.

We proposed a total of 16 core objectives and 4 menu objectives for eligible hospitals and CAHs for Stage 2. We proposed that an eligible hospital or CAH must meet the criteria or an exclusion for all of the core objectives and the criteria for 2 of the 4 menu objectives. We proposed that the policy for exclusions for EPs discussed in the preceding paragraph would also apply to eligible hospitals and CAHs for Stage 1 beginning in 2014 and for Stage 2.

We received many comments on the appropriateness of individual objectives placement in the core or menu set. We discuss these comments below for each individual objective.

Comment: Commenters expressed concern over the small number of objectives in the menu set. They were concerned that the small number of objectives limited the usefulness of the menu set to providers.

Response: Stage 2 does contain a more specialized and smaller menu set than Stage 1. We see this as a natural result of moving up the staged path towards improved outcomes and adding fewer new objectives. We also see specialization as necessary for meaningful use to be applicable to all EPs. Due to comments received we are adding two objectives for hospitals and one for EPs which will be in the menu, as further explained later in this section.

After consideration of the public comments received, we finalize the concept of a core and menu set for Stage 2.

We finalize a total of 17 core objectives and 6 menu objectives for EPs for Stage 2. We finalize that an EP must meet the criteria or an exclusion for all of the core objectives and the criteria for 3 of the 6 menu objectives unless an exclusion can be claimed for more than 3 of the menu objectives in which case the criteria for the remaining non-excluded objectives must be met.

We finalize a total of 16 core objectives and 6 menu objectives for eligible hospitals and CAHs for Stage 2. We finalize that an eligible hospital or CAH must meet the criteria or an exclusion for all of the core objectives and the criteria for 3 of the 6 menu objectives.

We also finalize our proposal to change the menu set exclusions policy for Stage 1. Beginning in 2014, qualifying for an exclusion from a menu set objective will no longer reduce the number of menu set objectives that an EP or hospital must otherwise satisfy to demonstrate meaningful use for Stage 1. There is an exception for EPs who meet the criteria to exclude five or more of the menu set objectives, in which case the EP must meet the criteria for all of the remaining non-excluded menu set objectives. This exception would not be applicable to hospitals due to the number of hospital menu set objectives that include exclusions.

(1) Discussion of Whether Certain EPs, Eligible Hospitals or CAHs Can Meet All Stage 2 Meaningful Use Objectives Given Established Scopes of Practice

We noted in the proposed rule that we do not believe that any of the proposed new objectives for Stage 2 make it impossible for any EP, eligible hospital or CAH to meet meaningful use. Where scope of practice may prevent an EP, eligible hospital or CAH from meeting the measure associated with an objective, we discussed the barriers and included exclusions in our descriptions of the individual objectives. We proposed to include new exclusion criteria when necessary for new objectives, continue the Stage 1 exclusions for Stage 2, and continue the option for EPs and hospitals to defer some of the objectives in the menu set unless they meet the exclusion criteria for more objectives than they can defer as explained previously.

We recognized in the proposed rule that at the time of publication, our data (derived internally from attestations) only reflected the meaningful use attestations from Medicare providers. There have been no significant changes in the data derived from meaningful use attestations since the publication of the proposed rule.

We did not receive any comments on this provision.

(2) EPs Practicing in Multiple Practices/Locations

We proposed for Stage 2 to continue our policy that 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. 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. We gave the following in the proposed rule example: if the EP practices at a federally qualified health center (FQHC) and within his or her individual practice at 2 different locations, we would include in our review all 3 of these locations, and CEHRT would have to be available at one location or a combination of locations where the EP has 50 percent or more of his or her patient encounters. If CEHRT is only available at one location, then only encounters at this location would be included in meaningful use assuming this one location represents 50 percent or more of the EP's patient encounters. If CEHRT is available at multiple locations that collectively represent 50 percent or more of the EP's patient encounters, then all encounters from those locations would be included in meaningful use.

In the proposed rule we stated that we have received many inquiries on this requirement since the publication of the Stage 1 final rule. We define patient encounter as any encounter where a medical treatment is provided and/or evaluation and management services are provided. This includes both individually billed events and events that are globally billed, but are separate encounters under our definition. We define 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. This can be accomplished in 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, or the EP could access CEHRT remotely using computing devices at the practice/location. Although it is currently allowed under Stage 1 for an EP to create a record of the encounter without using CEHRT at the practice/location and then later input that information into CEHRT that exists at a different practice/location, we do not believe this process takes advantage of the value CEHRT offers. We proposed not to allow this practice beginning in 2013. We have also received inquiries whether the practice locations have to be in the same state, to which we clarify that they do not. Finally, we received inquiries regarding the interaction with hospital-based EP determination. The determination of whether an EP is hospital-based or not occurs prior to the application of this policy, so only nonhospital-based eligible professionals are included. Furthermore, this policy, like all meaningful use policies for EPs, only applies to outpatient settings (all settings except the inpatient and emergency department of a hospital).

Comment: Some commenters suggested that for EPs practicing in multiple locations that meaningful use attestations should be limited to just reporting on meaningful use for the most prevalent location due to the difficulty in aggregating data across locations.

Response: We continue to believe that for the core measures, aggregating data is not overly burdensome. We allow the numerators and denominators calculated by CEHRT to be summed across an EP's various practice locations.

Comment: We received request for clarification on what to do when an EP is practicing in multiple locations that select different menu objectives to pursue, and the EP does not control this selection.

Response: An EP who does not have the same menu objectives implemented across each of their practice locations equipped with CEHRT would attest to the three menu objectives that represent the greatest number of their patient encounters. For example, if six menu objectives are implemented between two locations, an EP would attest to the three menu objectives implemented at the location where they have the greatest number of encounters during the EHR reporting period. For measures that utilize a percentage threshold, they can limit the denominator to the location or locations that pursued that menu objective.

After consideration of the public comments received, we are finalizing the proposed provisions with the modifications previously discussed.

(3) Discussion of the Reporting Requirements of the Measures Associated With the Stage 2 Meaningful Use Objectives

In our experience with Stage 1, we found the distinction between limiting the denominators of certain measures to only those patients whose records are maintained using CEHRT, but including all patients in the denominators of other measures, to be complicated for providers to implement. We proposed to remove this distinction for Stage 2 and instead include all patients in the denominators of all of the measures associated with the meaningful use objectives for Stage 2. We believe that by the time an EP, eligible hospital, or CAH has reached Stage 2 of meaningful use all or nearly all of their patient population should be included in their CEHRT, making this distinction no longer relevant.

Comment: We received comments that maintain that this distinction is still necessary for Stage 2 because there are situations where significant patient records may still be maintained outside of CEHRT. Examples provided by commenters include worker's compensation or other special contracts for certain patients, specialized departments or units in a hospital for which CEHRT is not tailored and patient requests to keep their records on paper.

Response: We continue to believe that nearly all patient records will be stored in CEHRT by the time a provider reaches Stage 2. However, we acknowledge that if this assertion is correct then there is no practical consequence of maintaining the distinction, while if it is not, removing the distinction could have adverse impacts on providers.

After consideration of the comments, we are not finalizing our proposed change. Instead, 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 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's or CAH's inpatient or emergency department during the EHR reporting period.

Comment: Some commenters suggested that the denominators should be limited to either just Medicare-covered patients for those participating in the Medicare EHR Incentive Program or just Medicaid-covered patients for those participating in the Medicaid EHR Incentive Program. Commenters presented two arguments in favor of this suggestion. First, that requiring a provider to include all patients was more burdensome than including just Medicare-covered or Medicaid-covered patients and that this burden was not offset by the incentive payments that are based (for Medicare only) on charges submitted to Medicare. Second, that if identifiable patient data was included in Medicare or Medicaid meaningful use reporting for patient not covered by Medicare or Medicaid this would raise serious privacy concerns and possibly require patient consent. Other commenters were supportive of current denominators that does not account for payers.

Response: We discussed the burden differences between all patients versus patients differentiated by payer in our Stage 1 final rule (75 FR44332). We continue to believe that it is highly unlikely that providers will use different record keeping systems based on payer. Where there are differences in patient populations such as age we account for them directly in the measure not indirectly with payer as a generalized proxy. The burden of breaking out the patients by payer for purposes of meaningful use measurement would have only increased from the publication of the Stage 1 final rule as measurement tools have been designed and implemented to measure patients regardless of payer. If at a future date, the demonstration of meaningful use includes the submission of identifiable patient data we will certainly address the privacy implications of that requirement. However, the Stage 1 objectives and measures and Stage 2 objectives and measures included in this final rule do not require the submission of identifiable patient information. We are not making any changes to this policy in this final rule.

We proposed new objectives that could increase reporting burden. To minimize the burden, we proposed to create a uniform set of denominators that would be used for all of the Stage 2 meaningful use objectives, as discussed later.

Many of our meaningful use objectives use percentage-based measures if appropriate. To provide a check on the burden of reporting of meaningful use, we proposed for Stage 2 to use 1 of 4 denominators for each of the measures associated with the meaningful use objectives. We focused on denominators because the action that moves something from the denominator to the numerator usually requires the use of CEHRT by the provider. These actions are easily tracked by the technology.

The four proposed denominators for EPs are—

- Unique patients seen by the EP during the EHR reporting period (stratified by age or previous office visit);
- Number of orders (medication, labs, radiology);
- Office visits, and
- Transitions of care/referrals.

Comment: We received many comments supporting our efforts to minimize the variety of denominators. Some commenters argued that any variation (such as by age or orders of different types) should be considered separate denominators.

Response: We appreciate the support for our proposal to minimize the variety of denominators. Our base of four denominators are only modified by information that must be entered into CEHRT in order to meet meaningful use; therefore, we believe that such modifications represent a small burden and are in keeping with our overall goal in minimizing the variety of denominators.

In the proposed rule, we stated that the term ''unique patient'' means that if a patient is seen or admitted more than once during the EHR reporting period, the patient only counts once in the denominator. Patients seen or admitted only once during the EHR reporting period will count once in the denominator. A patient is seen by the EP when the EP has an actual physical encounter with the patient in which they render any service to the patient. A patient seen through telemedicine will also still count as a patient ''seen by the EP.'' In cases where the EP and the patient do not have an actual physical or telemedicine encounter, but the EP renders a minimal consultative service for the patient (like reading an EKG), the EP may choose whether to include the patient in the denominator as ''seen by the EP'' provided the choice is consistent for the entire EHR reporting period and for all relevant meaningful use measures. For example, a cardiologist may choose to exclude patients for whom they provide a one-time reading of an EKG sent to them from another provider, but include more involved consultative services as long as the policy is consistent for the entire EHR reporting period and for all meaningful use measures that include patients ''seen by the EP.'' EPs who never have a physical or telemedicine interaction with patients must adopt a policy that classifies at least some of the services they render for patients as ''seen by the EP,'' and this policy must be consistent for the entire EHR reporting period and across meaningful use measures that involve patients ''seen by the EP''—otherwise, these EPs will not be able to satisfy meaningful use, as they will have denominators of zero for some measures. In cases where the patient is seen by a member of the EP's clinical staff the EP can include or not include those patients in their denominator at their discretion as long as the decision applies universally to all patients for the entire EHR reporting period and the EP is consistent across meaningful use measures. In cases where a member of the EP's clinical staff is eligible for the Medicaid EHR incentive in their own right (for example, nurse practitioners (NPs) and certain physician assistants (PA)), patients seen by NPs or PAs under the EP's supervision can be counted by both the NP or PA and the supervising EP as long as the policy is consistent for the entire EHR reporting period.

Comment: While generally supporting the concept of a unique patient as a good tool to address the fact that not all meaningful use objectives need be addressed at every patient encounter or rendering of medical service, some commenters expressed concern about the ability to identify unique patients across CEHRTs in situations where an EP practices at multiple locations or in situations where an EP might switch CEHRT during an EHR reporting period.

Response: We agree that determining unique patients across CEHRTs is difficult. When aggregating performance on meaningful use measures across multiple practice locations using different CEHRTs we do not require that it be determined that a patient seen at one location was not also seen at another location. While this could result in the same patient appearing more than once in the denominator of unique patients seen, we believe that the burden of seeking out these patients is greater than any gain in measurement accuracy. Furthermore, it is not possible for a provider to increase only the numerator with this policy as any increase in the numerator would also increase the denominator. Accordingly, we are adopting a final policy that will give EPs who practice at multiple locations or switch CEHRT during the EHR reporting period some flexibility as to the method for counting unique patients in the denominators. We leave it up to the EP to decide for the EHR reporting period whether to count a unique patient across all locations equipped with different CEHRT (for example, 1 patient seen at 3 locations with different CEHRT counts once) or at each location equipped with CEHRT (for example, 1 patient seen at 3 locations with different CEHRT counts thrice). In cases where a provider switches CEHRT products at a single location during the EHR reporting period, they also have the flexibility to count a patient as unique on each side of the switch and not across it (for example, 1 patient seen before the switch and after the switch could be counted once or twice). EPs in these scenarios must choose one of these methods for counting unique patients and apply it consistently throughout the entire EHR reporting period.

With the flexibility for EPs practicing in multiple locations using different CEHRT or switching CEHRT during the

EHR reporting period, we otherwise finalize our description of ''unique patient'' as proposed.

We proposed that an office visit is defined as any billable visit that includes: (1) Concurrent care or transfer of care visits; (2) consultant visits; or (3) prolonged physician service without direct, face-to-face patient contact (for example, telehealth). A consultant visit occurs when a provider is asked to render an expert opinion/service for a specific condition or problem by a referring provider. The visit does not have to be individually billable in instances where multiple visits occur under one global fee.

Comment: We received comments requesting that we establish a list of billing codes that constitute an office visit for purposes of clarity.

Response: We continue to believe that the use of a list of billing codes would inappropriately limit the discretion of EPs that we have built into this measure. We finalize as proposed our description of an office visit and emphasize that there is room for EP discretion in this definition and that the most important consideration in utilizing that discretion is that the policy apply for the entire EHR reporting period and across all patients.

We proposed to describe 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. Currently, the meaningful use measures that use transitions of care require there to be a receiving provider of care to accept the information. Therefore, a transition home without any expectation of follow-up care related to the care given in the prior setting by another provider is not a transition of care for purpose of Stage 2 meaningful use measures as there is no provider recipient. A transition within one setting of care does not qualify as a transition of care. Referrals are cases where one provider refers a patient to another, but the referring provider maintains their care of the patient as well. Please note that a ''referral'' as defined here and elsewhere in this final rule is only intended to apply to the EHR Incentive Programs and is not applicable to other Federal regulations.

Comment: We have received many comments that determining when a transition of care occurs is very difficult under our current Stage 1 rule, particularly when the provider is on the receiving end of the transition of care. Commenters suggest that the only reliable way to know if a patient saw another provider is to ask the patient at each encounter and even then this is not guaranteed. Several suggestions were presented to make the definition more precise on both the receiving and transitioning side. They were as follows:—

- Discharges for eligible hospitals/CAHs and referrals to other providers who do not share the same CEHRT as the EP are very clearly identified and should be the focus of the numerator/denominator.
- A transition within one setting of care does not qualify as a transition of care. Referral is defined as care ''where one provider refers a patient to another, but the referring provider maintains their care of the patient as well.''
- A patient is referred to another provider (for EPs) or a patient is discharged (for eligible hospitals).
- Sharing data with health plans.

Response: In reviewing the comments, we agree that a refinement of our transitions of care definition is needed. We also agree with the suggestions to point to specific events that identify a transition of care has occurred without relying entirely on asking the patient. Therefore, we revise our description of transitions of care for the purpose of defining the denominator. For an EP who is on the receiving end of a transition of care or referral, (currently used for the medication reconciliation objective and measure), 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. The summary of care record can be provided either by the patient or by the referring/transiting provider or institution. We believe that both of these situations would create information in the CEHRT that can be automatically recorded. For an EP who is initiating a patient transfer to another setting and/or referring a patient to another provider, (currently used for providing summary of care documents at transitions of care), the initiating/referring EP would count the transitions and/or referrals that were ordered by the EP in the measure denominator. If another provider also sees the same patient, only the EP who orders the transition/referral would need to account for this transition for the purpose of this measure. EPs are not responsible for including patient-initiated transitions and referrals that were not ordered by the EP. For example, if the EP creates an order for admission to a nursing home, this transition of care would be counted in the EP's measure denominator. If one of the EP's patients is admitted to a nursing home by another provider, this transition would only have to be counted by the EP who creates the order and not necessarily by other EPs who care for the patient. We want to emphasize that these transitions of care/referral descriptions have been developed for purposes of reducing the provider measurement burden for the EHR Incentive Program and do not necessarily apply to other programs or regulations. We also clarify that these descriptions are minimum requirements. An EP can include in the denominator transitions of care and referrals that fit the broader descriptions of these terms, but are not one of the specific events described previously.

The four proposed denominators for eligible hospitals and CAHs are—

- Unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department during the EHR reporting period (stratified by age);
- Number of orders (medication, labs, radiology);
- Inpatient bed days; and
- Transitions of care.

We noted in the proposed rule that our explanation of ''unique patients'' and ''transitions of care'' for EPs would also apply for eligible hospitals and CAHs.

Comment: Commenters suggested a problem with unique patients could arise if a hospital switched CEHRT during the EHR reporting period.

Response: Our final policy on EPs who switch CEHRT during the EHR reporting period counting unique patients in the denominator would also apply for hospitals in the same situation.

Comment: We have received many comments that determining when a transition of care occurs is very difficult under our Stage 1 regulations, particularly when the provider is on the receiving end of the transition of care. Commenters suggest that the only reliable way to know if a patient saw another provider is to ask the patient at each encounter and even then this is not guaranteed. Several suggestions were presented to make the definition more precise on both the receiving and transitioning side, which we summarized previously in the discussion of the proposed denominators for EPs.

Response: For the same reasons as discussed for EPs, we agree that pointing to specific occurrences is needed to accurately measure this denominator. For transitions of care when the hospital is on the receiving end, (currently used for the medication reconciliation objective and measure), we include all admissions to the inpatient and emergency departments.

For transitions of care when the hospital is transitioning the patient, (currently used for providing summary of care documents at transitions of care), we include all discharges from the inpatient department and after admissions to the emergency department when follow-up care is ordered by an authorized provider of the hospital. As with EPs, these are the minimum events that must be included in the denominator for the transitions of care measure. Hospitals can include additional transitions of care that match the full description of transitions of care, but are not one of these specific events.

We proposed that admissions to the eligible hospital or CAH can be calculated using one of two methods currently available under Stage 1 of meaningful use. The observation services method includes all patients admitted to the inpatient department (POS 21) either directly or through the emergency department and patients who initially present to the emergency department (POS 23) and receive observation services. Details on observation services can be found in the Medicare Benefit Policy Manual, Chapter 6, Section 20.6. Patients who receive observation services under both the outpatient department (POS 22) and emergency department (POS 23) should be included in the denominator under this method. The all emergency department method includes all patients admitted to the inpatient department (POS 21) either directly or through the emergency department and all patients receiving services in the emergency department (POS 23).

Comment: Commenters expressed near universal support for the continuance of the two options in defining an admission to the emergency department.

Response: We continue to believe that not all information required by meaningful use may be relevant to all encounters in the emergency department and that this decision is best left to the hospital; therefore, we are finalizing this as proposed.

We proposed that inpatient bed days are the admission day and each of the following full 24-hour periods during which the patient is in the inpatient department (POS 21) of the hospital. For example, a patient admitted to the inpatient department at noon on June 5th and discharged at 2 p.m. on June 7th will be admitted for 2-patient days: the admission day (June 5th) and the 24 hour period from 12 a.m. on June 6th to 11:59 p.m. on June 6th.

We did not receive comments on this proposal. This denominator is not used by the proposed meaningful use objectives and measures nor the finalized objectives and measures.

As discussed later in this section, we are including the menu objective for hospitals of ''Provide structured electronic lab results to ambulatory providers''. The measure associated with the objective uses a denominator that was not included in our proposal. The denominator is the number of electronic lab orders received by the hospital from ambulatory providers. For this objective, we use the same description of ''laboratory services'' as for our Stage 2 CPOE objective: any service provided by a laboratory that could not be provided by a nonlaboratory. We also use the definition of ''laboratory'' at § 493.2 as for the Stage 2 CPOE objective. Any order for a laboratory service will be considered a lab order. For the order to be considered received electronically, it must be received by the hospital utilizing an electronic transmission method and not through methods such as physical electronic media, electronic fax, paper document or telephone call.

After consideration of public comments, we are finalizing the following denominators for EPs:

- Unique patients seen by the EP during the EHR reporting period (stratified by age or previous office visit);
- Number of orders (medication, labs, radiology);
- Office visits; and
- Transitions of care/referrals including at a minimum one of the following:

++ 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.

We are finalizing the following denominators for eligible hospitals and CAHs:

- Unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department during the EHR reporting period (stratified by age);
- Number of orders (medication, labs, radiology);
- Transitions of care including at a minimum one of the following:

++ When the hospital is the recipient of the 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; and

- Electronic lab orders received by the hospital from ambulatory providers.

(4) Discussion of the Relationship of Meaningful Use to CEHRT

We proposed to continue our policy of linking each meaningful use objective to certification criteria for CEHRT. As with Stage 1, EPs, eligible hospitals, and CAHs must use the capabilities and standards that are certified to meet the objectives and associated measures for Stage 2 of meaningful use. In meeting any objective of meaningful use, an EP, eligible hospital or CAH must use the capabilities and standards that are included in certification. We noted that in some instances, meaningful use objectives and measures require use that is not directly enabled by certified capabilities and/or standards. In these cases, the EP, eligible hospital and CAH is responsible for meeting the objectives and measures of meaningful use, but the way they do so is not constrained by the capabilities and standards of CEHRT. In the proposed rule we gave the following example: in e-Rx and public health reporting, CEHRT applies standards to the message being sent and enables certain capabilities for transmission in 2014; however, to actually engage in e-Rx or public health reporting many steps must be taken outside of these standards and capabilities such as contacting both parties and troubleshooting issues that may arise through the normal course of business.

Comment: We received many comments that expressed confusion of when the capabilities and standards included in certification must be used and when they do not.

Response: Nearly all of these comments were objective-specific, so we address them at the referenced objective. With each measure we include a universal statement on the applicability of the specific standards and capabilities included in the 2014 edition of certification criteria for EHR technologies and, if applicable, specific allowances for that measure.

After consideration of the public comments received, we are finalizing these provisions as proposed.

(5) Discussion of the Relationship Between a Stage 2 Meaningful Use Objective and Its Associated Measure

We proposed to continue our Stage 1 policy that regardless of any actual or perceived gaps between the measure of an objective and full compliance with the objective (such as a measure threshold of less than 100 percent or a

measure designed to account for circumstances where 100 percent compliance in not the intention of the objective), meeting the criteria of the measure means that the provider has met the objective for Stage 2.

We did not receive any comments and we are finalizing these provisions as proposed.

(6) Objectives and Their Associated Measures

(a) Objectives and Measures Carried Over (Modified or Unmodified) From Stage 1 Core Set to Stage 2 Core Set

Proposed Objective: Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

In the proposed rule, we outlined the following benefits of CPOE. 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. Consistent with the recommendations of the HIT Policy Committee, we proposed to expand the orders included in the objective to medication (which was included in Stage 1), laboratory, and radiology. We believe that the expansion to laboratory and radiology furthers the goals of the CPOE objective, that such orders are commonly included in CPOE roll outs and that inclusion of the entry of these orders using CPOE is a logical step in the progression of meaningful use. We note that this does not require the electronic transmission of the order.

We proposed to continue to define CPOE as 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 safety and efficiency of the ordering process. We further proposed that the CPOE function of CEHRT must be used by the ordering provider or licensed healthcare professionals under his or her direction to create the first record of that order, or it would not count as CPOE. As this proposed objective limits the use of CPOE to the creation of the first record of the order (a more restrictive standard than in Stage 1), we invited public comment on whether the stipulation that the CPOE function be used only by licensed healthcare professionals remains necessary or if CPOE can be expanded to include non-licensed healthcare professionals such as scribes.

Comment: Commenters focused primarily on CPOE's value as the trigger for clinical decision support interventions. It was suggested the term be revised from computerized provider order entry to computerized order evaluation. This focus led to the suggestion by several commenters that as long as the ordering providers ''signs'' or otherwise authorizes the order before it is carried out this should count for CPOE. These commenters maintain that meaningful use should not dictate any of the processes that lead up to this authorization including who enters the order into CEHRT nor what types of record of the order may exist prior to entry into CEHRT.

Response: We agree that CPOE as the trigger for CDS interventions is the primary value creating function of CPOE. However, we disagree that it is the only one. We believe automating aspects of and/or eliminating steps in the ordering process prior to final authorization of the order does reduce communication and other errors. Furthermore, it is our understanding from both commenters and our own experiences with CEHRT that many EHRs use the entry of the order as the trigger for CDS interventions and either display them again at authorization or do not display them at all at authorization. For these reasons, we continue to focus the definition and measurement of CPOE on when and by whom the order is entered into CEHRT and not on when it is authorized by the ordering provider in CEHRT.

Comment: Commenters stated that the authentication of verbal orders is already covered by the conditions of participation for hospitals at 42 CFR482.24(c)(1)(iii) which states that ''[a]ll verbal orders must be authenticated based upon Federal and state law. If there is no state law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours.'' Meaningful use should adopt this same standard.

Response: We are not adopting this standard for two reasons. First, as this is in an incentive program, we do not believe it is logical to base a requirement for meaningful use solely on a condition of participation. Hospitals already must comply with the conditions of participation, so we believe as an incentive program meaningful use should be incentivizing behavior beyond the conditions of participation. Second, as discussed later, we are not limiting the communication of orders prior to CPOE to verbal orders so there is not a direct corollary between this condition of participation and our description of CPOE. Section 482.23(c)(2) also speaks to verbal orders. First, it states, ''If verbal orders are used, they are to be used infrequently. Second, it states, ''When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and state law.'' We discuss who may enter the order later in comment and response, but reiterate our position that meaningful use should incentivize behavior that benefits patients beyond that required by the conditions of participation.

Comment: Commenters objected to our proposal to change our policy regarding CPOE from ''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'' to ''the order created using the EHR must be the first record of that order or it would not count as CPOE''. The commenters stressed that if they used a process that created a record of the order that was not part of the patient's medical record, then the proposed policy requiring this record not be retained is not advisable. The commenters asserted that even if it was not part of the patient's medical record the initial record of the order could be used for quality control purposes.

Response: Our proposed policy change was intended as an evolution from the Stage 1 requirements for CPOE. However, after reviewing the comments received, we agree that requiring an electronic or written order that is not created using the CPOE function of CEHRT to not be retained in order for it to count as CPOE could have unforeseen and possibly detrimental consequences for quality control. We continue to believe that our original proposal would have increased CPOE's ability to improve safety and efficiency and encourage all providers to streamline the ordering process to minimize the number of steps involved. However, we do not have sufficient information to determine whether the gains of the proposal are greater than or less than the potential cost of not retaining written or electronic orders issued before the use of the CPOE function. Therefore, we are not finalizing the proposed revised

description of when the CPOE function must be utilized during the ordering process and instead finalize our existing Stage 1 description 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. Based on the questions we have received on CPOE to date, the limiting criterion is the first time the order becomes part of the patient's medical record rather than the limitation of before any action can be taken on the order. The provider must make the determination as to what constitutes the patient's medical record and what does not based on their existing policies and applicable state and Federal law. Our only requirements in this regard are that the determination be made by the provider prior to the start of the EHR reporting period and be uniformly applied.

Comment: We have received many comments on who can enter the order into CEHRT for it to count as CPOE. Four possibilities received comment support. First, only the ordering provider be able to enter the order into CEHRT. Second, any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines can enter the order into CEHRT. This is the current policy which was proposed to continue. Third, an expansion to any licensed, certified or appropriately credentialed healthcare professional (some commenters replaced medical assistant with healthcare professional) who can enter orders into the medical record per state, local and professional guidelines. Fourth, an expansion to allow anyone, including those commonly referred to as scribes, enter the orders into the medical record per state, local and professional guidelines. We also note that there was some confusion among commenters as to our current limitation and proposal of any licensed healthcare professional using CPOE to create the first entry of the order into the patient's medical record as we received many comments suggesting that nurses should be able to enter the orders. We clarify that nurses who are licensed and can enter orders into the medical record per state, local and professional guidelines may enter the order into CEHRT and have it count as CPOE.

Response: As we did not revise our description of when in the ordering process the CPOE function must be used, we are inclined to not revise our description of who may enter it into CEHRT. However, we are particularly concerned with CPOE usage by EPs in this regard. Many EPs practice without the assistance of other licensed healthcare professionals. These EPs in their comments urged the expansion indicated in the third possibility of credentialed healthcare professionals/medical assistants. We believe that this expansion is warranted and protects the concept that the CDS interventions will be presented to someone with medical knowledge as opposed to a layperson. The concept of credentialed healthcare professionals is over broad and could include an untold number of people with varying qualifications. Therefore, we finalize the more limited description of including credentialed medical assistants. The credentialing would have to be obtained from an organization other than the employing organization. Our responses to earlier comments factored into this decision as well. Based on the public comments received, questions submitted by the public on Stage 1 and demonstrations of CEHRT we have participated in, 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 could be required to enter the order correctly, evaluate CDS 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 CDS intervention or bypass the intervention. We do not believe that a layperson is qualified to do this, and as there is no licensing or credentialing of scribes, there is no guarantee of their qualifications.

Comment: We received comments on a particular category of orders referred to as ''protocol'' or ''standing'' orders. The defining characteristic of these orders is that they are not created due to a specific clinical determination by the ordering provider for a given patient, but rather are pre-determined for patients with a given set of characteristics (for example, administer medication X and order lab Y for all patients undergoing a certain procedure or refills for given medication). Commenters maintain that these orders require special treatment in regards to when they are entered into CEHRT and who enters them. Commenters indicate that administrative staff should be allowed to enter them, but not override any CDS interventions that may appear.

Response: 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. We therefore 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. We foresee two circumstances where a provider would not want to exclude this category of orders. The first is that they disagree that these type of orders warrant different considerations and therefore enter them according to our description of CPOE. The second is providers who are unable to separate them from other orders in their calculation of the denominator and numerator.

Comment: Commenters mostly support the expansion to the laboratory and radiology orders. Three concerns were raised. First, commenters believed that as laboratory and radiology orders were new additions they should have a lower threshold than medication orders. Second, commenters desired a more descriptive definition on what constitutes a laboratory and particularly a radiology order. Third, commenters suggested that laboratory and radiology orders should be delayed for EPs until more laboratory and radiology providers could receive the order electronically.

Response: We discuss the measure separately later in this section and address the comments on the threshold there. We describe laboratory services as any service provided by a laboratory that could not be provided by a non-laboratory. Laboratory is defined at 42 CFR 493.2 as: ''a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.'' We describe radiologic services as any imaging service that uses electronic product radiation. Electronic product radiation is defined at 21 CFR 1000.3 as: ''any ionizing or nonionizing electromagnetic or particulate radiation, or [a]ny sonic, infrasonic, or ultrasonic wave that is emitted from an electronic product as the result of the operation of an electronic circuit in such product.''

If the provider desires to include other types of imaging services that do not rely on electronic product radiation they may do so as long as the policy is consistent across all patients and for the entire EHR reporting period. Finally, as we discuss in the next comment and response, electronic transmission of the order is not a requirement for CPOE.

Comment: Some commenters stated that while CPOE is a commonly understood function in the hospital setting, in the ambulatory setting its use is more ambiguous. For medication orders, the difference between CPOE for the medication and e-prescribing the medication is more subtle. The expansion to laboratory and radiology further complicates this in the ambulatory setting as most laboratory and radiology orders are sent to a third party which may or may not be able to receive such orders electronically.

Response: While we agree that the concept of CPOE is a more definitive action in the ordering process in the hospital setting, we believe that it is still integral to the ambulatory setting and serves the same purposes in both settings as a trigger for CDS interventions and as a way to increase the efficiency and safety of the ordering process. CPOE is the entry of the order into the patient's EHR that uses a specific function of CEHRT. It is not how that order is filled or otherwise carried out. For medications, on the ambulatory side CPOE feeds into e-prescribing, and on the hospital side electronic medication administration record may be used, but neither of these are requirements for CPOE. For example, a medication could be entered into CEHRT using CPOE and then be electronically transmitted to a pharmacy. This would be both CPOE and e-prescribing. However, a medication could be entered into CEHRT using CPOE and then a printed copy of the prescription could be generated by CEHRT and given to the patient. This would still be CPOE, but not e-prescribing. Similarly, whether the ordering of laboratory or radiology services using CPOE in fact results in the order being transmitted electronically to the laboratory or radiology provider does not dictate whether CPOE was met. 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.

After consideration of the public comments received, we are modifying this objective for EPs as § 495.6(j)(1)(i) and for eligible hospitals and CAHs at § 495.6(l)(1)(i) to use the same language as Stage 1 (with the addition of laboratory and radiology orders), as we did not finalize our proposed changes to when the order must be entered: ''Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local, and professional guidelines.''

Proposed Measure: More than 60 percent of medication, laboratory, and 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.

In Stage 1 of meaningful use, we adopted a measure of 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. In the Stage 1 final rule, we adopted a threshold of 60 percent for this measure for Stage 2.

In our proposed rule, we discussed how our experience with Stage 1 has shown that the denominator of all orders created by the EP or in the hospital would not be unduly burdensome for providers and creates a better measurement for CPOE usage, particularly for EPs who infrequently order medications. We explained that the denominator recommended by the HITPC of ''patients with at least one type of order'' is a proxy measure for the number of orders issued. We asked for comments on whether the barriers to collecting information for our proposed denominator would be greater in a hospital or ambulatory setting. We also requested that commenters suggest different denominators or measures and encouraged any commenter proposing an alternative denominator to discuss whether the proposed threshold or an alternative threshold should be used for this measure and to include any exclusions they believe are necessary based on their alternative denominator.

We also stated in our proposed rule that we believed providers do not roll out CPOE for only one order type, but rather for a package of order types. The HITPC had recommended a percentage threshold for laboratory orders, but a yes/no attestation of one order for radiology (not for both laboratory and radiology, as we mistakenly stated in the proposed rule). We also expressed concerns in the 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 proposed a percentage threshold for all three types of orders: medication, laboratory, and radiology.

Comment: Commenters both supported and opposed the new denominator for CPOE. Those supporting the proposed denominator did so for its simplicity and greater accuracy for measuring actual CPOE usage. Commenters that opposed the proposed denominator did so for one of two reasons. Either they were concerned with the burden associated with counting paper or other orders that are never entered into CEHRT or they were concerned that the proposed denominator requires much higher performance of CPOE usage. For example, in the hospital setting an inpatient might have 20 orders during a stay. Under the proposed denominator, 13 of those orders would have to be entered using CPOE, while under the current denominator only one order would have to be entered using CPOE. A few commenters opposed the new denominator for both reasons.

Response: In regards to the perceived higher performance of CPOE usage required by switching from the Stage 1 denominator to the Stage 2 proposed denominator, the sole purpose of the proxy measure for CPOE used in Stage 1 was to alleviate the measurement burden, not create a lower level of CPOE usage than implied by the percentage threshold. Therefore, as a more accurate measure is possible, it should reflect the percentage of CPOE use indicated by the established thresholds. In regards to the burden of the measure, we had stated in our proposed rule that the reason we believed we could move to the proposed denominator was feedback from many providers indicating that they could in fact measure the proposed denominator. In addition due to problems associated with the proxy for EPs who have comprehensive medication lists for their patients, but were not the ordering provider for many of those medications some EPs were having to use an alternative measure issued through guidance (*https://questions.cms.gov/faq.php?id=5005&faqId=3257*) that allowed them to only include patients with medications the EP had ordered. We assume in determining the measures of meaningful use that the patient's medical record conforms to existing Federal and state laws, which we believe would generally require that all orders issued by a provider for a patient become part of the patient's medical record (for example, 42 CFR 482.24(c)(2)(vi)). Therefore, the concept that some orders do not become part of

the CEHRT means that the provider is maintaining patient medical records both electronically in CEHRT and outside of CEHRT using either paper charts or another electronic system. When a provider starts their first Stage 2 EHR reporting period, they will have been using CEHRT for at least 15 months. In our proposed rule, we have stated our belief that most providers would have fully transitioned patients' medical records to CEHRT by the time they start Stage 2. However, as discussed previously, we are leaving open the option for limiting certain measures to only those records maintained in CEHRT. As this is one of those measures, there is no reason to change the measure to accommodate patient records not maintained in CEHRT as provider can choose to not include records not maintained in CEHRT in the denominator. Thus, we finalize the denominator as proposed.

Comment: Commenters requested clarification on whether the measure puts all medication, laboratory and radiology orders in the same denominator and therefore it was potentially possible to meet the 60 percent threshold without CPOE being used 60 percent of the time for one or more order type, up to and including the possibility that CPOE may never be used for one or more order type. Many commenters suggested that if all orders were in the same denominator this was not a good measure of the expansion of CPOE to laboratory and radiology and that the orders should be broken out separately. Only a few commenters suggested that the denominator should be the aggregate of all three types of orders.

Response: We agree with the commenters that an aggregate denominator does not best reflect our expansion to laboratory and radiology and therefore create a separate denominator for each order type. This is consistent with the suggestions of the majority of commenters and most accurately reflects the use of CPOE. While CPOE does not require the electronic transmission of the order, many CEHRT will be linked to the technology systems that manage medication, as well as those for laboratories and radiology departments. These systems may be different thereby presenting unique challenges for each order type that could result in differing roll out times and utilization rates. In addition, a provider with a high number of one order type compared to others may even be able to reach a combined threshold without implementing CPOE for one or more of the order types. This would negate the benefits of expanding CPOE to these order types. We have 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: We received several suggestions on the percentage threshold for medication orders to reduce it below 60 percent. The suggestions ranged from 50 percent to 30 percent. Two reasons were given. First, that 60 percent was simply too high. Second, that the proposed denominator made 30 percent a much higher bar than it was when the proxy was in place and the threshold should not be raised until we have data based on the proposed denominator.

Response: As we stated previously, the purpose of the proxy denominator was not to create a lower bar than CPOE usage at 30 percent, but to address measurement burden. While we agree that the information generated using the proxy denominator for CPOE is different from the finalized denominator, this is only true in a limited set of circumstances, especially for EPs. For it to be different at all, a provider must have ordered more than one medication for a patient during the EHR reporting period. Furthermore, this is most likely limited to providers who see a patient on more than one occasion. We believe it would be highly unlikely that a provider would use CPOE to order one medication and then not use it to order another during the same encounter or admission. For these reasons, we believe that while not a perfect correlation the information gained through Stage 1 attestations. The Stage 1 attestations provide a reasonable basis on which to set the Stage 2 thresholds. We believe it is reasonable to expect the actual use of CPOE to increase from 30 percent in Stage 1 to 60 percent in Stage 2 and consist with the expectations that were finalized in the Stage 1 regulations. Therefore, for medication orders, we finalize the threshold at 60 percent.

Comment: Some commenters maintain that the addition of laboratory and radiology orders to CPOE is a new function and should not be introduced at the same threshold.

Response: Based on the same logic supporting the 60 percent threshold for medication orders (that is, 30 percent is reasonable when CPOE is first introduced for an order type, and 60 percent in the next stage following CPOE introduction), we agree with the commenters that the thresholds should be different. We finalize a threshold of 30 percent for each laboratory and radiology orders.

After consideration of the public comments received, we are splitting the proposed measure into three measures and changing the threshold for radiology and laboratory orders at § 495.6(j)(1)(ii) for EPs and § 495.6(l)(1)(ii) for eligible hospitals and CAHs.

- 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.
- More than 30 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.
- More than 30 percent 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.

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 CEHRT at 45 CFR 170.314(a)(1).

As discussed in the comment and response section, an EP, eligible hospital or CAH can limit the denominators to only include medication, laboratory and radiology orders for patients whose records are maintained using CEHRT.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *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.

- *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.

• *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.

An EP through a combination of meeting the thresholds and/or exclusions must satisfy all three measures for this objective.

A hospital must meet the thresholds for all three measures.

Proposed EP Objective: Generate and transmit permissible prescriptions electronically (eRx).

In the proposed rule, we noted that 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 EP generates the prescription electronically, CEHRT can recognize the information and can provide decision support to promote safety and quality in the form of adverse interactions and other treatment possibilities. The CEHRT can also provide decision support that promotes 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. Transmitting the prescription electronically promotes efficiency and 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. This comparison allows for many of the same decision support functions enabled at the generation of the prescription, but bases them on potentially greater information.

We proposed to continue to define prescription as the authorization by an EP to dispense a drug that will not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We proposed to define a permissible prescription as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II–V *http://www.deadiversion.usdoj.gov/schedules/index.html.* Although the Drug Enforcement Administration's (DEA) interim final rule on electronic prescriptions for controlled substances (75 FR 16236) removed the Federal prohibition to electronic prescribing of controlled substances, some challenges remain including more restrictive state law and widespread availability of products both for providers and pharmacies that include the functionalities required by the DEA's regulations. We asked for public comments as to whether over the counter (OTC) medicines will be routinely electronically prescribed and proposed to continue to exclude them from the definition of a prescription.

In our proposed rule we discussed several different workflow scenarios are possible when an EP prescribes a drug for a patient. First, the EP could prescribe the drug and provide it to the patient at the same time, and sometimes the EP might also provide a prescription for doses beyond those provided concurrently. Second, the EP could prescribe the drug, transmit it to a pharmacy within the same organization, and the patient would obtain the drug from that pharmacy. Third, the EP could prescribe the drug, transmit it to a pharmacy independent of the EP's organization, and the patient would obtain the drug from that pharmacy. Although each of these scenarios would result in the generation of a prescription, the transmission of the prescription would vary. In the first situation, there is no transmission. In the second situation, the transmission may be the viewing of the generation of the prescription by another person using the same CEHRT as the EP, or it could be the transmission of the prescription from the Certified EHR Technology used by the EP to another system used by the same organization in the pharmacy. In the third situation, the EP's Certified EHR Technology transmits the prescription outside of their organization either through a third party or directly to the external pharmacy. These differences in transmissions create differences in the need for standards. We proposed that only the third situation would require standards to ensure that the transmission meets the goals of electronic prescribing. In the first two scenarios one organization has control over the whole process. In the third scenario, the process is divided between organizations. In that situation, standards can ensure that despite the lack of control the whole process functions reliably. To have successfully e-prescribed, we proposed that the EP needs to use CEHRT as the sole means of creating the prescription, and when transmitting to an external pharmacy that is independent of the EP's organization such transmission must use standards adopted for EHR technology certification.

We did not receive any public comments on this objective, therefore, we are finalizing this objective at § 495.6(j)(2)(i) as proposed.

Proposed EP Measure: More than 65 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using CEHRT.

We proposed a new exclusion for Stage 2 that would allow EPs to exclude this objective if no pharmacies within 25 miles of an EP's practice location at the start of his/her EHR reporting period accept electronic prescriptions. This is 25 miles in any straight line from the practice location independent of the travel route from the practice location to the pharmacy. We stated that EP's practicing at multiple locations would be eligible for the exclusion if any of their practice locations that are equipped with CEHRT meet this criteria. 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 25-mile radius regardless of whether that pharmacy can accept electronic prescriptions from EPs outside of the organization. We also proposed an exclusion for EPs who write fewer than 100 prescriptions during the EHR reporting period.

Comment: Most commenters agreed with the exclusion of controlled substances in the denominator. They were concerned about industry readiness as well as potentially conflicting state regulations. Other commenters expressed concerns that specialists (that is, surgeons, psychiatrists) who write prescriptions that are not permissible (that is, controlled substances) would not be able to meet the measure.

Response: We agree with the commenters and will continue to exclude controlled substances from the denominator. However, we are also adding an alternative denominator to provide additional flexibility for EPs who are able to electronically prescribe controlled substances and want to count these prescriptions in the measure.

Comment: Most commenters did not support the inclusion of OTC medicines in this objective, as OTC medicines are not usually intended for the pharmacy to fill. Those commenters who did support it noted that OTC medicines are

prescribed often times because it allows patients to use their health care spending accounts to pay for the cost.

Response: After consideration of public comments, we agree with the majority of commenters in that OTC medicines should not be included as a part of this objective. While some OTC medicines are ordered by the EP, the low prevalence of such occurrences means the costs of including them in both measurement and actual e-prescribing outweighs any benefit of inclusion.

Comment: Most commenters thought the proposed threshold was too high or just right. Those who thought it was too high expressed concerns about the abilities of mail-order pharmacies to accept electronic subscriptions. Some commenters suggested lowering the threshold to 50 percent. Other commenters expressed concerns that patients may prefer a paper prescription and suggested excluding those patients from the denominator. The commenters who thought the proposed threshold was ''just right'' noted that most EPs who successfully demonstrated meaningful use for Stage 1 far exceeded the Stage 1 threshold of 40 percent.

Response: Preliminary analysis of Stage 1 meaningful use attestation data shows that those EPs who successfully attested for this measure exceeded the 40 percent threshold—many reporting thresholds of 80–100 percent. However, the Surescripts Q4 2011 Report suggests that close to 40 percent of physicians who began e-prescribing in 2008 meet the 65 percent threshold. This report only represents the earliest adopters. Based on public comments, we believe the 65 percent threshold we proposed may be unattainable for many EPs and question whether any real difference in provider behavior is achieved with a 65 percent threshold versus a 50 percent threshold. This lower threshold also accounts for patients who may prefer a paper prescription, rather than having their prescription sent to a pharmacy electronically. After consideration of public comments, we are finalizing the threshold for this measure at 50 percent.

Comment: Most commenters supported comparing prescriptions written by the EP to a drug formulary, but not without concern. Many noted that drug formularies are not always readily available, are linked to specific payers, or may not otherwise be readily available.

Response: After review of the public comments, we realize this measure needs to be further clarified. We recognize that not every patient will have a formulary that is relevant for him or her. Therefore, we require not that the CEHRT check each prescription against a formulary relevant for a given patient, but rather that the CEHRT check each prescription for the existence of a relevant formulary. If a relevant formulary is available, then the information can be provided. We believe that this initial check is essentially an on or off function for the CEHRT and should not add to the measurement burden. Therefore, with this clarification of the check we are referring to, we are finalizing the drug formulary check as a component of this measure. We look forward to the day when a relevant formulary is available for every patient. We also modified the measure to use the word ''query'' instead of ''compare'' because it better explains the process in which the EP uses the CEHRT to consult the information provided in the formulary.

Comment: Many commenters expressed concerns about patients who request paper copies of their prescriptions and how they would be accounted for in this measure. Commenters also expressed concerns about patients who prefer to use mail-order pharmacies that do not accept eRx.

Response: We have accounted for patient preferences by lowering the threshold for this measure from 65 percent to 50 percent.

Comment: Many commenters expressed concerns that the word ''permissible'' was omitted from the proposed exclusion for EPs who write fewer than 100 prescriptions during the EHR reporting period.

Response: We agree with commenters in that we inadvertently omitted the word ''permissible'' from this exclusion. After consideration of public comments, we are finalizing this exclusion as ''EPs who write fewer than 100 *permissible* prescriptions during the EHR reporting period.''

Comment: Many commenters supported this exclusion but expressed concerns about how it was proposed and would be implemented. Some commenters suggested reducing the radius to 10 miles or less in urban areas and leaving it at 25 miles in rural areas. Other commenters suggested revising this exclusion for EPs where less than 20 percent of pharmacies e-prescribe within a 25-mile radius of their office. Other commenters expressed concerns that there may only be a limited number of pharmacies in their geographic area that can accept prescriptions electronically. Yet others suggested including a grace period for EPs in areas where no pharmacies e-prescribe at the beginning of their EHR reporting period, but later begin accepting eRx.

Response: We appreciate the commenters' concerns about this exclusion. We agree with commenters in that a 25-mile radius may be too large. We believe the 10-mile radius is more reasonable as it takes the country's geographic diversity (urban, suburban, rural areas) into account. We are therefore finalizing that if no pharmacies within a 10-mile radius of an EP's practice location at the start of the EHR reporting period accept electronic prescriptions, the EP would qualify for this exclusion, unless the EP is part of an organization that owns or operates a pharmacy within the 10-mile radius. As for patient preference, we agree with commenters that not all patients will want to go to a particular pharmacy just because they accept electronic prescriptions. However, we believe we accounted for patient preference by lowering the threshold for the measure to 50 percent.

After consideration of public comments, we are revising the measure at § 495.6(j)(2)(ii) to read: ''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 further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(b)(3) and 45 CFR 170.314(a)(10).

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: (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/her EHR reporting period.

Consolidated Objective: Maintain an up-to-date problem list of current and active diagnoses.

Consolidated Objective: Maintain active medication list.

Consolidated Objective: Maintain active medication allergy list.

For Stage 2, we proposed to consolidate the objectives for maintaining an up-to-date problem list, active medication list, and active medication allergy list with the Stage 2 objective for providing a summary of care for each transition of care or referral. We stated that we continue to believe that an up-to-date problem list, active medication list, and active medication allergy list are important elements to be maintained in CEHRT. However, the continued demonstration of their meaningful use in Stage 2 would be required by other objectives focused on the transitioning of care of patients removing the necessity of measuring them separately. Providing this information is critical to continuity of care, so we proposed to add these as required fields in the summary of care for the following Stage 2 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 should provide a summary care record for each transition of care or referral.'' We stated that EPs and hospitals would have to ensure the accuracy of these fields when providing the summary of care, which we believe would ensure a high level of compliance in maintaining an up-to-date problem list, active medication list, and active medication allergy list for patients. The required standards for these fields are discussed in the ONC standards and certification final rule published elsewhere in this issue of the **Federal Register**.

Comment: Overall, we received very few comments on our proposal to consolidate the up-to-date problem list, active medication list, and active medication allergy list objectives. Some commenters opposed our proposal as they believe it would detract from the importance of these items. However, the vast majority of those who commented on this proposal supported the consolidation of these objectives.

Response: After consideration of public comments, we are finalizing the consolidation of these objectives as proposed for the reasons discussed in the proposed rule. The objectives of maintaining an up-to-date problem list, active medication list, and active medication allergy list will be consolidated with the Stage 2 objective for providing a summary of care for each transition of care or referral.

Proposed EP Objective: Record the following demographics: preferred language, gender, race and ethnicity, and date of birth.

Proposed Eligible Hospital/CAH Objective. Record the following demographics: preferred language, gender, race and ethnicity, date of birth, and date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

We proposed to continue the policy that EPs, eligible hospitals and CAHs collect baseline demographic data for all unique patients in the EHR using OMB standards for race and ethnicity. The proposed rule outlines some of the numerous benefits from recording basic patient demographic information in the EHR, including improved patient-centered care and management of the health of populations. In response to multiple comments from the Stage 1 final rule regarding the preliminary cause of death data element required for eligible hospitals and CAHs, we clarified the following; this element is the preliminary cause of death recorded by the hospital and is not required to be amended when additional information becomes available, there is no specified timeframe for recording this element, and we invited additional public comment regarding these clarifications in the proposed rule. We also asked for public comment on the burden and ability to include additional measures of disability status, gender identity and/or sexual orientation.

Comment: We received many comments suggesting CMS differentiate between the terms sex and gender. One commenter provided the definition that the term sex is used in recording vital health statistics that describe the physiological characteristics at time of birth. The term gender incorporates behaviors, roles, and expectations corresponding to an individual's sex and is generally self reported.

Response: We appreciate this clarification and will incorporate the change in terminology for the final rule using the term sex instead of gender in EP, eligible hospital and CAH objectives for recording demographics. This change in terminology aligns with vital statistic reporting and the HHS final demographic data collection standards published October 31, 2011.

Comment: Several commenters indicated that the collection of race and ethnicity demographic information can be sensitive and patients may be unwilling or uncomfortable reporting this information to the individual collecting demographic data. Other comments supported CMS clarification in the Stage 1 final rule that providers can be allowed to account for patients who decline to provide elements of demographic information. Additional comments suggested that a single system parameter be developed to identify states that prohibit data reporting should be available to the EHR.

Response: If a patient declines to provide information of ethnicity or race or if capturing a patient's ethnicity or race is prohibited by state law, this should be duly noted as structured data in the EHR and this would still count as an entry for the purpose of meeting this measure. A study by the Agency for Healthcare Research and Quality (AHRQ) states that current state prohibitions on the collection of ethnicity and race apply to health plans' collection of data at the time of enrollment. Title VI of the Civil Rights Act of 1964 permits health care organizations to collect race, ethnicity, and preferred language patient data for the purpose of quality improvement.

Comment: Several commenters suggested that CMS use the same definition for race and ethnicity as the Centers for Disease Control and Prevention (CDC) and the United States Census Bureau. Other commenters were concerned about the need to collect data granular enough to identify differences between subpopulations and aligned across government programs.

Response: We recognize that the CDC has developed codes that allow for the mapping of more detailed race and ethnicity categories such as those maintained by the U.S. Bureau of the Census to the less detailed OMB standard. We appreciate that providers may need to collect more granular demographic data to manage their patient populations. For purposes of achieving Stage 2 of meaningful use, we will continue to rely on the OMB standard as a minimum standard for the collection of race and ethnicity data. EPs, eligible hospitals, and CAHs who wish to collect more granular level data on patient race and ethnicity may do so as long as they can map the data to 1 of the 5 races included in the existing OMB standards. The standards associated with the meaningful use objectives and measures are discussed further in the ONC standards and certification criteria final rule and we refer readers to that regulation published elsewhere in this issue of the **Federal Register**.

Comment: Many commenters agreed with the need to incorporate disability status in EHR technology. However, it was also clear that several of these commenters varied in their definition of disability with interpretations that ranged from physical, mental, occupational, and economic disability

status. Commenters also differed regarding the most appropriate location for the capture and storage of disability status data elements within the EHR. Suggestions for where to incorporate disability status data varied (for example; from the demographic objective, to physician notes, and/or the problem list component of the summary of care document). Another commenter suggested that the demographic objective should be limited to collecting data with static values and the active problem list, electronic notes and/or care summary documents that are continually updated would be more appropriate for recording changes in patient disability status.

Response: We wish to clarify that the term disability status used in the proposed rule was meant to be all-encompassing by incorporating both the concepts of physical and cognitive disabilities as well as the concept of functional status limitations that impact an individual's capability to perform activities in different environments. This latter concept incorporates metrics useful for planning and coordination across care settings. Commenters varied in their responses regarding the level of consensus on measurement standards for each of these health status measures. Since publishing the proposed rule we have learned that significant progress has been made regarding the capture of functional status into the consolidated clinical document architecture (C–CDA) standard for summary of care records. The C–CDA Implementation Guide provides the following examples that may be incorporated under functional status; assessments of a patient's language, vision, hearing, activities of daily living, behavior, general function, mobility, self-care status, physical state and cognitive function.[1] The C–CDA standards support the exchange of clinical documents between those involved in the care of a patient and allow for the re-use of clinical data for clinical care giving, public health reporting, quality monitoring, patient safety and clinical trials. This inclusion is addressed more fully under the discussion of the transition of care objective in this final rule.

We strongly support the adoption, implementation and meaningful use of CEHRT for all individuals and the reduction of barriers for persons with disabilities. In finalizing this rule, we also considered the operational challenges that could result from the lack of consensus noted by many commenters to incorporate a physical disability standard measure in the demographic section of CEHRT at this time. As a result, we will not require the collection of disability status data under the demographic objective for Stage 2 of meaningful use. However, we suggest that providers examine the questions developed by the HHS as required by section 4302 of the Affordable Care Act. The questions resulted from an interagency process and are closely aligned to the Census Bureau's American Community Survey and the International Classification of Disability. These questions may be found on the HHS Web site at *http://minorityhealth.hhs.gov/templates/content.aspx?ID=9232#1*. The answers to these questions could be incorporated as functional status or other data elements in the C–CDA summary of care document mentioned above and discussed more fully in the transition of care objective later in this rule.

We will continue to work with ONC, other federal agencies and seek the advice of the HIT Policy Committee to explore further how disability status could be included in meaningful use Stage 3.

Comments: Many commenters supported the proposed inclusion of recording gender identity and/or sexual orientation as part of the demographic objective. Other commenters suggested that the collection of this information is extremely sensitive and could be considered offensive for some patients especially when collected by administrative staff. Still other commenters did not see the clinical significance of collecting and recording this information in the demographic section of the EHR. Others commenters were against recording gender identity and/or sexual orientation because they did not consider this would provide additional clinical benefit. Still others suggested that the reporting of gender identity or sexual orientation be optional and up to individual clinician judgment whether or not it is appropriate to collect this information.

Similar to the comments for the proposed inclusion of disability status, commenters noted both the data collection challenges and data reporting burden. Many commenters were opposed to the mandatory collection of all three additional measures for Stage 2 of meaningful use and suggested that reporting could be optional.

Response: Considering the lack of consensus for the definition of the concept of gender identity and/or sexual orientation as well as for a standard measure of the concept and where it would be most appropriate to store the data within the EHR, we will await further development of a consensus for the goal and standard of measurement for gender identity and/or sexual orientation. Additionally, we note that many commenters raised concerns as to whether such data collection is necessary for all EPs, eligible hospital, and CAH regardless of specialty.

Comments: Several additional measures were suggested under the demographic objective including; measuring the level of access to and use of the internet, measuring computer literacy, and measuring standardized occupation using established industry codes.

Response: We appreciate the numerous comments suggesting additional demographic information that will allow providers to improve the quality of individual patient centered care as well as population health. We may consider these suggestions further in the development of Stage 3 of meaningful use.

Comment: A minority of commenters recommended removing the preliminary cause of death element altogether from the eligible hospital/CAH objective. Others suggested that the eligible hospital/CAH measure for preliminary cause of death be modified to simply capture whether or not the patient had a cause of death recorded, regardless of when that information was entered into the EHR, because the preliminary cause of death may often be inaccurate since by law the coroner or medical examiner makes the final determination for the patient's death certificate.

Response: We appreciate the suggestion for measure simplification. However, for this measure we want to respect the existing hospital workflow where a clinician evaluates the patient to pronounce the death. This preliminary cause of death is documented by the clinician in the patient's chart. We recognize that these workflows may change as EHR technology develops and becomes more widely adopted and the exchange of health information is able to link to vital statistic reporting. However, for the time being the measure of preliminary cause of death under the demographic objective will remain unchanged.

After consideration of the public comments received, we are modifying the meaningful use objective at § 495.6(j)(3)(i) of our regulations as follows: EPs ''Record all of the following demographics: Preferred language, sex, race, ethnicity, and date of birth.''

After consideration of the public comments received, we are modifying the meaningful use objective at § 495.6(l)(2)(i) of our regulations as

[1] Implementation Guide for CDA Release 2.0 (US REALM) July 2012, © 2012 Health Level Seven, Inc. Ann Arbor, MI.

follows: Eligible hospitals and CAHs ''Record all of the following demographics: Preferred language, sex, race, ethnicity, date of birth, date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.''

Proposed Measure: More than 80 percent of all unique patients 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 demographics recorded as structured data.

Comment: Most commenters were supportive of the increased threshold for this measure.

Response: Our analysis of the meaningful use data for Stage 1 found that over 90 percent of EPs, eligible hospitals and CAHs were able to successfully report the demographic measure. Therefore, based on comments and actual performance data we do not foresee a burden in increasing the measure threshold from more than 50 percent in Stage 1 to greater than 80 percent in Stage 2.

After consideration of public comments, we are finalizing this measure for EPs at § 495.6(j)(3)(ii) and for eligible hospitals and CAHs at § 495.6(l)(2)(ii) as proposed.

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 CEHRT at 45 CFR 170.314(a)(3).

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to 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 have all the elements of demographics (or a specific notation if the patient declined to provide one or more elements or if recording an element is contrary to state law) recorded as structured data.
- *Threshold:* The resulting percentage must be more than 80 percent in order for an EP, eligible hospital or CAH to meet this measure.

If a patient declines to provide one or more demographic elements this can be noted in the CEHRT and the EP or hospital may still count the patient in the numerator for this measure. The required elements and standards for recording demographics and noting omissions because of state law restrictions or patients declining to provide information will be discussed in the ONC standards and certification rule, published elsewhere in this issue of the **Federal Register**.

Proposed Objective: Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0–20 years, including BMI.

We proposed to continue our policy objective from Stage 1 to collect and record basic vital sign data for patients across health care settings. In the proposed rule, we outlined the benefits of documenting basic vital signs including that the data provides important clinical information on both the patient's current condition as well as the ability to track changes in patient status over time. For Stage 2, we proposed to remove the age restrictions on recording height/length and weight, and also proposed to remove the age restrictions on calculating and displaying BMI and growth charts. In addition, we proposed to modify the Stage 1 blood pressure guideline to align with the American Academy of Pediatrics guideline recommendations to measure blood pressure for children 3 years of age and older. We also proposed to continue our exclusions policy from Stage 1 (with modifications, as discussed below) for EPs who believe that recording and charting vital signs is outside the scope of their practice.

Comment: Several commenters questioned why all providers need to collect vital sign data when this information should be available from a robust health information exchange across providers.

Response: We will continue the Stage 1 meaningful use policy that any method of obtaining height, weight and blood pressure is acceptable for the purpose of this objective as long as the information is recorded as structured data in the CEHRT. As stated in the proposed rule, the vital sign information can be entered into the patient's medical record in a number of ways including: direct entry by the EP, eligible hospital, or CAH; entry by a designated individual from the EP, eligible hospital, or CAH's staff; data transfer from another provider electronically, through an HIE or through other methods; or data entered directly by the patient through a portal or other means. Some of these methods are more accurate than others, and it is up to the EP or eligible hospital to determine the level of accuracy needed to care for their patient and how best to obtain this information. We also look forward to the time when a more robust health information exchange network will allow providers to share relevant data across settings and/or alert providers when additional data should be obtained.

Comment: We received comments requesting that CMS include a statement clarifying which specialties would be included or excluded from this objective.

Response: We appreciate commenter's efforts to clarify this objective. However, we will continue our more general policy from Stage 1 (with modifications, as explained later) of allowing EPs to exclude this objective if they believe recording and charting changes in vital signs is not relevant to their scope of practice. We cannot define the scope of practice and/or interventions necessary for each individual patient and will continue to rely on provider determinations based on individual patient circumstances. Consider a hypothetical example of an elderly patient with multiple chronic conditions that includes depression. When the patient is seen by his behavioral healthcare provider to manage his depression, it is up to that provider to determine whether it would be medically necessary to record and chart the patient's weight in order to manage the patient's care.

After consideration of public comments, we are finalizing this objective for EPs at § 495.6(j)(4)(i) and for eligible hospitals and CAHs at § 495.6(l)(3)(i) as proposed.

Proposed Measure: More than 80 percent of all unique patients 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 blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

We proposed to split the exclusions from Stage 1 such that an EP could choose to record height/length and weight only and exclude blood pressure, or record blood pressure only and exclude height/length and weight. We encouraged comments on this split and whether it should go both ways. We proposed to increase the threshold from more than 50 percent to more than 80 percent for this measure.

Comment: Several commenters agreed with the policy that height/length, weight, and blood pressure do not each need to be updated by a provider neither at every patient encounter nor even once per patient seen during the EHR reporting period.

Response: We will maintain our policy from Stage 1 that it is up to the EP or hospital to determine whether height/length, weight, and blood

pressure each need to be updated, the level of accuracy needed to care for their patient, and how best to obtain the vital sign information that will allow for the right care for each patient.

Comment: Another commenter suggested that CMS clarify that the growth charts and BMI are not part of the actual measure for this objective.

Response: We clarify that to satisfy the measure of this objective, the CEHRT must have the capability to calculate BMI and produce growth charts for patients as appropriate. Since BMI and growth charts are only produced when height/length and weight vital sign data are captured in the CEHRT, the measure is limited to these data elements.

Overall commenters supported the added flexibility of our proposal to split the exclusion and allow EPs to record blood pressure only or height/length and weight only. Our analysis of the meaningful use data for Stage 1 found that over 90 percent of EPs, eligible hospitals and CAHs were able to successfully report the vital signs measure. We did not propose additional measure elements that could increase the reporting burden at this time.

After consideration of the public comments received, we are finalizing this measure as proposed for EPs at § 495.6(j)(4)(ii) and for eligible hospitals and CAHs at § 495.6(l)(3)(ii).

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 CEHRT at 45 CFR 170.314(a)(4). The ability to calculate the measure is included in CEHRT.

To calculate the percentage, CMS and ONC have worked together to define the following:

- *Denominator:* Number of unique patients seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- *Numerator:* Number of patients in the denominator who have at least one entry of their height/length and weight (all ages) and/or blood pressure (ages 3 and over) recorded as structured data.
- *Threshold:* The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.
- *Exclusions:* Any EP who sees no patients 3 years or older is excluded from recording blood pressure. Any EP who believes that all 3 vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them. Any EP who believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure. Any EP who believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

Proposed Objective: Record smoking status for patients 13 years old or older.

We stated in the proposed rule that accurate information on smoking status provides context to a high number and wide variety of clinical decisions, such as immediate needs for smoking cessation or long-term outcomes for chronic obstructive pulmonary disease. Cigarette smoking is a key component to the current Million Hearts Initiative (*http://millionhearts.hhs.gov*). We did not propose rules on who may record smoking status or how often the record should be updated. In addition, we proposed to continue the age limitation at 13 years old. We also requested comments specifically on the possible inclusion of other forms of tobacco use and second hand smoke.

Comment: We have received comments that assert that the objective is not relevant to a significant number of EPs due to their scope of practice and that it is redundant to the clinical quality measure ''National Quality Forum (NQF) 28: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention''. Some of the comments suggest that it should be eliminated and those EPs for whom it is relevant select the CQM.

Response: We disagree that the proposed objective and the clinical quality measure identified by commenters serve the same purpose and therefore only one should be included. The objective seeks to ensure that information on smoking status is included in the patient's record. Furthermore, that the information is stored in a structured format so that it can automatically be identified by CEHRT as smoking status for possible reporting or exchanging. We also note that the clinical quality measure only focuses on patients 18 years or older, while the objective focuses on patients 13 years or older. In addition, many quality measures related to smoking are coupled with follow-up actions by the provider such as counseling. We consider those follow-up actions to be beyond the scope of what we hope to achieve for this objective and would move the objective beyond the scope of practice for many providers. We disagree that the objective is not relevant to EPs seeing patient 13 years old or older. We note that this is intended to inform the provider. The frequency of when the information is updated, detail beyond the standard included in certification of EHR technology and many other factors discussed later are all left up to the provider to decide and fit to their scope of practice and their patient population.

Comment: We received conflicting suggestions in comments regarding the age limitation. These comments can be divided into those suggesting a lower age (as low as 8 to 12), those supporting 13 years old and those who believe it should be raised to 18 to match the clinical quality measures associated with smoking.

Response: It is apparent from the comments that the appropriate age for smoking status is an elusive target highly dependent on the situation. For example, it was suggested in comments that the age be lowered for patients meeting certain characteristics such as parents who smoke or other risk factors, while remaining at 13 for other patients. In our review of the public comments, we do not believe a consensus has been reached on a different age limitation than our Stage 1 age limitation of 13 years old and therefore finalize the age limitation as proposed. As with other meaningful use objectives and measures, this represents a minimum requirement. We encourage each and every provider to evaluate whether their scope of practice and/or patient population calls for collecting smoking status on patients younger than 13 or more detailed information than required by this objective.

Comment: There continues to be strong support for expanding smoking to other forms of tobacco use. Commenters note that other types of tobacco use are supported by the clinical quality measure ''NQF 28: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention''.

Response: We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register** for discussions on the adoption of a standard that would support other types of tobacco use. As ONC did not adopt a standard supporting other forms of tobacco use, we do not expand the objective.

Comment: Some commenters expressed strong support for the inclusion of second-hand smoke either as part of this objective or as a separate objective.

Response: We agree with the importance of collecting second-hand smoke information for many EPs and hospitals. However, as with other forms of tobacco use, there is not a standard on which to base the requirement of

collection of this information as structured data.

After consideration of the public comments received, we are finalizing this objective as proposed for EPs as § 495.6(j)(5)(i) and for eligible hospitals and CAHs at § 495.6(l)(4)(i).

Proposed Measure: More than 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data.

In our proposed rule, based on Stage 1 data showing performance on this measure far exceeded the measure threshold of more than 50 percent, we proposed a threshold of more than 80 percent for this measure for Stage 2 of meaningful use.

Comment: We received comments asking for clarification on what must be recorded in the EHR and how often for the numerator to be met.

Response: Information on smoking status must be present as structured data using the standard specified at 45 CFR 170.314(a)(11). There is no requirement that the smoking status be entered into the record by a specific person or category of persons, there is no requirement that smoking status be entered into the CEHRT already in the terminology of the standard and there is no requirement on how frequently this information be updated. A patient indicating how many packs he smokes a day on a new patient questionnaire which is then entered by an administrative person and mapped in the CEHRT to one of the responses in the standard is valid for this measure. A physician could also ask a patient detailed questions to determine if the patient is a current smoker, input the information into the CEHRT, and select one of the responses of the standard. ONC has provided a mapping of SNOMED CT® ID to the descriptions at 45 CFR 170.314(a)(11).

Comment: We received a few comments on the threshold. Most were supportive, while others believe it should remain at 50 percent.

Response: Due to our analysis of performance on this measure from Stage 1 and the support received from commenters, we are finalizing the threshold as proposed.

After consideration of public comments, we are finalizing this measure as proposed for EPs at § 495.6(j)(5)(ii) and for eligible hospitals and CAHs at § 495.6(l)(4)(ii).

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 CEHRT at 45 CFR 170.314(a)(11).

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients age 13 or older seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.
- *Numerator:* The number of patients in the denominator with smoking status recorded as structured data.
- *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 that neither sees nor admits any patients 13 years old or older.

CQM Reporting as a Stage 2 Objective—We proposed to add CQM reporting to the definition of ''meaningful EHR user'' under § 495.4 instead of including it as a separate objective under § 495.6. Accordingly, we did not propose a CQM reporting objective for EPs and hospitals as part of the Stage 2 criteria under § 495.6.

Comment: While some commenters indicated that this change would be confusing, most commenters supported this change.

Response: We appreciate the support of commenters and believe including CQM reporting in the definition of ''meaningful EHR user'' under § 495.4 will actually alleviate confusion. Therefore, we are not finalizing an objective related to the reporting of CQMs in the Stage 2 criteria for meaningful use under § 495.6. Although CQM reporting is not listed as a separate objective and measure under § 495.6, it remains a condition for demonstrating meaningful use.

Consolidated Objective: Implement drug-drug and drug-allergy interaction checks.

For Stage 2, we proposed to make the objective for ''Implement drug-drug and drug-allergy checks'' one of the measures of the core objective for ''Use clinical decision support to improve performance on high-priority health conditions.'' 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 clinical decision support that focuses on patient health and safety, we proposed to include this functionality as part of the objective for using clinical decision support.

We discuss comments regarding this consolidation in the discussion of the clinical decision support objective.

Proposed Objective: Use clinical decision support to improve performance on high-priority health conditions.

We proposed to modify the clinical decision support (CDS) objective for Stage 2 such that CDS would be used to improve performance on high-priority health conditions. We stated it would be left to the provider's clinical discretion to select the most appropriate CDS interventions for their patient population. We also proposed that the CDS interventions selected must be related to five or more of the clinical quality measures (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 will result in improved patient outcomes.

Comment: A few commenters voiced concern regarding the maturity of the development of clinical decision support systems. Others voiced a misconception that not all CEHRT includes pre-built CDS interventions where both capabilities and content are vendor supplied. The commenter went on to clarify that the CDS interventions must be specific to each provider's requirements. Still others commented on the CMS change in terminology from CDS ''rules'' to CDS ''interventions'' increases the range of available interventions.

Response: We recognize commenters' concerns regarding the maturity of CDS systems. Closely linked to the development of EHRs, there are multiple factors impacting the evolution of CDS systems including; the increasing availability and sophistication of information technology in clinical settings, the increasing pace of publication of new evidence-based guidelines for clinical practice and the continual evaluation and improvements of CDS.[2] We clarify that all CEHRT includes CDS interventions. The companion ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register** includes further information regarding the criteria necessary to implement CDS in CEHRT

[2] Study Protocol for the Effects of computerized clinical decision support systems on practitioner performance and patient outcome: Methods of a decision-maker-researcher partnership systematic review. R Brian Haynes*, Nancy L Wilczynski and the Computerized Clinical Decision Support System (CCDSS) Systematic Review Team. IMPLEMENTATION SCIENCE 2010, 5:12.

for Stage 2 of meaningful use. With each incremental phase of meaningful use, CDS systems progress in their level of sophistication and ability to support patient care. For Stage 2 of meaningful use, it is our expectation that at a minimum, providers will select clinical decision support 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, we will consider a broad range of CDS interventions that improve both clinical performance and the efficient use of healthcare resources in measuring providers' ability to demonstrate the meaningful use of CEHRT for Stage 2.

After consideration of the public comments received, we are finalizing this objective as proposed for EPs at § 495.6(j)(6)(i) and for eligible hospitals and CAHs at § 495.6(l)(5)(i).

Proposed Measure: We proposed two measures for EPs, eligible hospitals and CAHs for this objective. Both of the measures must be met in order for the provider to satisfy this objective:

1. Implement five clinical decision support interventions related to five or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period; and

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.

We proposed to make the Stage 1 objective for ''implement drug-drug and drug-allergy interaction checks'' one of the measures of the CDS objective for Stage 2. Based on the HIT Policy Committee's recommendation, we proposed that each CDS intervention must enable providers to review all of the following attributes for the intervention: developer of the intervention, bibliographic citation, funding source of the intervention, and the release or revision date of each intervention. The ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register** provides additional information regarding the incorporation of the CDS in CEHRT. We proposed that providers must implement the CDS intervention at a relevant point in patient care when the intervention can influence clinical decisionmaking before an action is taken on behalf of the patient. We proposed that providers must implement five CDS interventions that they believe will result in improvement in performance for five or more of the clinical quality measures on which they report. If none of the clinical quality measures is applicable to an EP's scope of practice, the EP should implement a CDS intervention that he or she believes will be effective in improving the quality, safety, or efficiency of patient care.

Comment: Many commenters noted that at least one of the CDS interventions implemented should be tied to efficiency goals (for example, reducing the overuse of high-cost procedures).

Response: While we believe that it is entirely possible for a CDS intervention to improve both the quality of care and improve healthcare efficiency, we agree with the suggestion that at least one intervention could be tied directly to improving the efficient use of healthcare resources. In considering whether a CDS intervention increases healthcare efficiency, providers can consider improvements in any healthcare process. Some examples, of CDS interventions that may lead to improvements in healthcare efficiency include, alerts when duplicate tests, procedures or treatments are ordered for the same patient, using clinical guidelines for direct patient care processes, documentation templates to reduce variability in recording and alerting when outside of specified parameters, and using evidence based pre-specified order sets for blood products. Therefore, we are modifying the proposed CDS measure such that four of the CDS interventions are related to four or more CQMs, and the fifth CDS intervention should be related to improving healthcare efficiency. We clarify that any of the five CDS interventions may be related to both CQMs and improving healthcare efficiency.

Comment: Various comments were received in response to the proposed number of CDS interventions that are related to five or more CQMs. One commenter noted the potential for improved provider reporting and user efficiencies due to the inherent measure associations. Several commenters welcomed this improved alignment of CQM measures and reporting between the EHR Incentive Program and other CMS quality programs. Other commenters expressed the difficult burden for specialists and others who may not be able to identify sufficient CQMs related to their patient population. Still other comments suggested that providers could easily implement double the number of proposed CDS interventions.

Response: Overall comments were supportive of the proposed number of CDS interventions and of aligning these interventions with CQM reporting. If none of the clinical quality measures are applicable to an EP's scope of practice, the EP should implement a clinical decision support intervention that he or she believes will be effective in improving the quality, safety or efficiency of patient care. We believe that the proposed clinical quality measures for eligible hospitals and CAHs would provide ample opportunity for implementing clinical decision support interventions related to high-priority health conditions.

Comment: Commenters also supported continuing the requirement for providers to enable and implement drug-drug and drug-allergy interaction checks for the entire reporting period under the new CDS measure. An AHA Survey indicated that 73 percent of hospitals could perform the drug/drug and drug/allergy check, as well as at least one additional clinical decision support function in the Fall of 2011.

Response: We appreciate the commenters' overall support for consolidating this Stage 1 objective into one of the required clinical decision support measures. We also agree that drug-drug and drug-allergy interaction checks are important CDS tools contributing to improvements in patient safety and the overall quality of patient care.

Comment: Additional comments addressed concerns regarding the point at which professionals will be able to exercise clinical judgment about the CDS intervention before action is taken on behalf of the patient. The specific concern is that some interventions are only triggered when an action is about to be taken, and proposed that CMS revise this criterion to ''before or at the time an action is taken.''

Response: We 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.'' We clarify that the CDS implementation criterion which allow for CDS implementation at a relevant point in patient care includes interventions that may occur before or at the time an action is taken in the care delivery process.

Comment: Several commenters expressed concern with ''alert fatigue'' associated with increased use of clinical decision support interventions. These commenters cited studies that suggest

that multiple alerts may be disabled or ignored resulting in adverse effects in the quality of care and patient safety.

Response: We recognize that ''alert fatigue'' is a potential occurrence with the increased use of some types of clinical decision support interventions. However, meaningful use seeks to leverage the capabilities of CEHRT to improve patient care. The selection of CDS interventions should weigh both the potential for unintended consequences including alert fatigue against the benefits of each CDS intervention, and the appropriate selection of an intervention type that interferes minimally with the provider's clinical workflow and cognitive burden. We believe such determinations are best left to providers. CDS is included as a meaningful use objective because we believe that the overall benefit of CDS is to improve patient safety and the quality of care. Therefore, we will continue to require the implementation of clinical decision support interventions in order to achieve meaningful use. Finally, as defined in the ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register**, CDS is ''not simply an alert, notification, or explicit care suggestion.'' While some alerts may be helpful and necessary, we encourage EPs and hospitals to consider the selection of CDS interventions that are not alerts in order to reduce the burden of alert fatigue. Examples of non-alert CDS may include patient or disease specific order sets, referential decision support (presentation or availability of clinical reference information such as diagnostic guidance, dosing guidelines, or lab value interpretation assistance, or patient or disease specific documentation forms/templates that remind the provider to capture essential historical or physical exam findings for a patient with a certain condition). A common example of a CDS form/template would be a documentation form that is presented for patients with diabetes that includes a required section for the diabetic foot exam, where the same form would be presented for patients without diabetes and with the diabetic foot exam section removed.

Comment: Several commenters requested the flexibility to be able to change CDS interventions at any point during the reporting period so that in effect they would not be implementing the CDS intervention during the entire reporting period. Commenters cited provider uncertainty at the beginning of a reporting period of which CQMs they will ultimately report during the attestation process (for example, due to low counts for the measures). Many commenters requested the additional flexibility for providers to be permitted to implement CDS interventions relevant to any of the finalized panel of clinical quality measures specific to the provider type, even if the provider ultimately chooses different clinical quality measures to report. Commenters requested the opportunity to change CDS interventions during the reporting period and not be penalized for the CDS measure that requires the intervention during the entire reporting period. Commenters also wanted clarification whether they have to align CDS interventions with the same CQM measures reported for meaningful use.

Response: We expect providers to align CDS interventions with CQMs to the extent possible, although we recognize that providers may not know at the beginning of a reporting period which CQMs they will end up selecting to report. Based on the comments, we clarify that EPs and hospitals may implement CDS interventions that are related (as defined in the proposed rule) to any of the clinical quality measures for EPs and hospitals, respectively, and that are finalized for the EHR Incentive Program for the relevant year of reporting. In other words, providers are not required to implement CDS interventions that are related to the specific CQMs that they choose to report for that year. 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. We will require providers to implement a minimum of five CDS interventions for the entire EHR reporting period. The provider may switch between CDS interventions or modify them during the EHR reporting period as long as a minimum of five are implemented for the entire EHR reporting period. We expect that providers may choose to implement a greater number of interventions from which they can select five interventions that have been enabled for the entire EHR reporting period when they attest to meaningful use.

Comment: Several providers recommend to be allowed to use their clinical judgment regarding which clinical decision support interventions would best benefit patients within the scope of their practice.

Response: We thank providers for this comment and want to clarify that in Stage 1; CMS allowed providers significant leeway in determining the clinical support interventions most relevant to their scope of practice. In Stage 2, we will continue to provide the flexibility for providers to identify high-priority health conditions that are most appropriate for CDS. As we stated in the proposed rule, for Stage 2 we will not require the provider to demonstrate actual improvements in performance on clinical quality measures for this objective. Because CQMs focus on high-priority health conditions by definition, to the extent possible, four of the five CDS interventions that are implemented must be related to CQMs. Providers are also reminded that the CDS interventions selected for Stage 2 represent only a floor. 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.

Comment: Several commenters voiced concern that CDS interventions must be predetermined at the beginning of an EHR reporting period but providers do not have to choose CQMs until the end of the attestation reporting period. There is concern that providers will be unable to change the CDS interventions if they decide to change the related CQMs in a reporting period.

Response: We proposed alignment with CQMs to facilitate provider reporting and measurement, but as we clarified earlier, 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. 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 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: Commenters supported the inclusion of drug-drug and drug-allergy checks noting that they are critical to ensuring the safety of the medications prescribed for patients, and agree with the inclusion of this measure. Other commenters noted the lack of an for EPs

who do not prescribe medications and thus would not be able to meet this core set objective.

Response: We received similar feedback after publication of the Stage 1 final rule and after careful consideration of the comments, we will allow an exclusion to this measure for EPs that write fewer than 100 medication orders during the EHR reporting period. We did not include this exclusion as a change to Stage 1 as this is primarily an implementation of a function of CEHRT and there is no requirement to update CEHRT in 2013. This exclusion aligns with the exclusion under the objective CPOE for medication orders discussed earlier in this rule.

Comment: There were several comments regarding the implementation of CDS and the attributes required for each intervention. Commenters did not believe that the information requested in order to support the inclusion of CDS attributes would be available to many providers, particularly for providers in a group practice. Commenters also requested clarification whether these attributes would be required for drug-drug and drug-allergy interactions. Other commenters requested additional clarification regarding the extent that CDS attributes are required when the interventions result from self-generated evidence. Other comments addressed provider concerns regarding the need to purchase additional expensive vendor products and upgrades to incorporate these requirements.

Response: We appreciate the many comments for the proposed CDS attributes. We clarify that the need for inclusion of attributes for each CDS intervention also applies to drug-drug and drug-allergy interventions as well as interventions based on self-generated evidence. The companion ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register** further describes CEHRT requirements for these CDS attributes in order to ensure that all users of CEHRT will have access to this new functionality. After consideration of the public comments and for the reasons discussed earlier, we are modifying the measures for EPs at § 495.6(j)(6)(ii) and for eligible hospitals and CAHs at § 495.6(l)(5)(ii) as follows:

- 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 . It is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency.
- 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 further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(8) and (a)(2).

Replaced Objective: Provide patients with an electronic copy of their health information.

Replaced Objective: Provide patients with an electronic copy of their discharge instructions.

For Stage 2, we did not propose the Stage 1 meaningful use objectives for EPs and hospitals to provide patients with an electronic copy of their health information and discharge instructions upon request. As we stated in the proposed rule, the HIT Policy Committee recommended that these objectives be combined with the objectives for view online, download, and transmit. We agreed with the HIT Policy Committee and proposed to replace the Stage 1 objectives above with objectives and measures for Stage 2 that would enable patients to view online and download their health information and hospital admission information. We stated that continued online access to such information is more useful and provides greater accessibility over time and in different health care environments than a single electronic transmission or a one-time provision of an electronic copy, especially when that access is coupled with the ability to download a comprehensive point in time record.

We received no comments that supported the retention of these objectives for Stage 2. Therefore, we are finalizing the replacement of these objectives for EPs, eligible hospitals, and CAHs as proposed. Please refer to the discussions later in this rule regarding view online, download, and transmit objectives for both EPs and eligible hospitals and CAHs for more information about the Stage 2 objectives that replace these Stage 1 objectives.

Proposed EP Objective: Provide clinical summaries for patients for each office visit.

In the proposed rule, we outlined the following benefits of providing clinical summaries for patients for each office visit: A summary of an office visit provides patients and their families with a record of the visit. This record can prove to be a vital reference for the patient and their caregivers about their health and actions they should be taking to improve their health. Without this reference, the patient must either recall each detail of the visit, potentially missing vital information, or contact the provider after the visit. Certified EHR technology enables the provider to create a summary easily and in many cases instantly. This capability removes nearly all of the barriers that exist when using paper records.

As noted in the proposed rule, clinical summaries for each office visit are important because without this reference the patient must either recall each detail of the visit, potentially missing vital information, or contact the provider after the visit. We also noted that this is a meaningful use requirement, which does not override an individual's broader 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. However, none of the HIPAA access requirements preclude an EP from releasing electronic copies of clinical summaries to their patients as required by this meaningful use provision. For Stage 2, we proposed this as a core objective for EPs.

Comment: Some commenters believed that this objective should be eliminated because the same information would be made available through the objective to ''Provide patients the ability to view online, download, and transmit their health information.'' Other commenters suggested combining these objectives with a concomitant rise in the measure threshold.

Response: While it is true that there may be overlap between the information in the clinical summary and the information made available through the objective to ''Provide patients the ability to view online, download, and transmit their health information,'' we believe the clinical summary after an office visit serves a different purpose than online access to health information. A summary of an office visit provides patients and their families with a record of the visit and specific lab tests or specific follow-up actions and treatment related to the visit. While this information is certainly part of the patient's overall electronic health record, the clinical summary serves to highlight information that is relevant to the patient's care at that particular

moment. Therefore, we decline to eliminate or combine the objective.

After consideration of the public comments, we are finalizing the meaningful use objective for EPs at § 495.6(j)(11)(i) as proposed.

Proposed EP Measure: Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.

In the proposed rule, we proposed to maintain several policies regarding this objective from Stage 1. As we stated, for purposes of meaningful use, an EP could withhold information from the clinical summary if they believe substantial harm may arise from its disclosure through an after-visit clinical summary. An EP could also choose whether to offer the summary electronically or on paper by default, but at the patient's request must make the other form available. The EP could select any modality (for example, online, CD, USB) as their electronic option and would not have to accommodate requests for different modalities. We also stated in the proposed rule that we do not believe it would be appropriate for an EP to charge the patient a fee for providing the summary. Finally, we stated that when a single consolidated summary is provided for an office visit that lasts for several consecutive days, or for an office visit where a patient is seen by multiple EPs, that office visit must be counted only once in both the numerator and denominator of the measure. We are finalizing all of these policies for Stage 2 as proposed.

Comment: Many commenters suggested that the measure should be changed from ''24 hours'' to ''1 business day.'' Other commenters believed that this timeframe was too short, especially for specialty providers who might not come into the office every day, and suggested either changing the timeframe to 48 hours or reverting to the 72-hour measure of Stage 1. Another commenter noted that delays past 24 hours can sometimes occur outside of the provider's control—for example, in the case of new patients where the provider might not have access to adequate previous records.

Response: We believe that Certified EHR technology enables the provider to create a summary with the required information easily and in most cases instantly. The feedback we have received on this objective in Stage 1 through discussions with providers indicates that most providers make this clinical summary available as patients leave the office visit, and we expect this workflow to continue for most providers. Therefore a longer timeframe of 48 or 72 hours should not be necessary for providing clinical summaries. We also note that the clinical summary contains information relevant to the patient's office visit and therefore the EP should not need to include information from previous records for most patients. However, we believe the threshold of more than 50 percent of office visits allows EPs to meet the measure of this objective despite these challenges for a small number of patients. We also agree that the measure should be changed from ''24 hours'' to ''1 business day'' since all providers may not have staff available to issue clinical summaries prior to the close of a work week or the beginning of a Federal holiday. Therefore, we are finalizing the change from ''24 hours'' to ''1 business day.''

Comment: A number of commenters raised questions regarding the provision of the clinical summary. They asked whether the summary should be given automatically to each patient or whether offering the summary at the end of an office visit was sufficient to meet the measure. Commenters also asked whether patients who refused a copy of the clinical summary should be counted in the numerator of the measure.

Response: It is the intention of this objective that clinical summaries be automatically given to patients within 1 business day of an office visit. However, we do recognize that some patients may decline a physical copy of their clinical summary. In the event that a clinical summary is offered to and subsequently declined by the patient, that patient may still be included in the numerator of the measure. We note that the clinical summary must be offered to the patient; a passive indication of the clinical summary's availability (for example, a sign at the reception desk, a note in form, etc.) would not serve as offering the clinical summary and those patients could not be counted in the numerator of the measure. However, the clinical summary does not necessarily need to be printed before being offered to the patient.

Comment: Commenters asked whether making clinical summaries available on a patient portal or as part of the objective to ''Provide patients the ability to view online, download, and transmit their health information'' would meet the measure of this objective. Some commenters suggested that patients should be permitted to demand an electronic copy of clinical summaries where an EP has chosen to provide them in hard copy form.

Response: We are continuing our policy from Stage 1 that the clinical summary can be provided through a patient portal or through other electronic means to satisfy this measure. A clinical summary provided through the same means that the provider makes other patient information available to meet the objective to ''Provide patients the ability to view online, download, and transmit their health information'' would also meet the measure of this objective. As stated previously, an EP can choose whether to offer the summary electronically or on paper by default, but at the patient's request must make the other form available. The EP could select any modality (for example, online, CD, USB) as their electronic option and would not have to accommodate requests for different electronic modalities.

Comment: Some commenters suggested that this measure should be based on the number of unique patients seen by the EP instead of office visits. Other commenters suggested that the threshold for the measure should be reduced.

Response: We do not agree that the measure should be based on unique patients. The purpose of the clinical summary is to provide patients and their authorized representatives with a record of an office visit and specific lab tests or specific follow-up actions and treatment related to that visit. Nor do we agree that the percentage threshold of this measure should be reduced. We note that the threshold for this measure in Stage 1 was also 50 percent; any reduction would constitute a step backward for the meaningful use of this capability.

Comment: Some commenters suggested that EPs should be permitted to charge a fee for provision of a clinical summary.

Response: Because the clinical summary is meant to summarize the office visit and any lab tests, follow-up actions, or treatments related to that visit, we do not believe it is appropriate for an EP to charge patients additional fees for its provision. Also, because this is a meaningful use requirement for the incentivized provider and not a response to a patient request, we do not believe it is appropriate for an incentivized provider to charge the patient. This is consistent with our position for this objective in Stage 1 (75 FR 44358).

Comment: Commenters suggested that clinical summaries provided to patient-authorized representatives should also be counted for this measure.

Response: We agree that the provision of a clinical summary to a patient-authorized representative should also be counted, and we have amended the measure accordingly.

Comment: Many commenters believed that the list of required elements to be included in the clinical summary was excessive and not useful to the patient. Commenters suggested that the list be shortened or left to the provider's discretion. Additionally, many commenters asked for clarification on whether certain fields could be left blank and still permit the EP to meet the measure of this objective. Finally, a number of commenters suggested that this objective should focus on whether the summary is provided and not on required information since CEHRT cannot distinguish between information not provided in a clinical summary because it is not relevant or because a provider has exercised discretion to withhold it.

Response: This measure is focused on the provision of the clinical summary. The clinical summary represents a patient's current care and health as a snapshot in time. When provided, we believe it can significantly improve a patient's overall awareness of the care they are receiving as well as any conditions they may need to manage between office visits. The required information listed at the end of this section are provided as a way to standardize and prioritize for the purposes of EHR technology certification the minimum amount of information that must be available to EPs to select. Further, we believe that the information in this minimum list is the most applicable and beneficial to improving patient care. This is a list of information, not a particular structure or format for the summary handed to the patient.

We have no requirements on the design of the summary just the information that must be present if it is in the CEHRT. The design of the summary should reflect the context of the visit. For example, the information of future appointments, referrals to other providers, future scheduled tests, and clinical instructions could all appear in a section of the summary called ''Next steps''. If all of these information areas were empty then ''next steps'' could just be none and all the feeding information elements would be covered. Alternatively, if the summary is provided on letterhead that includes the office location and the provider's name that information does not have to be repeated in the text of the summary. We cannot emphasize enough that this is required information for the summary not a particular required structure for the summary. We do not believe that the list of required information imposes an undue burden on providers because CEHRT will be able to automatically generate the clinical summary with at least all of the required information. In ONC's rule it has included in the certification criterion that correlates to this objective the capability for end-users to customize (for example, edit) the clinical summary to make it more relevant to the patient encounter.

In circumstances where there is no information available to populate one or more of the fields previously listed, either because the EP can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, no medication allergies or laboratory tests), an indication that the information is not available in the clinical summary would meet the measure of this objective. The feedback we have received on this objective in Stage 1 through discussions with providers indicates that the absence of information in the clinical summary sometimes offers an opportunity for reconciliation of misinformation; for example, if ''no medication allergies'' is listed but the patient has one, he or she may communicate that to the provider, thus improving the quality of the data in the EHR. We do note that the measure of this objective already focuses on provision of the clinical summary and is not specific to the information which is provided within the clinical summary; the list of required elements is meant to standardize the information given to patients, not to create an additional measure for the objective.

We also refer providers to our discussion of what constitutes an office visit. Many of the concerns we have heard regarding this summary are the result of misunderstandings about what constitutes an office visit. For example, in some cases removing sutures or giving allergy shots do not represent an office visit if that is the only service provided.

Comment: Commenters asked for clarification on ''current problem list and any updates,'' ''current medication list and any updates,'' and ''current medication allergy list and any updates,'' since updates would be included in any current problem list. They suggested simplifying these requirements to ''current problem list;'' ''current medication list;'' and ''current medication allergy list''.

Response: We agree that including the language ''and any updates'' is redundant since a current problem, medication, or medication allergy list would already include updated information. We are amending this language in the list of required elements below. However, the clinical summary should include both a current problem list and any diagnosis specifically related to the office visit as separate fields. The diagnosis related to the office visit should be expressed in the ''Reason for the patient's visit'' field, though it may also be included in the current problem list. We note that this is consistent documentation available in the Consolidated Clinical Document Architecture (CDA), which defines the ''Reason for the patient's visit'' field as the provider's description of the reason for visit and the ''Chief complaint field'' as the patient's own description.

Comment: Commenters asked for clarification on ''vital signs and any updates'' and suggested simplifying this requirement to ''Vitals taken during visit''.

Response: While we agree that vital signs taken during the visit would be most useful in the clinical summary, we also recognize that all vital signs may not be updated at each office visit. Therefore, we are amending this language to ''Vital signs taken during the visit (or other recent vital signs)'' in the list of required elements below.

Comment: Commenters asked us to clarify if the requirement relating to the inclusion of laboratory test results applies only to test results available at the time of the office visit or to test results that become available after the clinical summary is issued.

Response: By laboratory test results, we mean for the clinical summary to include results that are available at the time the clinical summary is issued to the patient. As we stated in the proposed rule, clinical summaries can quickly become out of date due to information not available to the EP at the end of the visit. The most common example of this is laboratory test results. We believe that EPs should make this information known to the patient when the results are available, but do not require that a new clinical summary must be issued when information needs to be updated.

Comment: Commenters asked us to clarify if the list of diagnostic tests pending indicates diagnostic tests that have been scheduled or diagnostic tests for which results are not yet available.

Response: Diagnostic tests pending refers to diagnostic tests that have been performed but for which results are not yet available. Laboratory or diagnostic tests that have been scheduled but not yet performed should be recorded under ''Future scheduled tests'' in the list of required elements later in this section.

Comment: Some commenters asked us to define clinical instructions. Other commenters asked if the instructions included as part of the care plan were

redundant with the ''clinical instructions'' element in the list of required information.

Response: By clinical instructions we mean care instructions for the patient that are specific to the office visit. Although we recognize that these clinical instructions at times may be identical to the instructions included as part of the care plan, we also believe that care plans may include additional instructions that are meant to address long-term or chronic care issues, whereas clinical instructions specific to the office visit may be related to acute patient care issues. Therefore, we maintain these as separate items in the list of required elements later.

Comment: A commenter noted that future appointments and future scheduled tests might be stored in a scheduling system that is separate from CEHRT and suggested that if the information is not available in CEHRT that the EP be excluded from having to provide it as part of the clinical summary.

Response: As noted previously, in circumstances where there is no information available to populate one or more of the fields previously listed, either because the EP can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, no medication allergies or laboratory tests), an indication that the information is not available in the clinical summary would meet the measure of this objective. This would also be true if the information is not accessible through CEHRT.

Comment: Commenters asked for clarification regarding demographics ''maintained by EP.'' Specifically, they asked whether the EP was required to enter demographics or whether these could be maintained by a member of his or her staff.

Response: By demographics we mean the demographics maintained within CEHRT. We do not intend to specify that only the EP can enter such information into the EHR; demographic information can be entered into CEHRT by any person or through any electronic interface with another system. Therefore, we are amending the language to ''Demographic information maintained within CEHRT'' in our list of required elements later in this section.

Comment: In regard to the inclusion of ''care plan field'' in the list of required information, some commenters believed that the wording was overly prescriptive since CEHRT could utilize multiple fields to structure care plans. Other commenters requested a more detailed definition of care plan.

Response: We agree that the language proposed could be viewed as prescriptive, and we do not intend to limit the inclusion of the care plan to a single field. Therefore, we are amending the language to ''Care plan field(s), including goals and instructions'' in our list of required elements below. However, we decline to provide an alternate definition that would limit the information in the care plan. We believe that the definition we proposed in the proposed rule is sufficient to allow for the inclusion of a variety of care plans in the clinical summary. For purposes of the clinical summary, we define a care plan as the structure used to define the management actions for the various conditions, problems, or issues. A care plan must include at a minimum the following components: problem (the focus of the care plan), goal (the target outcome) and any instructions that the provider has given to the patient. A goal is a defined target or measure to be achieved in the process of patient care (an expected outcome).

Comment: Some commenters asked for clarification about what is meant by patient decision aids.

Response: By patient decision aids we mean any educational resource or tool that the provider believes can inform patient decisions about their own care. An example is an educational handout on the pros and cons of having surgery for a particular condition.

Comment: Some commenters noted that because EHRs capture medical data, they will produce clinical summaries with medical terminology, whereas patients should receive summaries with nonmedical terminology and descriptions of both medications and lab test results that are easy to read and contain actionable items.

Response: While we agree that clinical summaries with nonmedical terminology and extended descriptions would be most beneficial to patients, we also believe that the utility of this objective must be balanced against the potential burden it places on EPs. Since clinical summaries can be automatically generated from existing data in CEHRT, this removes significant workflow barriers to providing a summary for patients. We believe that requiring providers or their staff to render all information in the clinical summary into nonmedical terms at this time would impose a significant burden on providers and reduce the number of clinical summaries that providers make available to patients, thereby reducing the effectiveness of this objective. However, we note that most of the information that is required as part of the clinical summary should be easily understandable by most patients. Also, there is nothing to prevent an EP from providing additional information if he or she believes it would be more effective for the overall quality of patient care. We further note that we anticipate that the capabilities of CEHRT may soon allow for the provision of non-medical terminology and extended descriptions and we are considering adding this requirement in future stages of meaningful use.

Comment: One commenter noted that the clinical summary contains a vast amount of protected health information (PHI) which could be compromised if patients discard the clinical summary insecurely. The commenter suggested requiring the clinical summary only for those patients who affirm they want it to eliminate any provider responsibility for security of the information.

Response: We do not believe that making protected health information available to patients in any way compromises either patients or providers. On the contrary, we believe that offering this information is critical to improving the overall quality of patient care by offering specific follow-up instructions, test results, and care plan information to patients so that they can actively participate in their own care. We believe that providers can take steps to inform patients about the need to securely dispose of PHI, and we further note that making clinical summaries available electronically through an online portal or other means can be used to keep such PHI secure. Therefore, we decline to change the measure for this objective.

After consideration of the public comments, we are finalizing the meaningful use measure for EPs as ''Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits'' at § 495.6(j)(11)(ii).

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(e)(2).

We clarify that the following information (or an indication that there is no information available) is required to be part of the clinical summary for Stage 2:

- Patient name.
- Provider's name and office contact information.
- Date and location of the visit.
- Reason for the office visit.
- Current problem list.
- Current medication list.
- Current medication allergy list.

- Procedures performed during the visit.
- Immunizations or medications administered during the visit.
- Vital signs taken during the visit (or other recent vital signs).
- Laboratory test results.
- List of diagnostic tests pending.
- Clinical instructions.
- Future appointments.
- Referrals to other providers.
- Future scheduled tests.
- Demographic information maintained within CEHRT (sex, race, ethnicity, date of birth, preferred language).
- Smoking status
- Care plan field(s), including goals and instructions.
- Recommended patient decision aids (if applicable to the visit).

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of office visits conducted by the EP during the EHR reporting period.
- *Numerator:* Number of office visits in the denominator where the patient or a patient-authorized representative is provided a clinical summary of their visit within 1 business day.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP to meet this measure.
- *Exclusion:* Any EP who has no office visits during the EHR reporting period.

Removed Objective: Capability to exchange key clinical information.

In Stage 2, we proposed to move to actual use cases of electronic exchange of health information through the following 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 should provide summary care record for each transition of care or referral.'' We also proposed to remove this objective for Stage 1 as well, but requested comments on other options. Please refer to the section titled ''Changes to Stage 1'' at II.A.3.b. of this final rule for details of the options considered. We are finalizing the removal of this objective as proposed in favor of the more robust, actual use case of electronic exchange through a summary of care record following each transition of care or referral. We believe that this actual use case is not only easier for providers to understand but it is also more beneficial because it contributes directly to the care of the patient through enhanced coordination between providers. A prudent provider will be preparing and testing to conduct actual exchange prior to the start of Stage 2 during their Stage 1 EHR reporting periods.

Proposed Objective: Protect electronic health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.

In the proposed rule, we outlined the following benefits of protecting health information: Protecting electronic health information is essential to all other aspects of meaningful use. Unintended and/or unlawful disclosures of personal health information could diminish consumers' confidence in EHRs and electronic health information exchange. Ensuring that health information is adequately protected and secured will assist in addressing the unique risks and challenges that may be presented by electronic health records.

Comment: A number of commenters supported the continued inclusion of this objective, yet several commenters requested the elimination of this objective as redundant to HIPAA regulations.

Response: We believe that it is crucial that EPs, eligible hospitals, and CAHs evaluate the privacy and security implications of CEHRT as part of the EHR Incentive Programs, particularly as they pertain to 45 CFR 164.308(a)(1) and the protection and safeguarding of personal health information in general. Therefore, we retain this objective and measure for meaningful use in the final rule.

After consideration of the public comments, we are finalizing the meaningful use objective for EPs at § 495.6(j)(16)(i) and eligible hospitals and CAHs at § 495.6(l)(15)(i) as proposed.

Proposed Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest 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.

In the proposed rule, we explained that this measure is the same as in Stage 1 except that we specifically address the encryption/security of data is that is stored in CEHRT (data at rest). Due to the number of breaches reported to HHS involving lost or stolen devices, the HIT Policy Committee recommended specifically highlighting the importance of an entity's reviewing its encryption practices as part of its risk analysis. We agree that this is an area of security that appears to need specific focus. Recent HHS analysis of reported breaches indicates that almost 40 percent of large breaches involve lost or stolen devices. Had these devices been encrypted, their data would have been secured. It is for these reasons that we specifically call out this element of the requirements under 45 CFR 164.308(a)(1) for the meaningful use measure. We did not propose to change the HIPAA Security Rule requirements, or require any more than is required under HIPAA. We only emphasize the importance of an EP or hospital including in its security risk analysis an assessment of the reasonable and appropriateness of encrypting electronic protected health information as a means of securing it, and where it is not reasonable and appropriate, the adoption of an equivalent alternative measure.

We proposed this measure because the implementation of CEHRT has privacy and security implications under 45 CFR 164.308(a)(1). 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.

In the proposed rule, we emphasized that our discussion of this measure and 45 CFR 164.308(a)(1) is only relevant for purposes of the meaningful use requirements and is not intended to supersede what is separately required under HIPAA and other rulemaking. Compliance with the HIPAA requirements is outside of the scope of this rulemaking. Compliance with 42 CFR Part 2 and state mental health privacy and confidentiality laws is also outside the scope of this rulemaking. EPs, eligible hospitals or CAH affected by 42 CFR Part 2 should consult with the Substance Abuse and Mental Health Services Administration (SAMHSA) or state authorities.

Comment: Some commenters asked if the Stage 2 requirements for this objective contradict earlier Stage 1 requirements and HIPAA regulations. Specifically, the addition of addressing encryption/security of data at rest to the measure was raised as a concern.

Response: We do not believe that the Stage 2 measure of this objective contradicts either the Stage 1 measure or current HIPAA regulations. As noted in the proposed rule, this measure is the same as in Stage 1 except that we specifically highlight the encryption/security of data that is stored in CEHRT (data at rest). Recent HHS analysis of reported breaches indicates that almost 40 percent of large breaches (breaches affecting 500 or more individuals) involve lost or stolen devices. Had these

devices been encrypted, their data would have been secured. It is for these reasons that we specifically call out this requirement under 45 CFR 164.308(a)(1). We did not propose to change the HIPAA Security Rule requirements, or require any more under this measure than is required under HIPAA. We only emphasize the importance of an EP or hospital including in its security risk analysis an assessment of the reasonable and appropriateness of encrypting electronic protected health information as a means of securing it, and where it is not reasonable and appropriate, the adoption of an equivalent alternative measure.

Comment: Several commenters asked for clarification of what constitutes an acceptable security risk analysis. Commenters also asked if the security risk analysis required in the measure should apply to health data stored in data centers with physical security.

Response: We did not propose to change the HIPAA Security Rule requirements or impose additional requirements under this measure than those required under HIPAA. 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. We refer providers to the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), of the HIPAA Security Rule for compliance. The HHS Office for Civil Rights (OCR) has issued guidance on conducting a security risk assessment pursuant to the HIPAA Security Rule (*http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf*). The scope of the security risk analysis for purposes of this meaningful use measure applies only to data created or maintained by CEHRT. This measure does not apply to data centers that are not part of CEHRT. However, we note that such data centers may be subject to the security requirements under 45 CFR 164.308(a)(1) and refer providers to the HIPAA Security Rule for compliance information.

Comment: One commenter asked if the measure of the objective required hospitals to report on data encryption methods.

Response: No, eligible hospitals and CAHs are not required to report to CMS or the states on specific data encryption methods used. However, they are required to address the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3).

Compliance with 42 CFR Part 2 and state mental health privacy and confidentiality laws is also outside the scope of this rulemaking. EPs, eligible hospitals or CAH affected by 42 CFR Part 2 should consult with the Substance Abuse and Mental Health Services Administration (SAMHSA) or state authorities.

We are making a change in this final rule to the language of ''data at rest'' to specify our intention of data that is stored in CEHRT. After consideration of the public comments, we are finalizing the meaningful use measure as ''Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security 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'' for EPs ''at § 495.6(j)(16)(ii) and eligible hospitals and CAHs at § 495.6(l)(15)(ii).

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 CEHRT at 45 CFR 170.314(d)(1) through 170.314(d)(8).

(b) Objectives and Measures Carried Over (Modified or Unmodified) from Stage 1 Menu Set to Stage 2 Core Set

We signaled our intent in the Stage 1 final rule to move the objectives from the Stage 1 menu set to the Stage 2 core set. The HIT Policy Committee also recommended that we move all of these objectives to the core set for Stage 2. We proposed to include in the Stage 2 core set all of the objectives and associated measures from the Stage 1 menu set, except for the objective ''capability to submit electronic syndromic surveillance data to public health agencies'' for EPs, which will remain in the menu set for Stage 2. As discussed later, we also proposed to modify and combine some of these objectives and associated measures for Stage 2—

Consolidated Objective: Implement drug formulary checks.

For Stage 2, we proposed to include this objective within the core objective for EPs ''Generate and transmit permissible prescriptions electronically (eRx)'' and the menu objective for eligible hospitals and CAHs of ''Generate and transmit permissible discharge prescriptions electronically (eRx).'' We believe that drug formulary checks are most useful when performed in combination with e-prescribing, where such checks can allow the EP or hospital to increase the efficiency of care and benefit the patient financially. We address the comments related to these proposals and state our final policy in the discussions of the eRx objectives for EPs and hospitals.

Proposed Objective: Incorporate clinical lab test results into CEHRT as structured data.

We propose to continue the policy from Stage 1 to incorporate clinical lab test results into CEHRT as structured data. We believe this measure contributes to the exchange of health information between providers of care, facilitates the sharing of information with patients and their designated representatives, and may reduce order entry errors which will contribute to patient care improvements.

We did not receive any comments for this objective. We are finalizing the meaningful use objective for EPs at § 495.6(j)(7)(i) and eligible hospitals and CAHs at § 495.6(l)(6)(i) as proposed.

Proposed Measure: More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in CEHRT as structured data.

We proposed to increase the measure threshold from more than 40 percent for Stage 1 to more than 55 percent for Stage 2. We also solicited public comment regarding the feasibility of continuing to account for individual lab tests separately from group and panel tests. In addition, we solicited comment on whether standards and other capabilities would allow for the expansion of this measure to include all quantitative lab results.

Comment: Many of the commenters voiced their concern that not all EHRs are capable of splitting out individual test results from panel tests and that it would not be feasible to require this for Stage 2 of meaningful use. Other commenters suggested modifying the current measure to use the number of laboratory test results in the EHR as the numerator and the total laboratory test results from the Lab Information System as the denominator. Others questioned the validity of the current measure that counts orders in the denominator and results in the numerator. Another comment is that not all providers have

access to a lab interface system and not all lab interfaces are compatible.

Response: We appreciate the many comments and suggestions submitted regarding this measure which were carefully considered as we developed the final regulation. Some commenters questioned the measure validity suggesting that the measure is imperfect since the numerator and denominator are incongruent. However, in considering the broader policy goal underlying this measure (to incorporate lab results into CEHRT in a standard format) the measure needs to be broad enough to allow providers to incorporate laboratory orders and results from multiple service providers. By incorporating all lab orders (whether panel or individual) in the denominator, and all lab test results in the numerator, providers will be able to capture structured lab data from a broad range of provider laboratory information systems into the CEHRT. We understand that the most likely scenario is that the denominator of total lab orders (if panel orders are counted as one) will be less than the numerator of laboratory results because results are provided for each individual test rather than by panel. Therefore, it is highly unlikely that the measure would impact a provider's ability to meet the increased threshold in this scenario.

Providers will need to continue to report individual lab test results recorded as structured data in the numerator, and in the denominator report all individual lab-tests ordered whether or not they are ordered individually or as part of a panel or group lab order. For example, one panel order of ten individual lab tests could be counted as 1 or 10 lab tests ordered in the denominator depending on the system that is used to incorporate this data into the CEHRT. We will monitor provider experience with this measure as technological capacity for the reporting and exchange of lab data continues to evolve.

Comment: Other commenters mentioned uncertainty regarding the proper vocabulary to use for the incorporation of lab test results in a structured format. Several commenters went on to mention that there is not one current vocabulary that encompasses all types of tests. Another comment proposed that CMS work to amend the clinical laboratory improvement amendments (CLIA) to require hospital labs to report results in standard vocabulary such as the Logical Observation Identifiers Names and Codes System (LOINC) by the time Stage 2 is implemented in 2014.

Response: We refer readers to the ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register** for vocabulary specifications.

Comment: Many commenters were confused by the clarification CMS provided in the proposed rule for expanding the measure to all quantitative results (all results that can be compared on as a ratio or on a difference scale). Comments were mixed on whether this measure should include all types of lab tests that produce quantitative results. One commenter suggested CMS should allow ordinal responses for the measure since that is what LOINC uses as the response rather than counting test results with either a positive, negative or numeric response since operationally, counting tests based on whether or not they have two allowed answer choices is difficult, where counting tests based on whether the LOINC code for them had a Scale of QN or Ord would be quite simple. Another commenter suggested most people would assume that ''numeric/quantitative tests'' would include decimals and whole numbers as well as results reported in a range (for example, >7.4 or <150) and ratios such as also titer levels (for example, 1:128).

Response: We appreciate the number of comments regarding an expansion of the existing measure as well as further clarification. Based on both CMS and companion ONC comments received, we clarify that the measure incorporate all numeric/quantitative tests that report whole or decimal numbers. The structured data for the numeric/quantitative test results may include positive or negative affirmations and/or numerical format that would include a reference range of numeric results and/or ratios.

Comment: Most commenters agreed that the increase measure threshold is appropriate. One commenter referenced a recent AHA survey that found ''60 percent of hospitals could perform this function in Fall 2011 at the raised threshold''.

Response: Our analysis of the Stage 1 attestation data shows that 91.5 percent of EPs and 95 percent of eligible hospitals and CAHs were able to successfully demonstrate meaningful use for this measure. Therefore, combined with the AHA survey data results, we will adopt the proposed threshold of 55 percent or more for this measure.

After consideration of the public comments received, we modify the measure for EPs at § 495.6(j)(7)(ii) and eligible hospitals and CAHs at § 495.6(l)(6)(ii) to:

More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in CEHRT as structured data.

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 CEHRT at 45 CFR 170.314(b)(5).

- *Denominator:* Number of lab tests ordered during the EHR reporting period by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) whose results are expressed in a positive or negative affirmation or as a number.
- *Numerator:* Number of lab test results which are expressed in a positive or negative affirmation or as a numeric result which are incorporated in CEHRT as structured data.
- *Threshold:* The resulting percentage must be more than 55 percent in order for an EP, eligible hospital, or CAH to meet this measure.
- *Exclusion:* Any EP who orders no lab tests where results are either in a positive/negative affirmation or numeric format during the EHR reporting period.

There is no exclusion available for eligible hospitals and CAHs because we do not believe any hospital will ever be in a situation where its authorized providers have not ordered any lab tests for admitted patients during an EHR reporting period.

Proposed Objective: Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

In the proposed rule, we outlined the following benefits of generating lists of patients by specific conditions: Generating patient lists is the first step in proactive management of populations with chronic conditions and is critical to providing accountable care. The ability to look at a provider's entire population or a subset of that population brings insight that is simply not available when looking at patients individually. Small variations that are unnoticeable or seem insignificant on an individual basis can be magnified when multiplied across a population. A number of studies have shown that significant improvements result merely due to provider awareness of population level information. We believe that many EPs and eligible hospitals will use these reports in combination with one of the

selected quality measures and decision support interventions to improve quality for a high priority issue (for example, identify patients who are in the denominator for a measure, but not the numerator, and in need of an intervention). The capabilities and variables used to generate the lists are defined in the ONC standards and certification final rule published elsewhere in this issue of the **Federal Register**; not all capabilities and variables must be used for every list.

We have combined the comments and responses for this objective with the measure below. After consideration of the public comments, we are finalizing the meaningful use objective for EPs at § 495.6(j)(8)(i) and eligible hospitals and CAHs at § 495.6(l)(7)(i) as proposed.

Proposed Measure: Generate at least one report listing patients of the EP, eligible hospital, or CAH with a specific condition.

We proposed to continue our Stage 1 policies for this measure. The objective and measure do not dictate the specific report(s) that must be generated, as the EP, eligible hospital, or CAH is best positioned to determine which reports are most useful to their care efforts. The report used to meet the measure can cover every patient or a subset of patients. We believe there is no EP, eligible hospital, or CAH that could not benefit their patient population or a subset of their patient population by using such a report to identify opportunities for quality improvement, reductions in disparities of patient care, or for purposes of research or patient outreach; therefore, we did not propose an exclusion for this measure. The report can be generated by anyone who is on the EP's or hospital's staff during the EHR reporting period. We also solicited comment on whether a measure that either increases the number and/or frequency of the patient lists will further the intent of this objective.

Comment: Most commenters voiced support for the objective and measure and wish it to remain unchanged in the final rule, although some commenters stated that the measure should only require demonstration that a list can be created and not require a certain number of patient lists until the needs to create certain patient lists are better ascertained.

Response: We appreciate the support for this objective, and we note that the measure of the objective remains unchanged from Stage 1. Demonstration only of the capability to generate lists of patients by specific conditions would represent a step backward from the Stage 1 measure, therefore we do not agree that this would be an appropriate measure for Stage 2. We also believe there is ample evidence to support the use of patient lists in a variety of quality improvement efforts.

Comment: Some commenters suggested that the measure requirements should be increased, either to require more than one report be generated during the EHR reporting period or to require that the report generated is linked to one of the EP's or eligible hospital's clinical decision support interventions. Another commenter suggested that the measure should indicate how the list should be used.

Response: We believe that moving the objective from the menu set to the core represents an adequate increase for Stage 2. We also continue to believe that an EP, eligible hospital, or CAH is best positioned to determine which reports are most useful to their care efforts. Therefore, we do not propose to direct certain reports be created or link reports to clinical decision support interventions at this time.

Comment: Some commenters suggested that lists should be generated according to specific clinical conditions or include specific elements, such as demographics, to aid analysis. One commenter wanted to know whether EPs retain flexibility in deciding the lists they generate, particularly in coordinating public health activities with state and local public health departments and Medicaid agencies. Another commenter suggested that the measure of the objective specify the continuous use of the report throughout the EHR reporting period.

Response: As noted previously, we are continuing our policy from Stage 1 that an EP, eligible hospital, or CAH is best positioned to determine which reports are most useful to their care efforts. Therefore, we do not propose to direct certain reports be created, nor do we require that specific conditions or elements be required for the reports. Also, we do not set requirements for the frequency of use of the report.

Comment: A commenter asked us to clarify whether the EP must generate the patient list or if the patient list could be generated by a member of the EP's staff in order to meet the measure.

Response: For this and most meaningful use objectives, we do not specify how information must be entered into CEHRT or who must complete the required action to meet the measure. Therefore an EP or a member of the EP's staff could generate the list and meet this measure. The exception to this rule is for computerized provider order entry (CPOE) of medication, laboratory, and radiology orders, which must be entered by a licensed healthcare professional per state, local, and professional guidelines.

After consideration of the public comments, we are finalizing the meaningful use measure for EPs at § 495.6(j)(8)(ii) and eligible hospitals and CAHs at § 495.6(l)(7)(ii) as proposed.

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 CEHRT at 45 CFR 170.314(a)(14).

Proposed EP Objective: Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.

In the proposed rule, we described the following benefits of this objective. By proactively reminding patients of preventive and follow-up care needs, EPs can increase compliance. These reminders are especially beneficial when long time lapses may occur as with some preventive care measures and when symptoms subside, but additional follow-up care is still required.

We also proposed to revise this objective for Stage 2 to ''Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care'' based on the HITPC recommendation. An EP should use clinically relevant information stored within the CEHRT to identify patients who should receive reminders. We believe that the EP is best positioned to decide which information is clinically relevant for this purpose.

Comment: A commenter stated that the language in the proposed objective is in conflict with the proposed measure. The proposed objective is to ''Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up,'' with no indication that the reminder be sent. However, the proposed measure refers to ''patient who had an office visit and were sent a reminder, per patient preference.''

Response: We agree with the commenter that the objective as proposed only speaks to the identification of the need for the reminder and that the proposed measure requires that the reminder be sent. The value of this objective is created when the reminder is sent to the patient and therefore, we revise the objective accordingly.

Comment: Commenters requested request clarification of the operative definition of ''reminder.'' Remembering to keep the appointment is an important first step to follow-up and preventive care and therefore should be counted.

Response: We believe that reminders should be limited to new actions that need to be taken not of actions that are already taken. For example, a reminder to schedule your next mammogram is a reminder to take action, while a reminder that your next mammogram is scheduled for next week is a reminder of action already taken. If we were to allow for reminders of existing scheduled appointments then every provider could meet this objective and measure without any patient ever learning new information. So we clarify that reminders for preventive/follow-up care should be for care that the patient is not already scheduled to receive. Reminders are not necessarily just to follow up with the reminding EP. Reminders for referrals or to engage in certain activities are also included in this objective and measure.

After consideration of the public comments received, we are modifying the objective at § 495.6(j)(9)(i) to ''Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminders, per patient preference.''

Proposed EP Measure: More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period were sent a reminder, per patient preference.

In Stage 1, the measure of this objective was limited to more than 20 percent of all patients 65 years old or older or 5 years old or younger. Rather than raise the threshold for this measure, the HIT Policy Committee recommended lowering the threshold but extending the measure to all active patients. We proposed to apply the measure of this objective to all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period. We believe this not only identifies the population most likely to consist of active patients, but also allows the EP flexibility to identify patients within that population who can benefit most from reminders. We solicited comments on the appropriateness of this timeframe. We also recognize that some EPs may not conduct face-to-face encounters with patients but still provide treatment to patients. These EPs could be unintentionally prevented from meeting this core objective under the measure requirements, so we proposed an exclusion for EPs who have no office visits in order to accommodate such EPs. Patient preference refers to the method of providing the reminder.

Comment: Commenters expressed concern that even with the proposed revisions many patients in the denominator might not require a reminder. One example given was some colonoscopies are done on a schedule of once every ten years. Another example provided was specialists who see some patients only for one-time consults. Suggestions by commenters to deal with patients in the denominator who do not require reminders involve either much more precise measurement such as tracking and following up when CEHRT identifies the need for a patient reminder, to specific exclusions of certain visit types in the measure or to move the requirement to the menu set. Others suggested that providers who do not typically send reminders be sent granted exclusions.

Response: We agree that not every active patient will require a reminder during the EHR reporting period, which is why the threshold is far below 100 percent. We believe that a low threshold of 10 percent is the best way to account for the contextually specific reasons a patient might not be sent a reminder. We proposed an exclusion for EPs who would typically not send reminders, specifically those without office-based visits. This may not include all providers who do not typically send reminders, but as an exclusion must contain definitive criteria we believe it is a good exclusion. We did not receive in comments precise criteria for an alternative exclusion.

Comment: We received many comments as to what constitutes an active patient in a practice. Many voiced the opinion that given the 24 month look back period in a typical practice, many patients would have moved to another practice. One suggestion given for an alternate way to count patients was to change the definition of ''active patients'' to be either three or more visits in 24 months or two or more visits in 12 months. Other commenters recommended that the time limitation be removed.

Response: We proposed active patients as a method to limit the denominator to patients more likely to require a reminder. The goal is to limit the denominator as much as possible without excluding patients who should receive a reminder. After reviewing the comments, we change the look back to patients with at least two office visits in the last 24 months. We believe this better establishes a relationship between the provider and the EP. This would account for those specialists that do not have continuing relationships with their patients, but rather hand their care back to the referring provider.

Comment: Several commenters raised concerns with the requirement that it be per patient preference. They asked for clarification on the definition of ''per patient preference.'' Specifically commenters asked if patient preference referred to whether the patient wanted reminders or what method of communication they wanted to receive the reminders. Second, clarification is requested on how providers should document these preferences. Third, there is concern that an insufficient number of patients will have their preferences recorded at the start of the EHR reporting period and if so, any method of communication should suffice for those patients.

Response: We clarify that patient preference is the method of communication that patients prefer to receive their reminders such as (but not limited to) by mail, by phone or by secure messaging. Given the look back period associated with this measure, we agree that it is not feasible to have all patient preferences recorded prior to the start of the EHR reporting period. Therefore, we clarify that reminders must be sent using the preferred communication medium only when it is known by the provider. This is limited to the type of communication (phone, mail, secure messaging, etc.) and does not extend to other constraints like time of day. Patients may decline to provide their preferred communication medium in which case the provider may select the communication medium. A patient may also decline to receive reminders. We believe that this will be rare enough that combined with the 10 percent through, patients declining to receive reminders will not affect the ability of an EP to meet this measure. It is our expectation that providers will begin to collect this information and that in the future as the look back period catches up to the publication of this final rule it will become possible to require that all reminders be sent per patient preference. We do not specify how things are documented beyond the capabilities and standards included in CEHRT.

After consideration of the public comments received, we are modifying the measure at § 495.6(j)(9)(ii) to ''More than 10 percent of all unique patients who have had 2 or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available.''

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(14).

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients who have had two or more office visits with the EP in the 24 months prior to the beginning of the EHR reporting period.
- *Numerator:* Number of patients in the denominator who were sent a reminder per patient preference when available during the EHR reporting period.
- *Threshold:* The resulting percentage must be more than 10 percent in order for an EP to meet this measure.
- *Exclusion:* Any EP who has had no office visits in the 24 months before the EHR reporting period.

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.

In the 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. In addition, we noted that this objective aligns with the Fair Information Practice Principles (FIPPs),[3] in affording baseline privacy protections to individuals.[4] In particular, the principles include Individual Access (patients should be provided with a simple and timely means to access and obtain their individually identifiable information in a readable form and format). We indicated that this objective replaces the Stage 1 core objective for EPs of ''Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies) upon request'' and the Stage 1 menu objective for EPs of ''Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within 4 business days of the information being available to the EP.'' The HIT Policy Committee recommended making this a core objective for Stage 2 for EPs, and we agreed with their recommendation consistent with our policy of moving Stage 1 menu objectives to the core set for Stage 2. Consistent with the Stage 1 requirements, we noted that the patient must be able to access this information on demand, such as through a patient portal or personal health record (PHR). However, we noted that providers should 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. Additionally, other health information may not be accessible. Finally, we noted that providers who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

Comment: Some commenters suggested that this objective should be part of the menu set instead of a core objective for Stage 2. This would permit EPs who do not believe they can meet the measure at this time to select different objectives.

Response: We do not agree that this objective should be part of the menu set. We proposed this objective as part of the core for EPs because it is intended to replace the previous Stage 1 core objective of ''Provide patients with an electronic copy of their health information upon request'' and the Stage 1 menu objective of ''Provide patients with timely electronic access to their health information.'' Although CEHRT will provide added capabilities for this objective, we do not believe the objective itself is sufficiently different from previous objectives to justify placing it in the menu set. Also, we believe that patient access to their electronic health information is a high priority for the EHR Incentive Programs and this objective best provides that access in a timely manner.

Comment: Some commenters expressed the opinion that this objective should not be included as part of meaningful use and was more appropriately regulated under HIPAA and through the Office for Civil Rights.

Response: We do not agree that this objective should not be included in meaningful use. Although we recognize that many issues concerning the privacy and security of electronic health information are subject to HIPAA requirements, we believe that establishing an objective to provide online access to health information is within the regulatory purview of the EHR Incentive Programs and consistent with the statutory requirements of meaningful use.

Comment: Some commenters suggested that this objective should be combined with the objective to ''Provide clinical summaries for patients after each office visit'' since much of the information provided in these objectives is identical.

Response: While it is true that there may be overlap between the information provided in the clinical summary and the information made available through this objective, we believe the clinical summary after an office visit serves a different purpose than online access to health information. A summary of an office visit provides patients and their families with a record of the visit and specific lab tests or specific follow-up actions and treatment related to the visit. While this information is certainly part of the patient's overall electronic health record, the clinical summary serves to highlight information that is relevant to the patient's care at that particular moment. Therefore, we decline to combine the two objectives.

After consideration of the public comments, we are finalizing the meaningful use objective for EPs at § 495.6(j)(10)(i) as proposed.

Proposed EP Measures: We proposed two measures for this objective, both of which must be satisfied in order to meet the objective:

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.

More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information.

Exclusions: Any EP who neither orders nor creates any of the information listed for inclusion as part of this measure may exclude both

[3] In 1973, the Department of Health, Education, and Welfare (HEW) released its report, *Records, Computers, and the Rights of Citizens,* which outlined a Code of Fair Information Practices that will create ''safeguard requirements'' for certain ''automated personal data systems'' maintained by the Federal Government. This Code of Fair Information Practices is now commonly referred to as fair information practice principles (FIPPs) and established the framework on which much privacy policy will be built. There are many versions of the FIPPs; the principles described here are discussed in more detail in *The Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information,* December 15, 2008. *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173.*

[4] The FIPPs, developed in the United States nearly 40 years ago, are well-established and have been incorporated into both the privacy laws of many states with regard to government-held records and numerous international frameworks, including the development of the OECD's privacy guidelines, the European Union Data Protection Directive, and the Asia-Pacific Economic Cooperation (APEC) Privacy Framework.*http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173.*

measures. 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 only the second measure.

As we stated in the proposed rule, transmission can be any means of electronic transmission according to any transport standard(s) (SMTP, FTP, REST, SOAP, etc.). However, the relocation of physical electronic media (for example, USB, CD) does not qualify as transmission although the movement of the information from online to the physical electronic media will be a download.

Comment: Some commenters suggested that the timeframe for the first measure should be expanded to 7 days, since the data required to be provided in order to meet the measure of this objective would sometimes be incomplete only 4 days after the patient's visit. Other commenters suggested the timeline for the first measure should be shortened to 2 business days or 24 hours.

Response: We do not agree that the timeframe for the measure should be lengthened. In the Stage 1 menu objective of ''Provide patients with timely electronic access to their health information,'' we established the measure for providing access within 4 business days. Also, we believe that most of the information required by this measure, except for lab tests, will be readily available within the specified time period. However, we also believe that 24 hours or 2 business days would not provide adequate time to make all information available online. Therefore, we maintain the requirement of making information available within 4 business days.

Comment: Some commenters asked for clarification on whether online access had to be made available using CEHRT or if the information could be made available through other means (patient portal, PHR, etc.).

Response: Both of the measures for this objective must be met using CEHRT. Therefore, for the purposes of meeting this objective, the capabilities provided by a patient portal, PHR, or any other means of online access and that would permit a patient or authorized representative to view, download, or transmit their personal health information would have to be certified in accordance with the certification requirements adopted by ONC. We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register**.

Comment: A commenter asked how long data should be made available online before it can be removed. In a related topic, another commenter asked which provider would be responsible for excluding data from sharing when multiple providers share CEHRT.

Response: It is the goal of this objective to make available to the patient both current and historical health information. Therefore, we would anticipate that the data should be available online on an ongoing basis. However, an EP may withhold or remove information from online access if they believe substantial harm may arise from its disclosure online. In regard to withholding data and which provider should be responsible for making the determination when multiple providers share CEHRT, we would expect that providers sharing the CEHRT would make a joint determination regarding the information to be withheld. Therefore, we leave this decision to the providers' discretion.

Comment: Some commenters asked for clarification on how access by the patient is defined.

Response: We define access as having been given when the patient possesses all of the necessary information needed to view, download, or transmit their information. This could include providing patients with instructions on how to access their health information, the Web site address they must visit for online access, a unique and registered username or password, instructions on how to create a login, or any other instructions, tools, or materials that patients need in order to view, download, or transmit their information.

Comment: Some commenters suggested that patients under the age of 18 should not have the same access to the same information to which adult patients have access and requested a separate list of required elements for patients under the age of 18.

Response: An EP may decide that online access is not the appropriate forum for certain health information for patients under the age of 18. Within the confines of the laws governing guardian access to medical records for patients under the age of 18, we would defer to the EP's judgment regarding which information should be withheld for such patients. In lieu of providing online access to patients under the age of 18, EPs could provide online access to guardians for patients under the age of 18, in accordance with state and local laws, in order to meet the measure of this objective. Providing online access to guardians in accordance to state and local laws would be treated the same as access for patients, and guardians could then be counted in the numerator of the measure. We recognize that state and local laws may restrict the information that can be made available to guardians, and in these cases such information can be withheld and the patient could still be counted in the numerator of the measure. No requirement of meaningful use supersedes any Federal, State or local law regarding the privacy of a person's health information.

Comment: Some commenters suggested that specialists should transmit information to the patient's primary care provider rather than providing online access to information in order to reduce the number of portals a patient must visit, which could cause confusion.

Response: We believe that much of this information will be transmitted between providers as part of the summary of care record following a transition of care. However, we also believe there is value to the patient in having online access to this information for all providers they visit, including specialists. Therefore, we maintain this measure for all EPs.

Comment: Many commenters voiced objections to the second measure of this objective and the concept of providers being held accountable for patient actions. The commenters believed that while providers could be held accountable for making information available online to patients, providers could not control whether patients actually accessed their information. Many commenters also noted that the potential barriers of limited internet access, computer access, and patient engagement with health IT for certain populations (for example, rural, elderly, lower income, visually impaired, non-English-speaking, etc.) might make the measure impossible to meet for some providers. There were also a number of comments stating that metrics used to track views or downloads can be misleading and are not necessarily the most accurate measure of patient usage. Commenters suggested a number of possible solutions to allow providers to overcome these barriers, including eliminating the percentage threshold of the measure or requiring providers to offer and track patient access but not requiring them to meet a percentage measure in order to demonstrate meaningful use. However, some commenters believed that the measure was a reasonable and necessary step to ensure that providers had accountability for engagement of their patients in use of electronic health information and integration of it into clinical practice. In

addition, commenters pointed to the unique role that providers can play in encouraging and facilitating their patients' and their families' use of online tools.

Response: While we recognize that EPs cannot directly control whether patients access their health information online, we continue to believe that EPs are in a unique position to strongly influence the technologies patients use to improve their own care, including viewing, downloading, and transmitting their health information online. We believe that EPs' ability to influence patients coupled with the low threshold of more than 10 percent of patients having viewed online, downloaded, or transmitted to a third party the patient's health information make this measure achievable for all EPs.

We recognize that certain patient populations face greater challenges in online access to health information. We address the potential barrier of limited Internet access in the comment regarding a broadband exclusion below. We address the potential barrier to individuals with disabilities through ONC's rules requiring that EHRs meet web content accessibility standards. While we agree that excluding certain patient populations from this requirement would make the measure easier for EPs to achieve, we do not know of any reliable method to quantify these populations for each EP in such a way that we could standardize exclusions for each population. We also decline to eliminate the percentage threshold of this measure because we do not believe that a simple yes/no attestation for this objective is adequate to encourage a minimum level of patient usage. However, in considering the potential barriers faced by these patient populations, we agree that it would be appropriate to lower the proposed threshold of this measure to more than 5 percent of unique patients who view online, download, or transmit to a third party the patient's health information. In addition, we are concerned that blanket exclusions for certain disadvantaged populations could serve to extend existing disparities in electronic access to health information and violate civil rights laws. All entities receiving funds under this program are subject to civil rights laws. For more information about these laws and their requirements (see *http://www.hhs.gov/ocr/civilrights/index.html*). We believe that this lower threshold, combined with the broadband exclusion detailed in the response that follow, will allow all EPs to meet the measure of this objective.

Comment: Some commenters suggested an alternate definition of the second measure based on the number of patients seen within the last 2 years that access their health information online.

Response: We believe that the current numerator and denominator for this measure encourage the active online access by patients of their health information. We further believe that broadening the time period of this measure to patients seen within the last 2 years does not encourage both EPs and current patients to use online access to health information in the active management of their care, which is one of the goals of the EHR Incentive Programs. Therefore, we decline to adopt this suggested alternate definition.

Comment: Some commenters asked for clarification on how view is defined.

Response: We define view as the patient (or authorized representative) accessing their health information online.

Comment: Some commenters noted that the potential financial burden of implementing an online patient portal to provide patients online access to health information. These commenters noted the added time burden for staff in handling the additional patient use of online resources, which may increase costs through the hiring of additional staff, as well as the need to modify their existing workflow to accommodate additional online messages from patients. Some commenters also believed that there would be an additional cost for sharing content before standards exist for content types and formats.

Response: We do not believe that implementing online access for patients imposes a significant burden on providers. While we note that in some scenarios it may be possible for an EP to receive reimbursement from private insurance payers for online messaging, we acknowledge that EPs are generally not reimbursed for time spent responding to electronic messaging. However, it is also true that EPs are generally not reimbursed for other widely used methods of communication with patients (for example, telephone). As we noted in the proposed rule, many providers have seen a reduction in time responding to inquires and less time spent on the phone through the use of health IT, including online messages from patients. We expect the same will be true for online access to health information by reducing continuous requests for health records, test results, and other pertinent patient information. Finally, we believe that the standards established for this objective by ONC will serve as a content standard that will allow this information to be more easily transmitted and uploaded to another certified EHR, thereby reducing additional costs.

Comment: Some commenters noted that patient engagement could occur effectively with or without online access, and patients should be encouraged to use any method (for example, telephone, internet, traditional mail) that suits them. These commenters noted that engagement offline reduces both the need and value for engagement online.

Response: We agree that patient engagement can occur effectively through a variety of media, and we also believe that electronic access to health information can be an important component of patient engagement. We do not believe that offline engagement reduces the need for online access, as patients may opt to access information in a variety of ways. Because of the variety of ways that patients/families may access information, we keep the threshold for this measure low. We also note that online access to health information can enhance offline engagement—for example, patients could download information from an office visit with their primary care provider to bring with them for a consult with a specialist—which is one of the primary goals of the EHR Incentive Programs.

Comment: Some commenters expressed concern that vendors would not be able to make these capabilities available as part of CEHRT in time for the beginning of Stage 2.

Response: Many CEHRT vendors already make patient portals available that would meet the certification criteria and standards required for this measure. In fact, many vendors have already incorporated these capabilities into their CEHRT products in order to meet the measure of the Stage 1 objective to ''Provide patients with timely electronic access to their health information.'' Although the Stage 2 measure requires some additional capabilities, we believe vendors will be able to make these capabilities available in time for the beginning of Stage 2.

Comment: Some commenters requested clarification on the exclusion regarding an EP ''who neither orders nor creates any of the information listed for inclusion as part of this measure may exclude both measures.'' Because the list of required elements for this measure includes the patient's name, provider's name, and office contact information, these commenters suggested that no EP could qualify for this exclusion.

Response: We amend the wording of the exclusion to accommodate providers who do not order or create any of the information listed, except for patient name, provider name, and office contact information.

Comment: Some commenters suggested that basing an exclusion on the broadband data available from the FCC Web site (*www.broadband.gov*) was suspect since the data originates from vendors.

Response: The broadband data made available from the FCC was collected from over 3,400 broadband providers nationwide. This data was then subject to many different types of analysis and verification methods, from drive testing wireless broadband service across their highways to meeting with community leaders to receive feedback. Representatives met with broadband providers, large and small, to confirm data, or suggest changes to service areas, and also went into the field looking for infrastructure to validate service offerings in areas where more information was needed. Therefore, we believe the data is appropriate for the exclusion to this measure. We note that since publication of our proposed rule the Web site has changed to *www.broadbandmap.gov* and the speed used has changed from 4Mbps to 3Mbps. We are updating our exclusion to reflect these changes.

Comment: Some commenters believe that broadband exclusions should be based on the patients' locations instead of the providers, since county-level data may not be granular enough to capture all areas of low broadband availability within a particular region.

Response: Although we agree that a broadband exclusion based primarily on the individual locations of each patient seen would be more accurate, we do not believe that there is any method of making this determination for every patient without placing an undue burden on the provider. We continue to believe that limited broadband availability in the EP's immediate practice area, coupled with the low threshold of this measure, adequately serves as an acceptable proxy for determining areas where online access can present a challenge for patients. Therefore, we retain the broadband exclusion as proposed.

Comment: Some commenters requested a clarification of the required element of ''Any additional known care team members beyond the referring or transitioning provider and the receiving provider.''

Response: With this element we mean for providers to indicate the names and contact information for any other health care professionals known to the EP. This could include referring providers, receiving providers, or any other provider inside or outside the EP's practice that provides care to the patient. We are amending the language for this required element to ''Any known care team members.''

Comment: Some commenters suggested that growth charts should not be included for either download or transmission, since these charts are simply visualizations of the height and weight data elements.

Response: We believe that growth charts can be a useful tool for both patients and providers, especially in instances where a patient may elect to download or transmit their health information to another provider. Therefore, we require them to be included to meet the measure of this objective.

Comment: One commenter suggested that images should not be included in the list of required elements to be provided to patients online. They cited specific difficulties in image viewing online, as well as concerns over file size.

Response: We note the commenter's concerns and further note that images are not among the required elements to meet the measure of this objective.

After consideration of the public comments, we finalize the first meaningful use measure for EPs as proposed at § 495.6(j)(10)(ii)(A). We finalize the second meaningful use measure for EPs as ''More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information'' at § 495.6(j)(10)(ii)(B). We finalize the following exclusions for EPs at § 495.6(j)(10)(iii): ''Any EP who neither orders nor creates any of the information listed for inclusion as part of both measures, except for ''Patient name'' and ''Provider's name and office contact information,'' may exclude both measures;'' ''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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude only the second measure''.

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(e)(1).

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:

- *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.

For the second measure for reporting on the number of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) who view, download or transmit health information, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP 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 5 percent in order for an EP to meet this measure.
- *Exclusions:* Any EP who neither orders nor creates any of the information listed for inclusion as part of both measures, except for ''Patient name'' and ''Provider's name and office contact information,'' may exclude both measures. 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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude only the second measure.

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, and

• Any known care team members including the primary care provider (PCP) of record.

As we stated in the proposed rule, this is not intended to limit the information made available by the EP. An EP can make available additional information and still align with the objective. In circumstances where there is no information available to populate one or more of the fields previously listed, either because the EP can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, no medication allergies or laboratory tests), the EP may have an indication that the information is not available and still meet the objective and its associated measure. Please note that while some of the information made available through this measure is similar to the information made available in the summary of care document that must be provided following transitions of care or referrals, the list of information above is specific to the view online, download, and transmit objective. Patients and providers have different information needs and contexts, so CMS has established separate required fields for each of these objectives.

Proposed Objective: Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

In the proposed rule, we explained that providing clinically relevant education resources to patients is a priority for the meaningful use of CEHRT. Based on our experience with this objective in Stage 1, we are clarifying that while CEHRT must be used to identify patient-specific education resources, these resources or materials do not have to be stored 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, that can be queried via CEHRT (that is, specific patient characteristics are linked to specific consumer health content). The EP or hospital should utilize CEHRT in a manner where the technology suggests patient-specific educational resources based on the information stored in the CEHRT. Certified EHR technology 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 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).

In the Stage 1 final rule (75 FR 44359), we included the phrase ''if appropriate'' in the objective so that the EP or the authorized provider in the hospital could determine whether the education resource was useful and relevant to a specific patient. Consistent with the recommendations of the HIT Policy Committee, we proposed to remove the phrase ''if appropriate'' from the objective for Stage 2 because we do not believe that any EP or hospital will have difficulty identifying appropriate patient-specific education resources for the low percentage of patients required by the measure of this objective.

We also recognized that providing education materials at literacy levels and cultural competency levels appropriate to patients is an important part of providing patient-specific education. However, we continue to believe that there is not currently widespread availability of such materials and that such materials could be difficult for EPs and hospitals to identify for their patients.

Comment: Many commenters sought clarification on the meaning of the term ''identified by CEHRT.'' They questioned how the CEHRT would identify resources and whether the education resources had to be stored in the CEHRT or if it could contain links to the materials.

Response: We clarified in the proposed rule (77 FR 13720) that while CEHRT must be used to identify patient-specific education resources, these resources or materials do not have to be stored within or generated by the Certified EHR Technology. We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register** which describes the capabilities and standards that CEHRT must include. For patient-specific education materials, this includes a general functional capability to identify educational materials as well as a capability to do so using the HL7 Context-aware Information Retrieval ''Infobutton'' standard. This measure requires that an EP or hospital use the capabilities CEHRT includes to identify patient education materials. To clarify, although CEHRT will include the ability to identify education materials using the HL7 Infobutton standard, such capability alone does not need to be used in order to be counted in the numerator (that is, the general capability to identify education materials also counts towards the numerator).

After reviewing the public comments, we finalize the objective for EPs at § 495.6(j)(12)(i) and for eligible hospitals and CAHs at § 495.6(l)(9)(i) as proposed.

Proposed EP Measure: Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all office visits by the EP.

In the proposed rule, we noted that the Stage 1 measure for this objective for EPs was ''More than 10 percent of all unique patients seen by the EP are provided patient-specific education resources.'' Because we proposed this as a core objective for Stage 2, we proposed to modify the measure for EPs to ''Patient-specific education resources identified by CEHRT are provided to patients for more than 10 percent of all office visits by the EP.'' We recognized that some EPs may not conduct face-to-face encounters with patients but still provide treatment to patients. These EPs could be prevented from meeting this core objective under the previous measure requirements, so we proposed to alter the measure to account for office visits rather than unique patients seen by the EP. We also proposed an exclusion for EPs who have no office visits in order to accommodate such EPs.

The resources will have to be those identified by CEHRT. If resources are not identified by CEHRT and provided to the patient then it will not count in the numerator. We do not intend through this requirement to limit the education resources provided to patient to only those identified by CEHRT. We proposed the threshold at only 10 percent for this reason. We believe that the 10 percent threshold both ensures that providers are using CEHRT to identify patient-specific education resources and is low enough to not infringe on the provider's freedom to choose education resources and to which patients these resources will be provided. The education resources will need to be provided prior to the calculation and subsequent attestation to meaningful use.

Comment: Many commenters expressed concerns about the availability of resources that would be available at the appropriate literacy level for their patient populations. Some stated that there is a dearth of low-literacy materials available as most education sites are geared toward

college-educated patients; others stated that most materials are designed to be appropriate for a broad spectrum of literacy levels. Some commenters expressed concerns about the lack of resources available for non-English speaking patients. Yet other commenters were unclear as to what appropriate sources of patient-specific education would be. Some commenters expressed concerns that another alert within the system may create physician fatigue.

Response: We understand the commenters concerns that the educational materials identified by the CEHRT may not be appropriate for certain patients. To accommodate these concerns, we are maintaining the threshold for this measure at 10 percent. As we stated in our proposed rule and in the Stage 1 Final Rule, we account for these concerns by maintaining a low threshold for this objective.

Comment: Some commenters expressed concerns that the CEHRT, not the provider, would ''choose'' which educational resources would be provided to the patient.

Response: We cannot define the scope of practice and/or appropriate educational resources to be shared with each individual patient and will continue to rely on provider determinations based on individual patient circumstances.

Comment: Many commenters were concerned that the denominator for the EP measure included the number of office visits by the EP during the EHR reporting period. Commenters agreed with the rationale that EPs might not have the opportunity to provide educational materials to a patient if the patient has not had an office visit with the EP, however, commenters also stated that if an EP has a series of office visits with a patient, it might not be appropriate to provide education at each visit (for example, a patient with heart disease or high blood pressure that would see the EP multiple times during the EHR reporting period). To avoid the potential for presenting redundant information to patients, commenters suggested that the denominator be based on unique patients with office visits. This is consistent with the denominator for eligible hospitals, as that denominator is based on unique patients admitted. Additionally, commenters noted that counting unique patients is more appropriate to account for patient-specific education resources that are not provided in the context of an office visit, such as reference materials available from a portal or PHR about a patient's medications, conditions, or lab results.

Response: We agree with commenters in that counting unique patients with office visits during the EHR reporting period for EPs, rather than office visits, is a more appropriate denominator for this measure. A patient with a chronic disease, such as diabetes or heart disease, may have multiple office visits with an EP during the EHR reporting period. While providing educational resources for these patients is important, presenting the same materials each office visit may prove to be redundant. We encourage EPs to refer educational resources to their patients with multiple visits during the EHR reporting period at their discretion.

Additionally, we do maintain that EPs with no office visits during the EHR reporting period can be excluded from this measure. Therefore, we are finalizing the denominator for this measure as the ''Number of unique patients with office visits seen by the EP during the EHR reporting period.''

Comment: Most commenters agreed that 10 percent was a reasonable threshold for this measure as it was proposed.

Response: We agree with commenters and are finalizing 10 percent as the threshold for this measure. It will remain unchanged from Stage 1.

After reviewing the public comments, we are finalizing the measure for EPs at § 495.6(j)(12)(ii) as ''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 further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(15).

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 Certified EHR Technology.
- *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 departments (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology.

After consideration of public comments, we are finalizing the measure for eligible hospitals and CAHs at § 495.6(l)(9)(ii) as proposed.

We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(15).

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's or CAH's 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 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 proposed rule we outlined the following benefits of this objective. 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 their direct patient care, it also improves the accuracy of information they provide to others through health information exchange.

In the proposed rule, we noted that 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. Information included in the process of medication reconciliation is appropriately determined by the provider and patient. In the proposed rule 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. We proposed that the electronic exchange of information is

not a requirement for medication reconciliation.

Comment: Commenters requested that the definition of medication reconciliation should specifically mention over-the-counter medications, vitamins, herbal or other alternative care medications in the definition.

Response: We believe our term medications is expansive and not limiting. We in no way limit what any provider chooses to include or not include in their conduct of a medication reconciliation. As we are focused on the use of CEHRT to assist in medication reconciliation it is not our intent to develop a definitive definition of what medication reconciliation is.

Comment: Commenters stated that the objective is so reliant on health information exchange that it should not be moved to core until health information exchange capability increases.

Response: Robust health information exchange is certainly of great assistance to medication reconciliation. However, it is not required for medication reconciliation. Nor is electronic health information exchange the only way EHRs can assist with medication reconciliation. So while we believe that medication reconciliation will become easier as health information exchange capability increases, it is not a prerequisite to performing medication reconciliation.

After consideration of the comments received, we are finalizing this objective as proposed for EPs at § 495.6(j)(13)(i) and for eligible hospitals and CAHs at § 495.6(l)(10)(i).

Proposed Measure: The EP, eligible hospital or CAH performs medication reconciliation for more than 65 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).

In the proposed rule, we stated that although the HITPC recommended maintaining this threshold at 50 percent we believed that due to this measure's role in information exchange that we seek to promote through meaningful use a higher measure was appropriate. Based on the performance of providers in Stage 1, we proposed to raise the measure to 65 percent.

Comment: If as stated in the proposed rule ''the majority chose to defer this measure in Stage 1,'' commenters asserted that this is insufficient information to justify raising the threshold to 65 percent and move the objective to core. Other commenters assert that any measure that moves from menu to core should maintain its Stage 1 threshold regardless of the particular measure's rate of deferral.

Response: After considering the arguments for lowering the threshold to 50 percent and the lack of robust data in support of the proposed threshold, we do lower the threshold to 50 percent. For this measure in particular, we agree that since most providers chose to defer this measure in Stage 1 the information available on performance from Stage 1 meaningful EHR users is not as robust as for other objectives and measures. We do not agree with the comment that all objectives that move from menu to core should maintain the same threshold. We believe such a blanket policy would be arbitrary and not properly account for the information available for each objective and measure. For example, if most Stage 1 meaningful EHR users had reported on this measure, there would be a robust data set of performance on which to judge a threshold. A blanket policy would ignore such information.

Comment: The denominator of transitions of care during the EHR reporting period for which the provider is the receiving part of the transition is imprecise and therefore difficult to determine, especially when neither the transitioning provider or patient notifies the provider of the transition.

Response: We addressed this comment earlier in this section in our discussion of meaningful use denominators and provided a minimum set of specific actions that would indicate a transition of care has occurred.

Comment: While the objective speaks to relevant encounters, these are not included in the measure. This makes measurement difficult for those providers that conduct medication reconciliation at more than just transitions of care. If providers were allowed to include these encounters in the measure, measurement would both be easier and more representative of the actual use of CEHRT by the provider.

Response: We continue to believe that what is a relevant encounter is to variable to be included in the measure for all providers. However, a provider who institutes a policy for medication reconciliation at encounters encompassing more than just the minimum actions defined by the transitions of care denominator can include those encounters in their denominator and if medication reconciliation is conducted at the encounter in the numerator as well.

After consideration of the comments, we are modifying the threshold of the measure for EPs at § 495.6(j)(13)(ii) and for eligible hospitals and CAHs at § 495.6(l)(10)(ii). 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).

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 CEHRT at 45 CFR 170.314(b)(4).

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 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.

In the proposed rule, we outlined the following benefits of this objective. By assuring lines of communication between providers caring for the same patient, all of the providers of care can operate with better information and more effectively coordinate the care they provide. Electronic health records, especially when linked directly or through health information exchanges, reduce the burden of such communication. The purpose of this objective is to ensure a summary of care record is provided to the receiving provider when a patient is transitioning to a new provider or has been referred to another provider while remaining under the care of the referring provider.

In the proposed rule, we proposed to eliminate the Stage 1 objective for the exchange of key clinical information for Stage 2 and instead include such information as part of the summary of care when it is a part of the patient's electronic record. We also proposed to incorporate two separate Stage 2 recommendations from the HIT Policy Committee as required fields in the summary of care record—

• Record care plan fields, including goals and instructions, for at least 10 percent of transitions of care; and

• Record team member, including primary care practitioner, for at least 10 percent of patients.

ONC also proposed in their standards and certification criteria rule (77 FR 13848 to include these as standard fields required to populate the summary of care document so CEHRT will be able to include this information. We provided a description of a ''care plan'' as well as the minimum components it must include for purposes of meaningful use, although we recognized that the actual content would be dependent on the clinical context. We asked for comments on both our description of a care plan and whether a description is necessary for purpose of meaningful use.

We proposed certain elements that are listed in the proposed rule (77 FR 13722) to be included in the summary care document. In circumstances where there is no information available on an element, either because the EP, eligible hospital or CAH can be excluded from recording such information or because there is no information to record, the EP, eligible hospital or CAH may leave the field(s) blank and still meet the objective and its associated measure.

In addition, we proposed that all summary of care documents used to meet this objective must include the following:

• An up-to-date problem list of current and active diagnoses.

• An active medication list, and

• An active medication allergy list.

We proposed that all summary of care documents must contain the most recent and up-to-date information on these three elements to count in the numerator. We proposed to define problem list as a list of current and active diagnoses. We solicited comment on whether the problem list should be extended to include, ''when applicable, functional and cognitive limitations'' or whether a separate list should be included for functional and cognitive limitations. We proposed to define an up-to-date problem list as a list populated with the most recent diagnoses known by the EP or hospital. We proposed to define active medication list as a list of medications that a given patient is currently taking. We proposed to define active medication allergy list as a list of medications to which a given patient has known allergies. We proposed to define allergy as an exaggerated immune response or reaction to substances that are generally not harmful. In the event that there are no current or active diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies, confirmation of no problems, no medications, or no medication allergies would satisfy the measure of this objective. Note that the inclusion and verification of these elements in the summary of care record replaces the Stage 1 objectives for ''Maintain an up-to-date problem list,'' ''Maintain active medication list,'' and ''Maintain active medication allergy list.''

Comment: Commenters suggested that the required data for each type of referral and transitions varies and that rather than creating a list of elements, the provider should decide what is needed.

Response: While we agree that tailoring the summary of care document for each referral and transition of care is desirable, we disagree that this means a list of basic elements that should be in each summary of care documents is not appropriate. We note that most organizations that try and tackle the issue of summary of care documents have required fields, core sets or other nomenclature for elements that they believe should be in all summary of care documents. For example, the CDA architecture used as the standard for the summary of care document contains required and optional fields. The American College of Physicians in their Neighborhood Model uses a core data set. None of these organizations intend for their list of elements to be limiting and nor do we intend our list to be limiting, but rather serve as a minimum. In our proposed rule we went further and said that if the provider does not have the information available to populate one or more of the fields listed, either because they can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the provider may leave the field(s) blank. The only exception to this is the problem list, medication list, and medication allergy list. Therefore, we are including a list of elements in this final rule.

Comment: Commenters stated that their understanding is that if any of the fields specifically for problem list, medication list, or allergy list is blank (meaning no entry of problems, medications or allergies nor an indication that it is known by the provider that the patient has no problems, medication or allergies), the EP or hospital will not meet the measure, but that if any other information is blank, the EP or hospital will still meet the measure. Please clarify whether this is a correct understanding of the proposal.

Response: This understanding of our proposed rule is generally correct. The problem list, medication list and medication allergy list must also either contain problems, medications and medication allergy or a specific notation that the patient has none. Leaving the field entirely blank with no entry whatsoever would not meet the measure. However, in cases where the provider does not have the information available to populate one or more of the other fields listed, either because they can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the provider may leave the field(s) blank. Note this does not allow a provider to disable a listed field from being generated by the CEHRT, but rather allows for when the CEHRT does not contain information on which to generate an entry for the field.

Comment: Some commenters suggested the substitution of past medical history for historical problem list in the list of required elements, since past medical history could provide additional information valuable to patient care.

Response: CMS' Evaluation and Management Services Guide defines a past medical history as the patient's past ''experiences with illnesses, operations, injuries and treatments'' (see *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/eval_mgmt_serv_guide-ICN006764.pdf*, p. 11). In our proposed rule, we referred to ''current and historical problem list'' as this is more concrete and standards based than the definition for past medical history. We believe the concept of past medical history is inclusive of current and historical problem list. We understand that providers are more familiar with the term past medical history and will evaluate expanding historical problem list to past medical history for Stage 3. However, for Stage 2, we are finalizing current and historical problem list. For summary of care documents at transitions of care we encourage 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 they are active or resolved, that have ever populated the problem list. While a current problem list should always be included, the provider can use his or her judgment in deciding which items historically present on the problem list, PMHx list (if it exists in CEHRT), or surgical history list are

included given the clinical circumstances.

Comment: Commenters stated that it is too burdensome to determine whether the problem list, medication list and medication allergy list are included in each summary of care document.

Response: We disagree that this is too burdensome. We note that in Stage 1 measuring the completeness of the problem list, medication list and medication allergy list is already a requirement. Summary of care documents are generated by the CEHRT based on the information available to it. Therefore, there are only two causes of error that would have to be discovered to make the determination of whether the problem list, medication list and medication allergy list are included. The problem list, medication list and medication allergy list do not contain information for a given patient and/or there is an error in the generation of the summary of care document. This discovery constitutes the burden of this measure. We have already noted that the ability to know whether the lists contain information is already a Stage 1 measure. The second issue is prevalent in nearly every meaningful use measure that requires CEHRT to generate a measurement so that burden is already integral to meaningful use.

Comment: Commenters stated that the different descriptions of problem list throughout the proposed rule create confusion. The four terms used are ''an up-to-date problem list of current and active diagnoses'', ''problem list'', ''Current problem list and any updates to it'' and ''problem list maintained by the hospital on the patient''. CMS should use this term uniformly. Furthermore, the limitation of the problem list to only current and active diagnoses is inconsistent with how problem lists are used and historical problems should also be included.

Response: We only proposed one definition of the base term ''problem list'', which is a list of current and active diagnoses. We then use descriptors to tailor the term to the objective in which it is being utilized. For example, ''up-to-date'' means that the problem list in the CEHRT is populated with the most recent diagnoses known by the EP or hospital. The description used for office visit summary ''Current problem list and any updates to it'' was intended to separate problems that were known before the visit and those that were determined during the visit. We agree that our limitation of the ''problem list'' to just current and active diagnoses is unnecessarily limiting. The C–CDA, which is the standard adopted for EHR technology certification, for summary of care documents states that ''at a minimum, all pertinent current and historical problems should be listed''. We revise our definition of ''problem list'' to include historical problems. This is a minimum. We do not limit the provider to just including diagnoses on the problem list. We agree that there should be just one definition of the base term ''problem list''; however, we disagree that the same list is appropriate for every case especially with the addition of the historical problems. Some objectives call for the current problem list which includes only those diagnoses of problems currently affecting the patient. Other objectives call for the current and historical problem list, which would include problems currently affecting the patient as well as those that have been resolved. For purposes of clarity, we are consolidating across all of the meaningful use objectives to just two descriptions of our term ''problem list'': ''current problem list'' and ''current and historical problem list.'' This consolidation also removes the need for a separate item of past relevant diagnosis as these would be included in a historical problem list. We define active medication list as a list of medications that a given patient is currently taking. We define active medication allergy list as a list of medications to which a given patient has known allergies. We define allergy as an exaggerated immune response or reaction to substances that are generally not harmful. 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. In the event that there are no current or active diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies, confirmation of no problems, no medications, or no medication allergies would satisfy the measure of this objective.

Comment: Many commenters recommended against any specification of problem list content regarding functional and cognitive limitations citing insufficient consensus around the appropriate classification of these functions. Commenters also stated that if included, functional and cognitive limitations should be further defined.

Response: As noted earlier in this final rule under the demographic objective, we wish to clarify that both the concepts of physical and cognitive disabilities as well as the concept of functional limitations that impact an individual's capability to perform activities were included in our description of disability status for the purpose of this rule. The latter concept is a common metric for care planning and care coordination across settings because knowledge of a patient's abilities (for example, functional and/or cognitive status) are also necessary for clinical practice. While many commenters noted the lack of consensus for the terms and standards necessary to support the inclusion of disability, functional and cognitive status assessment and observations into the Consolidated CDA for summary of care records, we understand that this standard was updated to include section- and data-entry level templates that can describe a patient's functional and cognitive status. However, we agree that there are insufficient definitions for disability, functional and cognitive status assessment and observations to include them as part of the problem list. Therefore, we are including ''functional status, including functional, cognitive and disability'' as a separate element in the summary of care document.

Comment: In regard to the inclusion of ''care plan field'' in the list of required information, some commenters believed that the wording was overly prescriptive since CEHRT could utilize multiple fields to structure care plans. Other commenters requested a more detailed definition of care plan and/or the standards that are available or required.

Response: We agree that the language proposed could be viewed as prescriptive, and we do not intend to limit the inclusion of the care plan to a single field. Therefore, we are amending the language to ''Care plan field(s), including goals and instructions'' in our list of required elements below. However, we decline to provide an alternate definition that would limit the information in the care plan. We believe that the definition we proposed in the proposed rule is sufficient to allow for the inclusion of a variety of care plans in the clinical summary. For purposes of the clinical summary, we define a care plan as the structure used to define the management actions for the various conditions, problems, or issues. A care plan must include at a minimum the following components: Problem (the focus of the care plan), goal (the target outcome), and any instructions that the provider has given to the patient. A goal is a defined target or measure to be achieved in the process of patient care (an expected outcome).

Comment: Commenters stated that while the care team members are clearly important data elements and key to clinical coordination, they recommended further research into true standards to support these elements before any requirements are imposed.

Response: Our proposal is to include ''Any additional known care team members beyond the referring or transitioning provider and the receiving provider''. We believe that the ability to identify providers is well established. We note that there is no requirement to identify the role of each provider which we would agree are not well established beyond PCP and referring provider. We also note that this is only for cases when the other care team members are known by the transitioning provider. These allowances are sufficient to accommodate the current standard limitations and therefore we finalize as proposed.

Comment: As referrals are included in the denominator as well as transitions of care, the summary of care document should include the reason for the referral.

Response: We agree with this comment and add reason for referral for EPs. The reason for the referral is the clinical question the referring provider wants answered for a consultation or the procedure to be performed. If the consultation is more open ended, then a brief summary of the case details pertinent to referral suffices.

After consideration of the comments, 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.

After consideration of public comments, we are finalizing this objective for EPs at § 495.6(j)(14)(i) and for eligible hospitals and CAHs at § 495.6(l)(11)(i) as proposed.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 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 electronically transmits a summary of care record using CEHRT to a recipient with no organizational affiliation and using a different CEHRT vendor than the sender for more than 10 percent of transitions of care and referrals.

First Measure: We proposed that if the provider to whom the referral is made or to whom the patient is transitioned has access to the medical record maintained by the referring provider, then the summary of care record would not need to be provided and that patient should not be included in the denominators of the measures of this objective. We stated in the proposed rule that different settings within a hospital using the same CEHRT would have access to the same information, so providing a clinical care summary for transfers within the hospital would not be necessary.

Comment: If as stated in the proposed rule ''the majority chose to defer this measure in Stage 1'', commenters asserted this is insufficient information to justify raising the threshold to 65 percent and move the objective to core. Other commenters assert that any measure that moves from menu to core should maintain its Stage 1 threshold regardless of the particular measure's rate of deferral.

Response: After considering the arguments for lowering the threshold to 50 percent and the lack of a robust data set in support of the proposed threshold, we do lower the threshold to 50 percent. For this measure in particular, we agree that since most providers chose to defer this measure in Stage 1 the information available on performance from Stage 1 meaningful EHR users is not as robust as for other objectives and measures. We do not agree with the comment that all objectives that move from menu to core should maintain the same threshold. We believe such a blanket policy would be arbitrary and not properly account for the information available for each objective and measure. For example, if most Stage 1 meaningful EHR users had reported on this measure, there would be a robust data set of performance on which to judge a threshold. A blanket policy would ignore such information.

Comment: Commenters questioned and requested clarification on situations where the recipient of the transition or referral is using the same instance of CEHRT or otherwise has access to the CEHRT of the transitioning or referring provider. Some of these commenters acknowledged our proposal to address this situation were also split between support for our proposal to exclude these from the denominator versus allowing them to be in the denominator and numerator of both measures. Also commenters expressed concern on whether this was a measurable constraint. Finally, commenters requested clarification on whether our proposal applied to one or both measures.

Response: We proposed that if the provider to whom the referral is made or to whom the patient is transitioned has access to the medical record maintained by the referring provider, then the summary of care record would not need to be provided and that patient should not be included in the denominators of the measures of this objective. We believe that different settings within a hospital using CEHRT would have access to the same information, so providing a clinical care

summary for transfers within the hospital would not be necessary. This is a continuance of our current Stage 1 policy. In response to comments, this policy applies to both measures. We clarify the first sentence that access to the medical record could be through several mechanisms. Some providers will be in the same organization and share CEHRT outright. Other providers might grant remote access to their CEHRT to providers not sharing their same CEHRT. We do not limit the mechanisms through which access is granted. We disagree that this access should count in the denominator or numerator of either measure. A summary of care document generated by CEHRT conforms to specific standards and could in many cases be automatically integrated into the recipient's CEHRT. Access provides no such capability. For this reason, we finalize our policy of excluding these transitions and referrals from the denominator. However, if a transitioning or referring provider provides both access and a summary of care document to providers outside their organization and wishes to include them in their denominator and as appropriate their numerator, they can do so. Finally, while we agree that it some cases it may be difficult to determine whether the recipient has access to the sender's CEHRT. We do not believe that we should remove an accommodation due to measurement difficulties. It is acceptable for a provider to include these transitions and referrals in the denominator, but only if a summary of care document is provided would it count in the numerator.

Comment: Commenters stated that there are some providers who may engage in a small number of transitions of care and referrals and the implementation burden of this objective is too high to require of those with only a small number. This is particularly true as the requirement for electronic health information exchange is introduced.

Response: We have previously allowed for a more than zero, but less than 100 exclusion for our other objective requiring electronic health information exchange (eRx); therefore, in response to these comments we will apply that policy to this objective and measure as well and raise the exclusion from zero to less than 100 transitions of care and referrals. Transitions of care and referrals are additive so someone with 50 transitions of care and 75 referrals would not qualify for the exclusion.

After consideration of public comments, we are revising the measure for EPs at § 495.6(j)(14)(ii)(A) and for eligible hospitals and CAHs at § 495.6(l)(11)(ii)(A) to ''The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals.''

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 CEHRT at 45 CFR 170.314(b)(l) and (b)(2)(i).

To calculate the percentage of the first 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 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 provided.
- *Threshold:* The percentage must be more than 50 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 is excluded from all three measures.

Second Measure: For Stage 2, we proposed the additional second measure for electronic transmittal because we believe that the electronic exchange of health information between providers will encourage the sharing of the patient care summary from one provider to another and the communication of important information that the patient may not have been able to provide, which can significantly improve the quality and safety of referral care and reduce unnecessary and redundant testing. Use of common standards can significantly reduce the cost and complexity of interfaces between different systems and promote widespread exchange and interoperability. In acknowledgement of this, ONC has included certain transmission protocols in the proposed 2014 Edition EHR certification criteria.

These protocols would allow every provider with CEHRT to have the tools in place to share critical information when patients are discharged or referred, representing a critical step forward in exchange and interoperability. Accordingly, we proposed to limit the numerator for this second measure to only count electronic transmissions which conform to the transport standards proposed for adoption at 45 CFR 170.202 of the ONC standards and certification criteria rule.

To meet the second measure of this objective, we proposed that a provider must use CEHRT to create a summary of care document with the required information according to the required standards and electronically transmit the summary of care document using the transport standards to which its CEHRT has been certified. No other transport standards beyond those proposed for adoption as part of certification would be permitted to be used to meet this measure.

In the proposed rule, we acknowledged the benefits of requiring the use of consistently implemented transport standards nationwide, but at the same time want to be cognizant of any unintended consequences of this approach. ONC requested comments on whether equivalent alternative transport standards exist to the ones ONC proposes to exclusively permit for certification. These comments are addressed in the ONC standards and certification final rule published elsewhere in this issue of the **Federal Register**. We noted in the proposed rule that the use of USB, CD–ROM, or other physical media or electronic fax would not satisfy the measures for electronic transmittal of a summary of care record. We discussed in the proposed rule, in lieu of requiring solely the transmission capability and transport standard(s) included in a provider's CEHRT to be used to meet this measure, also permitting a provider to count electronic transmissions in the numerator if the provider electronically transmits summary of care records to support patient transitions using an organization that follows Nationwide Health Information Network (NwHIN) specifications (*http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__nhin_resources/1194*). This could include those organizations that are part of the NwHIN Exchange as well as any organization that is identified through a governance mechanism ONC would establish through regulation. We requested public comment on whether this additional flexibility should be added to our proposed numerator limitations.

In the proposed rule we raised another potential concern that another transport standard emerges after CMS' and ONC's rules are finalized that is not adopted in a final rule by ONC as part of certification, but nonetheless accomplishes the objective in the same way. To mitigate this concern, ONC indicated in its proposed rule that it

would pursue an off-cycle rulemaking to add as an option for certification transport standards that emerge at any time after these proposed rules are finalized in order to keep pace with innovation and thereby allow other transport standards to be used and counted as part of this measure's numerator. We asked for comments on how these standards will further the goal of true health information exchange.

Additionally, in order to foster standards based-exchange across organizational and vendor boundaries, we proposed to further limit the numerator by only permitting electronic transmissions to count towards the numerator if they are made to recipients that are—(1) not within the organization of the transmitting provider; and (2) do not have CEHRT from the same EHR vendor.

We proposed these numerator limitations because, in collaboration with ONC, our experience has shown that one of the biggest barriers to electronic exchange is the adoption of numerous different transmission methods by different providers and vendors. Thus, we explained that it would be prudent for Stage 2 to include these more specific requirements and conformance to open, national standards as it will cause the market to converge on those transport standards that can best and most readily support electronic health information exchange and avoid the use of proprietary approaches that limit exchange among providers. We recognized that because the 2011 Edition EHR certification criteria did not include specific transport standards for transitions of care, some providers and vendors implemented their own methods for Stage 1 to engage in electronic health information exchange, some of which would no longer be an acceptable means of meeting meaningful use if this proposal were finalized.

Therefore, in order to determine a reasonable balance that makes this measure achievable yet significantly advance interoperability and electronic exchange, we asked for comment on the following concerns stakeholders may have relative to the numerator limitations we proposed previously.

We discussed a potential concern related to the feasibility of meeting this proposed measure if an insufficient number of providers in a given geographic location (because of upgrade timing or some other factor) have EHR technology certified to the transport standards ONC has proposed to adopt. For example, a city might have had a widely adopted health information exchange organization that still used another standard than those proposed for adoption by ONC. While it is not our intent to restrict providers who are engaged in electronic health information exchange via other transport standards, we believe requiring the use of a consistent transport standard could significantly further our overarching goals for Stage 2.

We recognized that this limitation extends beyond the existing parameters set for Stage 1, which specified that providers with access to the same medical record do not include transitions of care or referrals among themselves in either the denominator or the numerator. We recognized that this limitation could severely limit the pool of eligible recipients in areas where one vendor or one organizational structure using the same EHR technology has a large market share and may make measuring the numerator more difficult. We sought comment on the extent to which this concern could potentially be mitigated with an exclusion or exclusion criteria that account for these unique environments. We believe the limitation on organizational and vendor affiliations is important because even if a network or organization is using the standards, it does not mean that a network is open to all providers. Certain organizations may find benefits, such as competitive advantage, in keeping their networks closed, even to those involved in the care of the same patient. We believe this limitation will help ensure that electronic transmission of the summary of care record can follow the patient in every situation.

Even without the addition of the proposed exclusions under the proposed measure, CEHRT would need to be able to distinguish between (1) electronic transmissions sent using standards and those that are not, (2) transmission that are sent to recipients with the same organizational affiliation or not, and (3) transmissions that are sent to recipients using the same EHR vendor or not. ONC sought comment in their proposed certification rule as to the feasibility of this reporting requirement for CEHRT.

Despite the possible unintended consequences of the parameters we proposed for the numerator, in the proposed rule we stated that we believed that these limitations would help ensure that electronic health information exchange proceeds at the pace necessary to accomplish the goals of meaningful use. We asked for comments on all these points and particularly suggestions that would both push electronic health information exchange beyond what is proposed and minimize the potential concerns expressed previously.

The HIT Policy Committee recommended different thresholds for EPs and hospitals for the electronic transmission measure, with a threshold of only 25 instances for EPs. However, we proposed a percentage-based measure is attainable for both EPs and eligible hospitals/CAHs and better reflects the actual meaningful use of technology. It also provides a more level method for measurement across EPs. We asked for comments on whether there are significant barriers in addition to those discussed above to EPs meeting the 10 percent threshold for this measure.

Comment: There were several comments that doubted that the technology will be ready for providers to meet this measure. They did not believe there is enough vendor support to create, customize, and implement the changes necessary to meet the new measure. Commenters expressed concern that many of the technologies, from EHRs to HIEs and transmission standards, needed to enable electronic health information exchange currently do not exist.

Response: We disagree that it is premature to include this measure for Stage 2. We note that as an incentive program it is expected that the requirements will reach beyond what is commonplace today. Many organizations and providers are successfully engaged in electronic health information exchange today and by including this measure in meaningful use those established practices will be adopted by a greater number of providers.

Comment: A commenter suggested that ONC's certification rule was the appropriate place to ensure cross-vendor interoperability, not the Stage 2 measures and objectives.

Response: While we agree that meaningful use should be enabled by the capabilities included in certification, the concept of meaningful use is to incentivize the use of such capabilities not just the acquisition of them.

Comment: Commenters expressed two concerns on the limitation on the numerator that limited it to recipients with no organizational affiliation and using a different CEHRT vendor. First, there was concern that in some markets an organization or CEHRT vendor may control such a significant share of the market that meeting 10 percent is not possible. Second, even if the 10 percent threshold was feasible in a given market, one organization or CEHRT vendor may have enough market share

that the provider's referral patterns would inappropriately be influenced to give preference to those using different CEHRT vendors or outside their organizations. Commenters support appropriate information exchange between all providers, where clinically relevant, regardless of provider affiliations, but have these concerns on our proposed measure for this objective. Commenters presented several different solutions including removing one or both limitations, replacing the limitations with an error reporting system for instances where electronic health information exchange fails, moving the limitations to the denominator and providing exclusions for areas of high vendor or organizational market penetrations.

Response: We agree that the measure as proposed runs both risks stated by commenters. Of the solutions presented by commenters, one directly alleviates both of these concerns. In drafting the final rule, we considered moving the limitations from the numerator to the denominator of the measure, both concerns are addressed. For example, if a provider makes 500 referrals during the EHR reporting period, 400 of which are to providers that either are affiliated with the same organization or use the same CEHRT vendor, then only 100 referrals are even eligible for the proposed numerator. This creates a bar that is much higher than 10 percent, as 50 percent of the eligible instances must be electronically transmitted to meet the proposed measure in this example, which we agree has the possibility of influencing referral patterns. However, applying the limitations of ''no organizational affiliation'' and ''different CEHRT vendor'' to the denominator instead of the numerator would result, in this example, in a denominator of 100 referrals instead of 500 and a true 10 percent threshold. There would be no need to change referral patterns as there would be no negative effect on the threshold for having a referral partner either in the same organization or using the same CEHRT vendor. We firmly believe that this solution is the best measure of the type of health information exchange that we proposed to target and that is supported in principle by nearly all commenters. However, we are not including this solution in the final rule as explained in the response to the next set of comments. Instead, we are removing the organizational and vendor limitations from this measure solely due to the burden of making these determinations for measurement.

Comment: Many commenters expressed concern over the ability to measure this objective especially the organization and vendor limitations. Commenters who were providers expressed concern over the ability of their CEHRT vendor to measure this objective, while vendors of CEHRT expressed concern over the ability of providers to measure the objective. Combined, it appears that neither the provider nor the vendor believed they could even measure on their own and had concerns on their partners on which they placed their hopes for measurement.

Response: In the proposed rule we determined that the CEHRT would have to be able to make three determinations to successfully calculate the numerator for this measure: (1) Electronic transmissions sent using standards and those that are not; (2) transmissions that are sent to recipients with the same organizational affiliation or not; and (3) transmissions that are sent to recipients using the same EHR vendor or not. We stated that ONC will seek comment in their proposed certification rule as to the feasibility of this reporting requirement for certified EHR technologies. ONC received comments similar to ours that making the determinations for the numerator was infeasible particularly in regard to the organizational and vendor limitations. Therefore, we are removing the organizational and vendor limitations from this measure solely due to the burden of making these determinations for measurement. Commenters did not suggest difficulties with determining that the electronic transmission was sent using the specified standards. Therefore, we finalize the stipulation that CEHRT be used, including its accompanying standards for this measure (''measure 2'').

However, we are not abandoning all efforts to ensure that cross vendor electronic exchange is possible for all meaningful EHR users in Stage 2. As discussed in the prior comment and response, the only reason we are not finalizing the stipulations on the denominator is the measurement burden. We believe that a third measure is needed that reduces the burden relative to the proposed measure, but still ensures that all providers have implemented CEHRT in a way that enables them to electronically exchange summary of care documents with a recipient using EHR technology designed by a different vendor. Therefore, we have added a third measure (''measure 3'') that requires providers to use their CEHRT to either—

- Conduct one or more successful electronic exchanges of a summary of care document, which is counted in measure 2 with a recipient who has EHR technology designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or
- Conduct one or more successful tests with the CMS designated test EHR during the EHR reporting period.

For the first option in measure 3, the sender must verify that the recipient's technology used to receive the summary of care record was not designed by the same EHR technology developer that designed the sender's EHR technology certified to 45 CFR 170.314(b)(2).

With respect to the second option in measure 3, and recognizing past difficulties and lessons learned from a ''test'' oriented measure in Stage 1, we have collaborated with ONC and NIST to initiate a project that would result in a public facing (hosted online) ''test EHR'' with which EPs, eligible hospitals, and CAHs could engage in electronic exchange. We expect that most providers will satisfy the first option in the normal course of meeting measure 2. However, in those rare instances where that does not occur this other second option would give every EP, eligible hospital, or CAH an alternative method to meet measure 3 with minimal burden by successfully testing electronic exchange with the CMS-designated test EHR. If this second option is used, we clarify that the use of test information about a fictional patient that would be identical in form to what would be sent about an actual patient (for example, ''dummy data'') must be used for the purposes of conducting a test with the CMS-designated test EHR. Providers that use the same EHR technology certified to 45 CFR 170.314(b)(2) and share a network for which their organization either has operational control or license to use can conduct one test that covers all providers in the organization. For example, if a large group of EPs with multiple physical locations use the same EHR technology certified to 45 CFR 170.314(b)(2) and those locations are connected using a network that the group has either operational control of or license to use, then a single test would cover all EPs in that group. Similarly, if a provider uses an EHR technology that is hosted (cloud-based) on the developer's network, then a single test would allow all EPs, eligible hospitals and CAHs using the EHR technology that is hosted (cloud-based) on the developer's network to meet the measure.

While making this does impose a burden on the provider, we believe the burden is outweighed by the benefits of ensuring that every provider who

becomes a meaningful EHR user is capable of exchanging a summary of care document electronically regardless of who developed the sender's EHR and the recipient's EHR.

We also seek to note for readers that while we have significantly reduced this objective's burden from what we proposed in measure 2, we continue to believe that making vendor to vendor standards-based exchange attainable for all meaningful EHR users is of paramount importance. In that regard, and as we look toward meaningful use Stage 3, we will monitor the ease with which EPs, eligible hospitals, and CAHs engage in electronic exchange, especially across different vendors EHRs. If we do not see sufficient progress or that continued impediments exist such that our policy goals for standards-based exchange are not being met, we will revisit these more specific measurement limitations and consider other policies to strengthen the interoperability requirements included in meaningful use as well as consider other policies and regulations through which the Department could effect the outcome we seek. Finally, we also intend to consider future meaningful use requirements that increase expectations for standards-based exchange and make information that is exchanged more searchable and usable for a broad array of clinical purposes imperative to care improvement. We envision that these requirements would rely on metadata tagging as well as more dynamic methods of electronic health information exchange.

Comment: Commenters expressed support for including in this measure's numerator electronic transmissions enabled by query-based exchange models, including organizations using NwHIN Exchange specifications. The commenters indicated that NwHIN Exchange specifications are appropriate for exchange use cases not covered as well by the Direct standards, and use of either standard should be counted. This is particularly important in cases where the summary is pulled instead of pushed. Providers and organizations that are part of the NwHIN Exchange or other organizations using these standards should receive credit for those exchanges in meeting interoperability measures.

Response: In Stage 2, all providers should be able to use CEHRT to share summary of care records in a ''push'' manner to support safe transitions and informed referrals. ''Pull'' (query) transactions can also support these goals. By ''pull'' transactions we refer to instances where the receiving provider retrieves the summary of care document from a location outside their own CEHRT as opposed to ''push'' transactions where the referring or transitioning provider sends the summary of care document to the receiving provider. Thus, such transactions should be counted towards the numerator of the provider initiating the transitions or referrals when the recipient (the provider ''receiving'' the transition or referral) actually receives or downloads the patient's summary of care record relevant to the transition or referral. The act of uploading the summary of care record to a repository that *can* be queried by the recipient—without validation that this query in fact occurred will not be sufficient to count towards the numerator. While we acknowledge that there may not be a simple, universal way for this to be measured, we believe it is important to make this accommodation for those who elect to engage in this form of exchange. Therefore, we are revising the second measure to include in the sending provider's numerator instances where the recipient receives the summary of care record via exchange facilitated by an organization that is an NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. The referring or transitioning provider would use their CEHRT to generate a summary of care document and to provide it an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. More information on NwHIN Exchange participants is available at *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__nhin_exchange/1407*. ONC issued a request for information regarding a governance mechanism for the nationwide health information network that is available at 77 FR 28543.

After considering the comments received, we are modifying the second measure for EPs at § 495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs at § 495.6(l)(11)(ii)(B) to ''The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network.''

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 CEHRT at 45 CFR 170.314(b)(l) and (b)(2).

To calculate the percentage of the second 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 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 a) electronically transmitted using CEHRT to a recipient or b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. The organization can be a third-party or the sender's own organization.
- *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 is excluded from all three measures.

Third Measure: After considering the comments received, we are adding a third measure for EPs at § 495.6(j)(14)(ii)(C) and for eligible hospitals and CAHs at § 495.6(l)(11)(ii)(C) to ''An EP, eligible hospital or CAH must satisfy one of the two following criteria:

- Conducts one or more successful electronic exchanges of a summary of care document, which is counted in ''measure 2'' (for EPs the measure at § 495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs the measure at § 495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or
- Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

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 CEHRT at 45 CFR 170.314(b)(2).

• *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 is excluded from all three measures.

(c) Public Health Objectives

General Public Health Discussion

In the proposed rule, due to similar considerations among the public health objectives, we discussed them together. Some Stage 2 public health objectives are proposed to be in the core set while others are proposed to be in the menu set. Each objective is identified as either core or menu in the following discussion.

• Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

• Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

• Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

• Capability to identify and report cancer cases to a state cancer registry except where prohibited, and in accordance with applicable law and practice.

• Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

We proposed the following requirements, which will apply to all of the public health objectives and measures. We proposed that actual patient data is required for the meaningful use measures that include ongoing submission of patient data.

We discussed in the proposed rule situations where PHAs partner with health information exchange (HIE) organizations to facilitate the submission of public health data electronically from EHRs. As we stated in guidance for Stage 1, (see FAQ #10764 at: *https://questions.cms.hhs.gov*) we clarified that such arrangements with HIE organizations, if designated by the PHA to simply transport the data, but not transforming content or message format (for example, HL7 format), are acceptable for the demonstration of meaningful use. Alternatively, if the intermediary is serving as an extension of the EP, eligible hospital or CAH's CEHRT and performing capabilities for which certification is required (for example, transforming the data into the required standard), then that functionality must be certified in accordance with the certification program established by ONC. In this situation, the EP, eligible hospital or CAH must still ensure the accomplishment of ongoing submission of reports to the actual immunization information system or registry (whether performed by the intermediary or not), except in situations when the PHA has explicitly designated delivery of reports to the intermediary as satisfying these requirements.

We proposed that an eligible provider is required to utilize the transport method or methods supported by the PHA in order to achieve meaningful use.

Unlike in Stage 1, under our proposed Stage 2 criteria a failed submission will not meet the objective. An eligible provider must either have successful ongoing submission or meet an exclusion criterion.

We stated in the proposed rule that we expect that CMS, CDC and PHAs will establish a process where PHAs will be able to provide letters affirming that the EP, eligible hospital or CAH was able to submit the relevant public health data to the PHA. This affirmation letter could then be used by the EP, eligible hospital or CAH for the Medicare and Medicaid meaningful use attestation systems, as well as in the event of any audit. We requested comments on challenges to implementing this strategy.

We proposed to accept a yes/no attestation and information indicating to which PHA the public health data were submitted to support each of the public health meaningful use measures.

Comment: Commenters asked for clarification of ongoing submission; additionally, due to the amount of time needed to prepare for submission of data, commenters asked for clarification on the timing to determine if a public health authority has the capacity to accept electronic data for ongoing submission. Other commenters noted that being ''in queue'' or in the process of validation for ongoing submission should count as meeting this measure. Commenters also noted that credit should be given for having moved into ongoing submission during Stage 1.

Response: To clarify the timing issue, the EP or hospital must determine if the PHA has the capacity to accept electronic data using the specification prescribed by ONC for the public health information for the objectives of meaningful use within the first 60 days of the EHR reporting period. If the PHA does not have the capacity to accept reporting (including situations when the PHA accepts electronic data but states it lacks capacity to enroll the EP, eligible hospital or CAH during that reporting period), the EP or hospital can claim an exclusion for this measure related to the data that cannot be accepted. In determining whether the PHA has the capacity, CMS anticipates developing a centralized repository for this information, including a deadline for the PHA to submit information. If the PHA fails to provide information to this centralized repository by the deadline, the provider could claim the exclusion. In the event, that we are unable to develop a centralized repository, providers will make the determination of PHA capacity by working directly with the PHA as is currently the case for Stage 1 of meaningful use. If the PHA does have the capacity, the measure may be satisfied through any of the following general public health criteria:

• Ongoing submission was already achieved for an EHR reporting period in a prior year and continues throughout the current EHR reporting period using either the current standard at 45 CFR 170.314(f)(1) and (f)(2) or the standards included in the 2011 Edition EHR certification criteria adopted by ONC during the prior EHR reporting period when ongoing submission was achieved.

• Registration with the PHA or other body to whom the information is being submitted of intent to initiate ongoing submission was made by the deadline (within 60 days of the start of the EHR reporting period) and ongoing submission was achieved.

• Registration of intent to initiate ongoing submission was made by the deadline and the EP or hospital is still engaged in testing and validation of ongoing electronic submission.

• Registration of intent to initiate ongoing submission was made by the deadline and the EP or hospital is awaiting invitation to begin testing and validation.

The measure will not be met if the provider—

• Fails to register their intent by the deadline; or

• Fails to participate in the on-boarding process as demonstrated by failure to respond to the PHA written requests for action within 30 days on two separate occasions.

Comment: Several commenters expressed concern that no data transport mechanism was included in the Stage 2 rule and/or EHR certification. Some expressed concern that the lack of a

standard may result in EPs paying more for interfaces than received in incentive payments. Other commenters supported including no transport mechanism to allow maximum flexibility for public health authorities.

Response: While we understand the concern of supporting multiple transport mechanisms, in order for data to flow to public health authority, vendors must support the transport mechanism utilized by the public health authority to which the EP or hospital reports. Public health authorities have moved to standardize transport mechanisms where feasible, and Health Information Exchanges are often facilitating the transport of data to public health. We stand by our policy that allows public health authorities to dictate the transport mechanism in their jurisdiction. Further, we clarify that this is independent of the EHR certification criteria as EHR certification does not address transport for public health objectives.

Comment: Commenters suggested that the expectation that public health agencies provide affirmation letters is too restrictive in accomplishing the goal of established a record of communication between the provider and the PHA. They maintain that there are simpler and less burdensome ways such as automated acknowledgment messages from immunization submissions.

Response: We agree that our proposal requiring it must be a letter is too restrictive and revise our expectation to allow for any written communication (which may be in electronic format) from the PHA affirming that the EP, eligible hospital or CAH was able to submit the relevant public health data to the PHA.

Comment: Commenters requested greater clarification on what is meant by ongoing submission. Some suggested that it be transitioned to a percentage measurement as with other objectives of meaningful use.

Response: We do not agree that a transition to a percentage measurement best serves the public health objectives. First, a percentage measure would only be applicable to those engaged in ongoing submission, and as indicated in an earlier response, we are allowing four different situations to meet the measure. Second, we believe that the requirement to submit information would be under applicable law, the agreements between the provider and PHA, or through meaningful use which requires submissions except where prohibited, so it is not necessary for meaningful use to monitor the already mandated submission. For greater clarification, we describe successful ongoing submission as electronic submission of reportable data during the normal course of a provider's operations. This is not to say all data that is reportable is sent to the PHA. A provider who is submitting any reportable data during their normal course of their operations is engaged in ongoing submission. A provider that can only submit reportable data in a test environment or other circumstance that is not part of their normal operations would not be engaged in ongoing submission.

Where a measure states ''in accordance with applicable law and practice,'' this reflects that some public health jurisdictions may have unique requirements for reporting and that some may not currently accept electronic data reports. In the former case, the proposed criteria for this objective will not preempt otherwise applicable state or local laws that govern reporting. In the latter case, EPs, eligible hospitals, and CAHs will be excluded from reporting.

Comment: Several commenters requested the removal of ''except where prohibited'' from the objective, while others expressed support for this phrase. Those that did not support note that CMS does not have the authority to direct reporting if not required by law or regulations, while supporters applauded CMS for supporting reporting where allowed but not required by law. Several commenters suggested removing the phrase ''in accordance with applicable law,'' while other commenters wrote in support of the addition of the phrase.

Response: We disagree with the commenters suggesting removal of these phrases and will keep them as part of the final rule. The phrase ''except where prohibited'' is meant to allow exemptions from reporting for providers who cannot by law report to the public health authority within their jurisdiction. For example, a sovereign Indian Nation may not be permitted to report immunization registry data to the public health authority in their jurisdiction. The phrase is meant to encourage reporting if a provider is authorized to do so. The ''in accordance with applicable law'' phrase allows public health authorities to utilize their existing laws and regulations for reporting.

Proposed Objective: Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

We proposed to include this objective in the Stage 2 core set for EPs, eligible hospitals and CAHs as recommended by the HITPC. We discussed in the proposed rule that the Stage 1 objective and measure acknowledged that our nation's public health IT infrastructure is not universally capable of receiving electronic immunization data from CEHRT, either due to technical or resource readiness. Immunization programs, their reporting providers and federal funding agencies, such as the CDC, ONC, and CMS, have worked diligently since the passage of the HITECH Act in 2009 to facilitate EPs, eligible hospitals and CAHs ability to meet the Stage 1 measure. We proposed for Stage 2 to take the next step from testing to requiring actual submission of immunization data. In order to achieve improved population health, providers who administer immunizations must share that data electronically, to avoid missed opportunities or duplicative vaccinations. Stage 3 is likely to enhance this functionality to permit clinicians to view the entire immunization registry/immunization information system record and support bi-directional information exchange.

We proposed that the threshold for Stage 2 should move from simply testing the electronic submission of immunization data (with follow-up submission if the test is successful) to ongoing submission. However, we asked for comments on the challenges that moving this objective from the menu set to the core set would present for EPs and hospitals.

Comment: Some commenters suggested that the term immunization information systems was all encompassing making the inclusion of immunization registries redundant.

Response: We agree that an information system could include registries; however, we do not believe that modifying the objective serves a distinct purpose and could confuse those accustomed to the term immunization registries.

Comment: Commenters, although supportive of moving immunization registry reporting from menu to core, expressed concern that PHAs did not have the capacity to accept electronic data from additional providers.

Response: We agree that not all PHAs will have the resources to onboard providers for immunization registry reporting. The final rule allows for an EP or hospital to be excluded from the measure if they operate in a jurisdiction for which no immunization registry is capable of accepting data. We further clarify that this exception applies not only if the technical capacity to receive the data does not exist, but also if the resources are not available within the

public health authority to initiate ongoing submission with the EP or hospital. We also permit (as earlier stated) an EP or hospital to meet the measure so long as they have registered to submit and are either still in the process of testing and validation (within the time limits established earlier), or are still awaiting an invitation to begin submission.

Comment: Numerous commenters encouraged the inclusion of bidirectional exchange of data with immunization registries. Many commenters noted that the EP or eligible hospital cannot take advantage of rich data and clinical decision support contained within an immunization registry without bidirectional exchange.

Response: While we agree that the need for bidirectional data exchange is clear, this measure aligns more with the goals of Stage 3 meaningful use stated in the proposed rule. Additionally, the standards and mechanisms for bidirectional data exchange need to be more standardized across public health authorities.

After consideration of the public comments received, we are finalizing this objective for EPs at § 495.6(j)(15)(i) and for eligible hospitals and CAHs at § 495.6(l)(12)(i) as proposed.

Proposed Measure: Successful ongoing submission of electronic immunization data from CEHRT to an immunization registry or immunization information system for the entire EHR reporting period.

Comment: Many commenters noted the lack of national standards for the collection of immunization data with specific examples such as CVS versus MVX coding vocabularies and also noted the need for centralized data collection at a national level. Commenters noted that the lack of standardization results in cost-prohibitive compliance with this measure.

Response: We agree that during the implementation of Stage 1 reporting of immunization data, the need for a more harmonized standard for immunization reporting was highlighted. To address this issue, the option of using version HL7 2.3.1 versus 2.5.1 for certification was removed and now only an HL7 2.5.1 message can be used for Stage 2 reporting of immunization data. The implementation guide for HL7 2.5.1 has been updated to remove much of the variability across states for immunization registry reporting. However, if EPs prior to CY 2014 and eligible hospitals and CAHs prior to FY2014 have achieved successful ongoing submission using EHR technology certified to the 2011 Edition EHR certification criteria (HL7 2.3.1 only) it is acceptable to continue this ongoing submission and meet the Stage 2 measure for as long as HL7 2.3.1 continues to be accepted by the immunizations information system or immunization registry. EPs and eligible hospitals and CAHs conducting submissions using HL7 2.5.1 will be able to get their arrangement certified to the 2014 Edition EHR certification criteria.

After consideration of the public comments received, we are finalizing this measure at for EPs at 495.6(j)(15)(ii) and for eligible hospitals and CAHs at 495.6(l)(12)(ii) as proposed, but we modify the exclusions to conform with the general criteria for public health objectives and to address redundancy in two of the proposed exclusions. In the general criteria for public health objectives section we established a centralized repository of information about PHA capacity. If a PHA does not provide capacity information to this repository in time for it to be made available to providers at the start of their EHR reporting period, then the providers in that PHA's jurisdiction will meet the modified exclusion. We proposed two exclusions: (1) The EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of receiving electronic immunization data in the specific standards required for CEHRT at the start of their EHR reporting period; and (2) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the version of the standard that the EP, eligible hospital or CAH's CEHRT can send at the start of their EHR reporting period. In both cases the limitation is the ability of the immunization registry or immunization information system to receive immunization data in the standards required by ONC for EHR certification in 2014. Therefore, we are combining these exclusions.

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 CEHRT at 45 CFR 170.314(f)(1) and (f)(2). However, if EPs prior to CY 2014 and eligible hospitals and CAHs prior to FY 2014 have achieved successful ongoing submission using EHR technology certified to the 2011 Edition EHR certification criteria (HL7 2.3.1 only), it is acceptable to continue this ongoing submission and meet the Stage 2 measure for as long as HL7 2.3.1 continues to be accepted by the immunizations information system or immunization registry. We note that our decision to continue to permit the use of EHR technology certified to the 2011 Edition EHR certification criteria is a special circumstance and emphasize that EPs, eligible hospitals, and CAHs will still need EHR technology certified to the 2014 Edition EHR certification criteria in order to meet the CEHRT definition beginning with the FY/CY 2014 EHR reporting period.

- *Exclusions:* Any EP, eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) The EP, eligible hospital or CAH does not administer any of the 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) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for CEHRT at the start of their EHR reporting period (3) the EP, eligible hospital or CAH operates in a jurisdiction where no immunization registry or immunization information system provides information timely on capability to receive immunization data; or (4) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system that is capable of accepting the specific standards required by CEHRT at the start of their EHR reporting period can enroll additional EPs, eligible hospitals or CAHs.

The second exclusion will not apply if an entity designated by the immunization registry or immunization information system can receive electronic immunization data submissions. For example, if the immunization registry cannot accept the data directly or in the standards required by CEHRT, but if it has designated a Health Information Exchange to do so on their behalf and the Health Information Exchange is capable of accepting the information in the standards required by CEHRT, the provider could not claim the second exclusion.

Proposed Eligible Hospital/CAH Objective: Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

We proposed that this objective is in the Stage 2 core set for eligible hospitals and CAHs. The same rationale for the

proposed changes between this proposed objective and that of Stage 1 are discussed earlier under the immunization registry objective. Please refer to that section for details on our proposals in this regard.

Comment: Commenters, although supportive of moving electronic laboratory reporting from menu to core, expressed concern that PHAs did not have the capacity to accept electronic data from additional providers.

Response: We agree that not all PHAs will have the resources to onboard providers for electronic laboratory reporting. The final rule allows for an EP, eligible hospital or CAH to be excluded from the measure if they operate in a jurisdiction for which no public health authority is capable of accepting electronic laboratory data. We further clarify that this exception applies not only if the technical capacity to receive the data does not exist, but also if the resources are not available within the public health authority to initiate ongoing submission with the EP, eligible hospital or CAH. We also permit (as earlier stated) an EP, eligible hospital or CAH to meet the measure so long as they have registered to submit and are either still in the process of testing and validation, or are still awaiting an invitation to begin submission.

Comment: Many commenters noted that lack of standards for reporting electronic laboratory data to public health authorities and also noted the variety of transport methods needed to support reporting to public health.

Response: ONC has adopted an updated implementation guide for electronic laboratory reporting from EHR technology in its 2014 Edition EHR certification criteria. Additionally, the Centers for Disease Control and Prevention in coordination with the Council of State and Territorial Epidemiologists have created the national Reporting Condition Mapping Table (*http://www.cdc.gov/EHRmeaningfuluse/rcmt.html*) that provides further guidance on appropriate vocabularies usable for reportable conditions across the country for reporting of ELR data.

Comment: Several commenters wrote in favor of expansion of this requirement to be inclusive of the surveillance of healthcare associated infections (HAI).

Response: While we agree that the reporting of healthcare associated infections is a critical part of public health surveillance, the methods and standards for reporting this information require very different standards for electronic laboratory reporting of reportable conditions. This measure aligns more with the goals of Stage 3 meaningful use.

Comment: Numerous commenters suggested that Electronic Laboratory Reporting is outside the scope of EHRs and should be excluded from the objectives. These commenters note that laboratory information systems (LIMS) already have ELR capabilities, and most EHRs do not. One commenter expressed concern that reporting from both laboratories and providers may cause duplicate reporting of a single case. The same commenter stated that many LIMS systems already have functionality to identify which laboratory results need to be reported to public health, which EHRs do not, and that building that capability into EHRs would be duplicative and burdensome.

Response: We disagree with the statement that ELR is ''outside the scope of EHRs and should be excluded'' because we share ONC's broad interpretation of the term EHR technology. Eligible Hospitals can choose to report data directly from any kind of EHR technology that has been certified to the certification criteria adopted by ONC. This could include EHR technology from a single EHR technology developer, a separate modularly certified component such as a LIMS certified as an EHR Module, or the technical capability offered by an HIE that is certified as an EHR Module for electronic laboratory reporting.

After consideration of the public comments, we are finalizing this objective for eligible hospitals and CAHs at 495.6(l)(13)(i) as proposed.

Proposed Eligible Hospital/CAH Measure: Successful ongoing submission of electronic reportable laboratory results from CEHRT to a public health agency for the entire EHR reporting period as authorized, and in accordance with applicable State law and practice.

Please refer to the general public health discussion regarding use of intermediaries.

Most comments received related to this measure have been addressed in the discussion of public health objectives in general or in the discussion of the objective associated with this measure.

Comment: Commenters pointed out that the proposed measure includes the statement ''as authorized, and in accordance with applicable State law and practice.'' Some commenters believed the phrase was simply redundant to the objective and was inconsistent with the other public health measures. Other commenters expressed concern that the addition of the phrase implied a more restrictive measure than other public health measures particularly with the limit to state law as opposed to just law.

Response: We agree with commenters that this phrase is redundant to the objective and may introduce confusion. Therefore, we are revising this measure to remove the phrase and make it consistent with the other public health measures.

Based on consideration of those comments, we are modifying this measure for eligible hospitals and CAHs at § 495.6(l)(13)(ii) to successful ongoing submission of electronic reportable laboratory results from CEHRT to a public health agency for the entire EHR reporting period.'' We also modify the exclusions to conform with the general criteria for public health objectives. In the general criteria for public health objectives, we plan to establish a centralized repository of PHA capacity information. If a PHA does not provide capacity information to this repository in time for it to be made available to providers at the start of their EHR reporting period, then the providers in that PHA's jurisdiction will meet the modified exclusion. If the repository is not established, the eligible hospital or CAH must consult their PHA jurisdiction for guidance.

We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(f)(4).

• *Exclusions:* The eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) operates in a jurisdiction for which no public health agency is capable of receiving electronic reportable laboratory results in the specific standards required for Certified EHR Technology at the start of the EHR reporting period; (2) operates in a jurisdiction where no public health agency provides information timely on capability to receive electronic reportable laboratory results or (3) the eligible hospital or CAH operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by CEHRT at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

Proposed Objective: Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.

We proposed that this objective is in the Stage 2 core set for eligible hospitals and CAHs and the Stage 2 menu set for EPs. The Stage 1 objective and measure

acknowledged that our nation's public health IT infrastructure is not universally capable of receiving syndromic surveillance data from CEHRT, either due to technical or resource readiness. Given public health IT infrastructure improvements and new implementation guidance, for Stage 2, we proposed that this objective and measure be in the core set for hospitals and in the menu set for EPs. It is our understanding from hospitals and the CDC that many hospitals already send syndromic surveillance data. The CDC has issued the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data [*http://www.cdc.gov/ehrmeaningfuluse/Syndromic.html*] as cited in the ONC final rule on EHR standards and certification. However, per the CDC and a 2010 survey completed by the Association of State and Territorial Health Officials (ASTHO), very few public health agencies are currently accepting syndromic surveillance data from ambulatory, non-hospital providers, and there is no corresponding implementation guide at the time of this final rule. CDC is working with the syndromic surveillance community to develop a new implementation guide for ambulatory and inpatient discharge reporting of syndromic surveillance information, which it expects will be available in the spring 2013. We anticipate that Stage 3 might include syndromic surveillance for EPs in the core set if the collection of ambulatory syndromic data becomes a more standard public health practice in the interim.

The HIT Policy Committee recommended making this a core objective for Stage 2 for EPs and hospitals. However, we did not propose to adopt their recommendation for EPs. We specifically invited comment on the proposal to leave syndromic surveillance in the menu set for EPs, while requiring it in the core set for eligible hospitals and CAHs.

Comment: Commenters noted that keeping the objective as menu for EPs is still problematic as most public health agencies are unable to accept the data. Commenters also expressed that for providers that are already reporting this objective, it makes sense to keep it as a menu set option.

Response: We agree that although not all public health authorities are able to accept syndromic surveillance data from Eligible Professionals, since many EPs already report this measure and some public health authorities have the ability to accept this data, the measure will remain as a menu set option.

Comment: Commenters noted that moving the objective as core is premature due to public health readiness. Commenters also expressed that for hospitals that have already reporting this objective, it makes sense to move the measure to core.

Response: We agree that not all public health authorities are able to accept syndromic surveillance data from hospitals; however, our exclusion criteria addresses this situation. Since many hospitals already report this measure and many public health authorities have the ability to accept this data, the measure will remain as core. If there are no public health authorities for the hospitals to report syndromic surveillance data to, the hospital can claim an exemption.

Comment: Many commenters noted that lack of standards for reporting syndromic surveillance data to public health authorities.

Response: While a single national implementation guide exists for syndromic surveillance data of emergency department data from hospitals, currently an implementation guide does not exist for syndromic surveillance reporting from the eligible professional. The Centers for Disease Control and Prevention is working in conjunction with the International Society for Disease Surveillance and draft guidance is currently available for the reporting of ambulatory based syndromic surveillance.

Comment: Several comments expressed concern about the level of reporting. Concern was expressed from entities with multiple locations that would need to report by facility or provider lever rather than as an organization.

Response: Currently public health departments that collect syndromic surveillance data streamline the data collection process and collect data at an organization or facility level depending on the provider. Syndromic surveillance data is not collected at the provider level, although attestation would be at the provider level where reporting by a single organization or facility could count for multiple providers.

After consideration of the public comments received, we are finalizing this objective for EPs in the menu set at § 495.6(k)(3)(i) and for eligible hospitals and CAHs in the core set at § 495.6(l)(14)(i) as proposed.

Proposed Measure: Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period.

All comments received related to this measure have been addressed in the discussion of public health objectives in general or in the discussion of the objective associated with this measure. After consideration of these public comments, we are finalizing this measure as proposed for EPs in the menu set at § 495.6(k)(3)(ii) and for eligible hospitals and CAHs in the core set at § 495.6(l)(14)(ii) as proposed, but we modify the exclusions to conform with the general criteria for public health objectives and to address redundancy in two of the proposed exclusions. In the general criteria for public health objectives, we plan to establish a centralized repository of PHA capacity information. If a PHA does not provide capacity information to this repository in time for it to be made available to providers at the start of their EHR reporting period, then the providers in that PHA's jurisdiction will meet the modified exclusion. We proposed two exclusions: (1) The EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period; and (2) the EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of accepting the version of the standard that the EP's, eligible hospital's or CAH's CEHRT can send at the start of their EHR reporting period. In both cases the limitation is the ability of the PHA to receive syndromic surveillance data in the standards required by ONC for EHR certification in 2014. Therefore, we are combining these exclusions.

We expect that the CDC will be issuing (in Spring 2013) the CDC PHIN Messaging Guide for Ambulatory Syndromic Surveillance and we may rely on this guide to determine which categories of EPs will not collect such information.

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 CEHRT at 45 CFR 170.314(f)(3). However, if EPs prior to CY 2014 and eligible hospitals and CAHs prior to FY 2014 have achieved successful ongoing submission using EHR technology certified to the 2011 Edition EHR certification criteria (HL7 2.3.1 only), it is acceptable to continue this ongoing submission and meet the Stage 2 measure for as long as HL7 2.3.1 continues to be accepted by the PHA in that jurisdiction. We note that our decision to continue to permit the use of EHR technology certified to the 2011 Edition EHR certification criteria is a special circumstance and

emphasize that EPs, eligible hospitals, and CAHs will still need EHR technology certified to the 2014 Edition EHR certification criteria in order to meet the CEHRT definition beginning with the FY/CY 2014 EHR reporting period.

• *Exclusions:* Any EP, eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) the EP is not in a category of providers that collect ambulatory syndromic surveillance information on their patients during the EHR reporting period; (2) the eligible hospital or CAH does not have an emergency or urgent care department; (3) the EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required by CEHRT at the start of their EHR reporting period; (4) the EP, eligible hospital or CAH operates in a jurisdiction where no public health agency provides information timely on capability to receive syndromic surveillance data; or (5) the EP, eligible hospital or CAH operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by CEHRT at the start of their EHR reporting period can enroll additional EPs, eligible hospitals or CAHs.

As was described under the immunization registry measure, the third and fourth exclusions do not apply if the PHA has designated an HIE organization or other intermediary to collect this information on its behalf and that intermediary can do so in the specific Stage 2 standards and/or the same standard as the provider's CEHRT. An urgent care department delivers ambulatory care, usually on an unscheduled, walk-in basis, in a facility dedicated to the delivery of medical care, but not classified as a hospital emergency department. Urgent care centers are primarily used to treat patients who have an injury or illness that requires immediate care but is not serious enough to warrant a visit to an emergency department. Often urgent care centers are not open on a continuous basis, unlike a hospital emergency department, which will be open at all times.

(d) New Core and Menu Set Objectives and Measures for Stage 2

We proposed the following objectives for inclusion in the core set for Stage 2: ''Provide patients the ability to view online, download, and transmit information about a hospital admission'' and ''Automatically track medication orders using an electronic medication administration record (eMAR)'' for hospitals; ''Use secure electronic messaging to communicate with patients'' for EPs. We proposed all other new objectives for inclusion in the menu set for Stage 2. While the HIT Policy Committee recommended making all objectives mandatory and eliminating the menu option, we believe a menu set is necessary for some of these new objectives in order to give providers an opportunity to implement new technologies and make changes to workflow processes and to provide maximum flexibility for providers in specialties that may face particular challenges in meeting new objectives.

Proposed Objective: Imaging results and information are accessible through CEHRT.

In the proposed rule, we outlined the following benefits for this objective. Making the image that results from diagnostic scans and accompanying information accessible through CEHRT increases the utility and efficiency of both the imaging technology and the CEHRT. The ability to share the results of imaging scans will likewise improve the efficiency of all health care providers and increase their ability to share information with their patients. This will reduce the cost and radiation exposure from tests that are repeated solely because a prior test is not available to the provider.

We stated in the proposed rule that most of the enabling steps to incorporating imaging relate to the certification of EHR technologies. As with the objective for incorporating lab results, we encourage the use of electronic exchange to incorporate imaging results into the CEHRT, but in absence of such exchange it is acceptable to manually add the image and accompanying information to CEHRT.

Comment: Some commenters expressed concerns over the ability of CEHRT to store the images.

Response: We did not propose that CEHRT store the images. Storing the images natively in CEHRT is one way to make them accessible through CEHRT, but there are many other ways.

Comment: Commenters stated that unless a HIE organization existed to facilitate imaging exchange, building out an unique interface for each imaging provider is cost prohibitive. Second, commenters were concerned that because stand-alone radiology centers are not subject to the EHR Incentive Program they may not agreeing to provide their images electronically to the provider through their EHR. These commenters therefore suggest that it is premature to include this objective.

Response: We agree that many advances in infrastructure are needed to fully enable this objective. We believe that from publication of this final rule to the start of Stage 2 significant progress will be made in part due to the inclusion of this objective in Stage 2. We do agree that these improvements in infrastructure will vary based on local conditions such as the presence of HIEs, the willingness of radiology centers to link to EHRs, and other factors and note that is a primary reason for this being a menu objective. We will also consider these comments below in relation to setting the threshold for the measure.

Comment: The resolution required for viewing imaging for diagnostic purposes requires specific hardware which would be cost prohibitive for all EPs. CMS should clarify that the image can be of any resolution.

Response: We do not impose limitations on the resolution of the image. To the extent this is a concern, it would be a capability of CEHRT not a requirement of meaningful use.

Comment: Commenters requested clarification on whether both the image itself and the accompanying results and information must be available, or just one or the other.

Response: The objective as proposed was intended to convey that the image itself is the result and that narratives/explanations and other information would be the additional information. Due to the many comments we received requesting clarification, we are revising the objective for clarity.

Comment: Commenters requested a more specific definition of imaging.

Response: We believe that imaging is a well understood term in the provider community. However, we agree that a more specific definition is required for purposes of measuring meaningful use. We adopt the description of radiology services from the Stage 2 CPOE objective as the minimum description of imaging. Providers are free to use a more expansive definition of imaging.

After review of the comments, we are revising the objective for EPs at 495.6 (k)(1)(i) and for eligible hospitals and CAHs at 495.6(m)(2)(i) to ''Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT.''

Proposed Measure: More than 40 percent of all scans and tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the

EHR reporting period are accessible through CEHRT.

For Stage 2, we did not propose the image or accompanying information (for example, radiation dose) be required to be structured data. Images and imaging results that are scanned into the CEHRT may be counted in the numerator of this measure. We defined accessible as either incorporation of the image and accompanying information into CEHRT or an indication in CEHRT that the image and accompanying information are available for a given patient in another technology and a link to that image and accompanying information. Incorporation of the image means that the image and accompanying information is stored by the CEHRT. We did not propose that meaningful use would impose any additional retention requirements on the image. A link to the image and accompanying information means that a link to where the image and accompanying information is stored is available in CEHRT. This link must conform to the certification requirements associated with this objective in the ONC final rule published elsewhere in this issue of the **Federal Register**. We encouraged comments on the necessary level of specification and what those specifications should be to define accessible and what constitutes a direct link.

Comment: Commenters suggested that the proposed threshold of 40 percent was too high given the dependency on the image provider and electronic exchange infrastructure discussed in the objective. The most popular suggested threshold was 10 percent. Commenters also suggested that an exclusion be created for providers who have no access to electronic images. A few of the commenters pointed to the lack of an imaging provider that could make electronic images available. Others were concerned that when a provider uses multiple imaging providers, 40 percent might be too high of a threshold even if at least one imaging provider that could make electronic images available.

Response: After reviewing the comments, we agree that 40 percent is too high of a threshold for this measure and revise it to 10 percent. Providers, especially EPs, may use many imaging providers, and we do not want an EP to have to defer this objective simply because they have three imaging providers, and the one allowing electronic access represents less than 40 percent of their orders. The comment regarding complete lack of an imaging provider that could make electronic images available speaks to the need for an exclusion. In considering an exclusion for those providers who have no access to electronic images, we take into account that it is a menu objective and also that there may be providers who fall into a situation where access is more than zero, but less than 10 percent. In regards to the menu, while it is true that a provider may defer this measure, the number of measures in the menu set are fewer and more specialized than in Stage 1. Furthermore, as an exclusion no longer counts towards meeting a menu objective, we are not concerned providers would choose this objective only to exclude it. For this reason, we are finalizing an exclusion for providers who have no access to electronic images. For those who cannot meet the 10 percent threshold even with access to an imaging provider who makes electronic images available, deferral remains a possibility as well as shifting more orders to imaging providers that do allow electronic access.

Comment: Several commenters disagreed with the proposed exclusion for EPs and believed it was inconsistent with the objective. These commenters believe the objective is intended for EPs who order imaging, whether or not they interpret the imaging studies themselves. These commenters suggested changing the exclusion to ''Any EP who orders (less than 100/50/no) diagnostic scans or tests whose result is an image during the EHR reporting period''.

Response: Our intention with the proposed exclusion was to distinguish between ordering providers who have need of the image and those that do not. Based on the comments the need to view the image depends on a combination of factors including previous experiences with the type of image, the imaging facility, the circumstances of the patient, whether a similar image has been ordered before for the patient and the reading clinician. Given the wide variety of factors, we agree that it is not possible to create a distinct line between ordering providers who need the image and those that do not. We believe this line can be partly drawn by adopting the exclusion recommended by comments with a high count of 100. This is both consistent with our other objectives and as a high number indicates a particular benefit to the provider as well as increasing the likelihood that factors align for the ordering provider to need the image.

Comment: Commenters stated that the use of the term ''scan'' is confusing and unnecessary. Scan frequently applies to actions and concepts other than certain types of imaging procedures.

Response: We agree that the term scan has multiple uses, as any scan would be an image and could be classified as a test. Therefore, we remove the word scan from the measure as duplicative.

After reviewing the comments, we modify the measure for EPs at § 495.6 (k)(1)(ii) and for eligible hospitals and CAHs at § 495.6(m)(2)(ii) to: More than 10 percent of all tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period are accessible through CEHRT.

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 CEHRT at 45 CFR 170.314(a)(12).

To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

- *Denominator:* Number of tests whose result is one or more images ordered by the EP or by an authorized provider on behalf of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period.
- *Numerator:* The number of results in the denominator that are accessible through CEHRT.
- *Threshold:* The resulting percentage must be more than 10 percent in order to meet this measure.
- *Exclusion:* Any EP who orders less than 100 tests whose result is an image during the EHR reporting period; or

Any EP who has no access to electronic imaging results at the start of the EHR reporting period.

No access means that none of the imaging providers used by the EP provide electronic images and any explanation or other accompanying information that are accessible through their CEHRT at the start of the EHR reporting period.

We solicited comments on a potential second measure for this objective that would encourage the exchange of imaging and results between providers. We considered a threshold of 10 percent of all scans and tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period and accessible through CEHRT also be exchanged with another provider of care.

Comment: While most commenters agree with the principle of exchange of images among providers of care, they nearly all agreed that this measure would be premature for Stage 2 due to

infrastructure concerns. Some suggested that it be considered for Stage 3 as a logical next step from our proposed Stage 2 measure.

Response: Given the comments, we are not including this measure in our final rule. We will consider the input provided when we develop our proposal for Stage 3.

Proposed Objective: Record patient family health history as structured data

In the proposed rule, we noted that every provider currently requests a family health history from the patient in order to obtain it. However, EHRs can allow the patient to contribute directly to the record and allow the record to be shared among providers, thereby greatly increasing the efficiency of collecting family health histories. Family health history is a major risk indicator for a variety of chronic conditions for which effective screening and prevention tools are available.

Comment: Commenters generally supported the inclusion of recording family health history as a menu set measure for EPs, eligible hospitals and CAHs, while some suggested deferring the measure until Stage 3 when they expect more robust standards will be available. Some commenters also suggested family health history is best collected by primary care physicians, not hospitals. Others still suggested modifying this objective to allow for the use of unstructured data.

Response: ONC has adopted standards requiring CEHRT to be able to use SNOMED–CT or the HL7 Pedigree standard to record a patient's family health history. We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register**. As a readily available standard is being adopted, we are maintaining this objective as proposed and including it in the menu set. We continue to believe that family history is part of regular physician and hospital workflow—even if it's collected at a very high level. While it may primarily be the physicians working in the hospital that consider this information, these same physicians typically use the hospital EHR when evaluating their hospitalized patients so having this information in the hospital EHR is just as important as having it in the physician's own EHR. We will also finalize the exclusion for EPs who have no office visits during the EHR reporting period to account for scope of practice concerns and the common collection of this information directly from patients.

After consideration of public comments, we are finalizing this objective for EPs at § 495.6 (k)(2)(i) and for eligible hospitals and CAHs at § 495.6(m)(3)(i) as proposed.

Proposed Measure: More than 20 percent of all unique patients seen by the EP, or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.

We proposed to adopt the definition of first degree relative used by the National Human Genome Research Institute of the National Institutes of Health. A first degree relative is a family member who shares about 50 percent of their genes with a particular individual in a family. First degree relatives include parents, offspring, and siblings. We considered other definitions, including those that address both affinity and consanguinity relationships and encourage comments on this definition. We noted that this is a minimum and not a limitation on the health history that can be recorded. We did not propose a time limitation on the indication that the family health history has been reviewed. The recent nature of this capability in EHRs will impose a de facto limitation on review to the recent past.

We proposed an exclusion to this measure for EPs who have no office visits during the EHR reporting period. We believe that EPs who do not have office visits will not have the face-to-face contact with patients necessary to obtain family health history information.

Comment: Many commenters wondered why recording family health history was limited to first-degree relatives. They noted that a patient's grandparents or other relatives may have equally relevant medical information that should be included in the EHR. Other commenters pointed out that not all patients may know their family health history, particularly patients who were adopted, and suggested including a code for ''unknown'' or ''not relevant.'' They noted that in some cultures, the patient may not be willing to provide the data or that the data they have may be unreliable (such as informal adoptions in Native American tribes).

Response: While information about second degree relatives may be useful for some diagnoses and conditions, we believe collecting medical history from first degree relatives is the floor, not the ceiling and encourage providers to collect additional information as they see fit. Additionally, we understand concerns about patients who may not know their family history. In these situations, we would find it acceptable for the provider to record the patient's family history as ''unknown.'' Either a structured data entry of ''unknown'' or any structured data entry identified as part of the patient's family history and conforming to the standards of CEHRT at 45 CFR 170.314(a)(13) must be in the provider's CEHRT for the patient to count in the numerator.

Comment: Some commenters suggested we introduce this measure with a lower threshold as this is a new requirement, but did not specify a threshold. They noted that providers who might have previously captured family history might not have that in a structured format or not coded against the standards chosen for CEHRT. This history would have to be redocumented.

Response: We proposed a low threshold of 20 percent. As this measure is not reliant on other organizations and providers the way imaging is we do not believe that is necessary to lower the threshold further.

Comment: Some commenters suggested this measure may not apply to certain specialty providers (for example, Urgent Care, Orthopedics) and suggested including an exclusion.

Response: We proposed an exclusion to this measure for EPs who have no office visits during the EHR reporting period. We continue to believe that EPs who do not have office visits would not have the face-to-face contact with patients necessary to obtain family health history information. However, this exclusion may not apply to certain specialty providers (like the aforementioned). We continue believe that recording family health history, regardless of specialty, is can be an important indicator for chronic conditions. Additionally, as this measure is being finalized as part of the menu set, providers are not required to report on this objective.

After consideration of public comments, we are finalizing the measure for EPs at § 495.6(k)(2)(ii) and for eligible hospitals and CAHs at § 495.6(m)(3)(ii) to ''More than 20 percent of all unique patients seen by the EP, or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23), during the EHR reporting period have a structured data entry for one or more first-degree relatives''.

We are finalizing the exclusion as proposed at § 495.6(k)(2)(iii).

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 CEHRT at 45 CFR 170.314(a)(13).

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.
- *Numerator:* The number of patients in the denominator with a structured data entry for one or more first-degree relatives.
- *Threshold:* The resulting percentage must be more than 20 percent in order to meet this measure.
- *Exclusion:* Any EP who has no office visits during the EHR reporting period.

Proposed EP Objective: Capability to identify and report cancer cases to a state cancer registry, except where prohibited, and in accordance with applicable law and practice.

We outlined the following benefits of this objective in the proposed rule. Reporting to cancer registries by EPs would address current underreporting of cancer, especially certain types. In the past most cancers were diagnosed and/or treated in a hospital setting and data were primarily collected from this source. However, medical practice is changing rapidly and an increasing number of cancer cases are never seen in a hospital or are cared for primarily in the outpatient setting. Data collection from EPs presents new challenges since the infrastructure for reporting is less mature than it is in hospitals. Certified EHR technology can address this barrier by identifying reportable cancer cases and treatments to the EP and facilitating electronic reporting either automatically or upon verification by the EP.

We proposed to include ''except where prohibited and in accordance with applicable law and practice'' because we want to encourage all EPs to submit cancer cases, even in rare cases where they are not required to by state/local law. Legislation requiring cancer reporting by EPs exists in 49 states with some variation in specific requirements, per the 2010 Council of State and Territorial Epidemiologists (CSTE) State Reportable Conditions Assessment (SRCA) (*http://www.cste.org/dnn/ProgramsandActivities/PublicHealthInformatics/StateReportableConditionsQueryResults/tabid/261/Default.aspx*).'' If EPs are authorized to submit, they should do so even if it is not required by either law or practice.'' In accordance with applicable law and practice'' reflects that some public health jurisdictions may have unique requirements for reporting, and that some may not currently accept electronic provider reports. In the former case, the proposed criteria for this objective would not preempt otherwise applicable state or local laws that govern reporting. In the latter case, eligible professionals would be exempt from reporting.

Comment: Nearly all commenters who wrote in support of the objective stated that the rule would decrease reporting burden for EPs because cancer diagnosis reporting in mandatory in most states. One commenter noted that the rule may increase compliance with mandatory reporting by reducing time and effort needed to submit cancer diagnosis report. Also, it was noted that incorporation of cancer reporting in meaningful use Stage 2 for eligible providers will improve completeness and quality of cancer reporting. Conversely, several of the commenters who recommended moving the objective to Stage 3 or remove the objective completely stated that inclusion of this object would place undue burden on EPs, especially because primary care providers rarely report to cancer registries. A commenter noted that the necessary EHR functionality currently exists primarily in oncology specialty EHRs, and EPs may be required to purchase additional modules to meet this object, and further states that this would be cost-prohibitive to EPs who only rarely diagnose cancer. One commenter suggested that the detailed reporting requirements would be too time-consuming for most EPs. Another commenter questions if responsibility for reporting cases, or presumptive cases, would shift to primary care providers. Other commenters suggest that the objective should be removed until such time that a national central repository can be established to simplify point-to-point connections.

Response: We agree that inclusion of this requirement is likely to reduce reporting burden for those already required to report to cancer registries. We also agree with commenters that this objective is not relevant to all providers. For those EPs who do not meet the proposed exclusion of not diagnosing or directly treating cancer, yet are not already under a requirement to report to cancer registries, we note that this is a menu objective and can be deferred. Between the proposed exclusions and the option to defer, we do not believe the measure imposes a reporting burden on providers who would not normally report to cancer registries.

Comment: The objectives of specialized registries and cancer registries reporting should be combined.

Response: In review of comments we found no compelling reason to change our proposal. No commenter disputed that the reporting to cancer registries has different level of existing reporting requirements and supporting standards than other specialized registries.

Comment: One commenter suggested changing the final rule to read, ''public health central cancer registry'' to clearly distinguish them from hospital-based cancer registries.

Response: We agree that the term public health central cancer registry is better than just cancer registries and more inclusive than just state cancer registries as used in the proposed objective, but not the proposed measure.

After consideration of the public comments received, we are modifying this objective for EPs at § 495.6 (k)(4)(i) to ''Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.''

Proposed EP Measure: Successful ongoing submission of cancer case information from CEHRT to a cancer registry for the entire EHR reporting period.

Comment: Commenters are concerned that under the proposed menu set providers will be required to choose one of: (1) Syndromic surveillance; (2) submitting to cancer registries; or (3) submitting to specialty registries if they do not meet the exclusions for all three. The commenters believe that CMS should be providing physicians with a legitimate selection of menu set measures from which to choose.

Response: Stage 2 does contain a more specialized and smaller menu set than Stage 1. We see this as a natural result of moving up the staged path towards improved outcomes. We also see it as necessary for meaningful use to be applicable to all EPs. We use exclusions to ensure that only those EPs who create reportable data have the obligation under meaningful use to report it so this would not be a barrier to meeting meaningful use. Furthermore, we added an objective to the menu set in this final rule for EPs so it is no longer true that an EP would be required to pick one of the three menu objectives mentioned by commenters.

After consideration of the public comments received, we are modifying this measure for EPs at § 495.6 (k)(4)(ii) to ''Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period'' and modify the exclusions to conform with the general criteria for public health objectives.

We further specify that in order to meet this objective and measure, an EP

must use the capabilities and standards of CEHRT 45 CFR 170.314(a), (c)(l), (f)(5), and (f)(6).

• *Exclusions:* Any EP that meets at least 1 of the following criteria may be excluded from this objective: (1) The EP does not diagnose or directly treat cancer; (2) the EP operates in a jurisdiction for which no public health agency is capable of receiving electronic cancer case information in the specific standards required for CEHRT at the beginning of their EHR reporting period; (3) the EP operates in a jurisdiction where no PHA provides information timely on capability to receive electronic cancer case information; (4) the EP operates in a jurisdiction for which no public health agency that is capable of receiving electronic cancer case information in the specific standards required for CEHRT at the beginning of their EHR reporting period can enroll additional EPs.

Proposed EP Objective: Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

In the proposed rule, we outlined the following benefits of this objective. We believe that reporting to registries is an integral part of improving population and public health. The benefits of this reporting are not limited to cancer reporting. We include cancer registry reporting as a separate objective because it is more mature in its development than other registry types, not because other reporting is excluded from meaningful use. We have included this objective to provide more flexibility in the menu objectives that EPs can choose. We believe that specialized registry reporting could provide many EPs with meaningful use menu option that is more aligned with their scope of practice.

Comment: The overwhelming majority of individuals and groups who commented on this objective expressed concern about the lack of specificity of this objective. Their concerns include: (1) Lack of specificity of the potential types of registries make planning for vendors and EPs very difficult; (2) lack of information about who would define which registries may be included; (3) leaving dozens or hundreds of possibilities; (4) lack of clarity as to the definition of 'specialized registry; (5) lack of standards for many registries; (6) or potential of needing to comply with standards not identified in the proposed rule; and (7) lack of public health readiness to accept data from EHRs.

Response: The purpose of this objective and measure is to give meaningful use credit to those EPs who are engaged in ongoing submission with specialized registries. It is not expected that every EP will select this objective and measure from the menu nor even that every EP will have the capability to submit to a specialized registry. We are purposefully general in our description of specialized registry because we do not wish to exclude certain registries in an attempt to be more specific. The only limitation we place on our description of specialized registries is that the specialized registry cannot be duplicative of any of the other registries included in other meaningful use objectives and measures. This means that an EP cannot meet the immunization, syndromic surveillance or cancer objectives and this objective by reporting to the same registry. EPs who either do not wish to participate with a specialized registry or cannot overcome the barriers to doing so can defer or exclude this measure as their situation warrants.

Comment: Commenters expressed support for expansion of the requirement to streamline and improve surveillance of healthcare-associated infections (HAIs), with the goal of improving patient care and safety.

Response: A registry that is focused on healthcare associated infections could certainly be considered a specialized registry.

After consideration of the public comments received, we are finalizing this objective for EPs at § 495.6 (k)(5)(i) as proposed.

Proposed EP Measure: Successful ongoing submission of specific case information from CEHRT to a specialized registry for the entire EHR reporting period.

Comment: Since the lack of specificity and named standards make it difficult to select this measure from the menu set, the actual viable measures available in the menu set are reduced to four and burdensome for providers who may need to pay for interfaces, costing the EPs extra time and money above the cost of the CEHRT.

Response: Stage 2 does contain a more specialized and smaller menu set than Stage 1. We see this as a natural result of moving up the staged path towards improved outcomes. We also see it as necessary for meaningful use to be applicable to all EPs. We include exclusions that allow for those providers who do not create reportable data so every provider who would is required to report public health data would have public health data to report. Furthermore, we added an objective to the menu in this final rule for EPs so it is no longer true that an EP would be required to pick one of the three menu objectives. The purpose of this measure is to provide meaningful use credit to those providers engaged in the beneficial use of CEHRT of participating in specialized registries. Other EPs can either meet the exclusions or defer this objective and thereby avoid the burden of compliance with this objective.

Comment: Given the large number of specialized registries, many of which have national scope, the exclusions are rendered meaningless.

Response: We agree with this comment, and for purposes of the exclusion only, we limit it to registries sponsored by national specialty societies and specialized registries maintained by PHAs. We believe this provides needed limitations on the exclusions. This limitation does not apply to the specialized registries that can be used to satisfy the measure as the benefits are not limited only to reporting to registries operated by Public Health Agencies or national medical specialty organizations. Specialized registries operated by patient safety organizations and quality improvement organizations also enable knowledge generation or process improvement regarding the diagnosis, therapy and prevention of various conditions that affect a population.

After consideration of the public comments received, we are finalizing this measure for EPs at § 495.6 (k)(5)(ii) as proposed, but we modify the exclusions to conform with the general criteria for public health objectives and in response to comments.

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT 45 CFR 170.314(f)(5) and (f)(6).

• *Exclusions:* Any EP that meets at least 1 of the following criteria may be excluded from this objective: (1) The EP does not diagnose or directly treat any disease associated with a specialized registry sponsored by a national specialty society for which the EP is eligible, or the public health agencies in their jurisdiction; (2) the EP operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible is capable of receiving electronic specific case information in the specific standards required by CEHRT at the beginning of their EHR reporting period; (3) the EP operates in a jurisdiction where no public health agency or national specialty society for which the EP is eligible provides information timely on capability to receive information into their specialized registries ; or (4) the EP

operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible that is capable of receiving electronic specific case information in the specific standards required by CEHRT at the beginning of their EHR reporting period can enroll additional EPs.

Proposed EP Objective: Use secure electronic messaging to communicate with patients on relevant health information.

In the proposed rule, we outlined the following benefits of using secure electronic messaging to communicate with patients: Electronic messaging (for example, email) is one of the most widespread methods of communication for both businesses and individuals. The inability to communicate through electronic messaging may hinder the provider-patient relationship. Electronic messaging is very inexpensive on a transactional basis and allows for communication even when the provider and patient are not available at the same moment in time. The use of common email services and the security measures that may be used when they are sent may not be appropriate for the exchange of protected health information. Therefore, the exchange of health information through electronic messaging requires additional security measures while maintaining its ease of use for communication. While email with the necessary safeguards is probably the most widely used method of electronic messaging, for the purposes of meeting this objective, secure electronic messaging could also occur through functionalities of patient portals, PHRs, or other stand-alone secure messaging applications.

We proposed this as a core objective for EPs for Stage 2. The additional time made available for Stage 2 implementation made possible the inclusion of some new objectives in the core set as proposed in the proposed rule. We chose to identify objectives that address critical priorities of the country's National Quality Strategy (NQS) (*http://www.healthcare.gov/law/resources/reports/quality03212011a.html*), with a focus on one for EPs and one for hospitals.

For EPs, secure electronic messaging is critically important to two NQS priorities—

- Ensuring that each person/family is engaged as partners in their care; and
- Promoting effective communication and coordination of care.

Secure messaging could make care more affordable by using more efficient communication vehicles when appropriate. Specifically, research demonstrates that secure messaging has been shown to improve patient adherence to treatment plans, which reduces readmission rates. Secure messaging has also been shown to increase patient satisfaction with their care. Secure messaging has been named as one of the top ranked features according to patients. Also, despite some trepidation, providers have seen a reduction in time responding to inquires and less time spent on the phone. We specifically sought comment on whether there may be special concerns with this objective in regards to behavioral health.

Comment: Some commenters noted that patient engagement and enhanced patient-provider communications facilitated by an EHR are important goals, and secure messaging between EPs and patients is an appropriate objective to consider for Meaningful Use criteria.

Response: We appreciate the commenters support of this objective and agree that electronic patient-provider communication is important to improving the overall quality of patient care.

Comment: Some commenters suggested that this objective should be part of the menu set instead of a core objective for Stage 2. This would permit EPs who do not believe they can meet the measure at this time to select different objectives.

Response: As we noted in the proposed rule, we placed this objective in the core because we believe it addresses critical priorities of the country's National Quality Strategy (NQS) (*http://www.healthcare.gov/law/resources/reports/quality03212011a.html*): Ensuring that each person/family is engaged as partners in their care; and promoting effective communication and coordination of care. We also believe that secure messaging could make care more affordable by using more efficient communication vehicles when appropriate. Specifically, research demonstrates that secure messaging has been shown to improve patient adherence to treatment plans, which reduces readmission rates (see Rosenberg SN, Shnaiden TL, Wegh AA, Juster IA (2008) ''Supporting the patient's role in guideline compliance: a controlled study'' American Journal of Managed Care 14(11):737–44; Gustafson DH, Hawkins R, Boberg E, Pingree S, Serlin RE, Graziano F, Chan CL (1999) ''Impact of a patient-centered, computer-based health information/support system'' American Journal of Preventive Medicine 16(1):1–9). Secure messaging has also been shown to increase patient satisfaction with their care (see Ralston JD, Carrell D, Reid R, Anderson M, Moran M, Hereford J (2007) ''Patient Web services integrated with a shared medical record: patient use and satisfaction'' Journal of the American Medical Informatics Association 14(6):798–806). Therefore, we are leaving this as a core objective for EPs for Stage 2.

Comment: Several commenters responded to our question about whether there were special concerns about implementing this objective for behavioral health patients. These commenters indicated that they did not believe this objective posed a special concern and that it would help behavioral health patients obtain needed support from clinicians.

Response: We appreciate the feedback from commenters regarding behavioral health.

After consideration of the public comments, we are finalizing the meaningful use objective for EPs at § 495.6(j)(17)(i) as proposed.

Proposed EP Measure: A secure message was sent using the electronic messaging function of CEHRT by more than 10 percent of unique patients seen by the EP during the EHR reporting period.

Comment: Many commenters voiced objections to the measure of this objective and the concept of providers being held accountable for patient actions. The commenters believed that while providers could be held accountable for making electronic messaging capabilities available to patients and encouraging patients to use electronic messaging, they could not control whether patients actually utilized electronic messaging. However, some commenters believed that the measure was a reasonable and necessary step to require vendors to make electronic messaging tools more widely available and for providers to incorporate electronic messaging into clinical practice. In addition, commenters pointed to the unique role that providers can play in encouraging and facilitating their patients' and their families' use of secure messaging.

Response: While we recognize that EPs cannot directly control whether patients use electronic messaging, we continue to believe that EPs are in a unique position to strongly influence the technologies patients use to improve their own care, including secure electronic messaging. We believe that EPs' ability to influence patients coupled with the low threshold make this measure achievable for all EPs.

Comment: Other commenters did not object to the principle of providers

being held accountable for patient actions but noted that the potential barriers of limited internet access, computer access, and electronic messaging platforms for certain populations (for example, rural, elderly, lower income, visually impaired, non-English-speaking, etc.) might make the measure impossible to meet for some providers. Commenters suggested a number of possible solutions to allow providers to overcome these barriers: granting exclusions for certain patient populations, lowering the proposed threshold of the measure, or eliminating the percentage threshold of the measure.

Response: We recognize that certain patient populations face greater challenges in utilizing electronic messaging. We address the potential barrier of limited internet access in the comment regarding a broadband exclusion below. While we agree that excluding certain patient populations from this requirement would make the measure easier for EPs to achieve, we do not know of any reliable method to quantify these populations for each EP in such a way that we could standardize exclusions for each population. In addition, we are concerned that blanket exclusions for certain disadvantaged populations could serve to extend existing disparities in electronic access to health information. We also decline to eliminate the percentage threshold of this measure because we do not believe that a simple yes/no attestation for implementation of electronic messaging is adequate to encourage a minimum level of patient usage. However, in considering the potential barriers faced by these patient populations, we agree that it would be appropriate to lower the proposed threshold of this measure to more than 5 percent of unique patients sending an electronic message. We believe that this lower threshold, combined with the broadband exclusion detailed in the response below, will allow all EPs to meet the measure of this objective.

Comment: Several commenters suggested that the exclusion for FCC-recognized areas with under 50 percent broadband availability, which was proposed in the objective to ''Provide patients the ability to view online, download, and transmit their health information,'' should be extended to the electronic messaging objective.

Response: We agree that the infrastructure required for electronic messaging is similar to the infrastructure required for successful usage of an online patient portal as described in the objective to ''Provide patients the ability to view online, download, and transmit their health information.'' Therefore, we believe an exclusion to this measure based on the availability of broadband is appropriate and are finalizing the exclusion in the language below. We note that since publication of our proposed rule the Web site has changed to *www.broadbandmap.gov* and the speed used has changed from 4Mbps to 3Mbps. We updated our exclusion.

Comment: Some commenters expressed concern about including all patients seen by the EP in the denominator and suggested limiting the denominator instead to patients who have indicated secure electronic messaging as their communication preference. Other commenters suggested the denominator should not be limited to patients seen by the EP and should also include patients who make inquiries or who attempt to make an appointment with the EP during the reporting period.

Response: We do not agree that limiting the denominator to patients who have indicated secure electronic messaging as their communication preference is appropriate. The purpose of the measure is for EPs to promote wider use of electronic messaging as a regular communication vehicle for their patients, and we are concerned that limiting the denominator in the manner suggested would not lead to an increase in the promotion or usage of electronic messaging as an important communication vehicle between patients and providers. We also do not agree that expanding the denominator to patients not seen by the EP during the reporting period is appropriate. Another purpose of the measure is for secure messaging to include clinically relevant information, and we do not believe that patients seeking introductory information or making an appointment are likely to include clinically relevant information in secure messaging.

Comment: Some commenters noted that patients whose only office visit with an EP occurs near the end of the reporting period might not be able to send an electronic message in time to be included in the numerator of the measure.

Response: While we agree that patients with a single office visit near the end of the reporting period may not utilize electronic messaging and be eligible for inclusion in the numerator of the measure during the EHR reporting period, we believe that the threshold of this measure will be sufficiently low to permit EPs to meet the measure even without the participation of these patients.

Comment: Several commenters requested clarification on the definition of a secure message.

Response: We define a secure message as any electronic communication between a provider and patient that ensures only those parties can access the communication. This electronic message could be email or the electronic messaging function of a PHR, an online patient portal, or any other electronic means. However, we note that the secure message also must use the electronic messaging function of CEHRT in order to qualify for the measure of this objective.

Comment: Some commenters suggested that EPs or patients should be permitted to use an electronic messaging function that is not part of CEHRT in order to meet the measure.

Response: We believe that allowing patients to use multiple electronic messaging functions in order to communicate with the provider under this measure could create confusion for the EP and potentially lead to electronic messages that are missed or not responded to. We also believe that by encouraging patients to use the electronic messaging function that is part of CEHRT EPs can better ensure that electronic messages are sent securely to protect patient's health information. Finally, we are concerned that CEHRT would not be able to track electronic messaging that is not part of the EHR, which would place an extra burden for reporting on EPs in meeting this measure. For all of these reasons, we require that patients use the electronic messaging function that is part of CEHRT in order to be included in the measure of this objective.

Comment: Commenters agreed with our decision not to include in the definition for this measure ''relevant health information.'' Commenters did not believe CEHRT could support the categorization of electronic messages in a way that would satisfy such a requirement.

Response: We appreciate the support offered by commenters. As we stated in the proposed rule, 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 EP is the best judge of what health information should be considered relevant in this context. We do not specifically include the term ''relevant health information'' in the measure because we believe the provider is best equipped to determine whether such information is included. We agree that it would be too great a burden for CEHRT to determine whether

the information in the secure message has such information.

Comment: Some commenters expressed concerns that we did not propose to measure provider response to patient electronic messaging. These commenters believed that the proposed measure places too much focus on patient messaging and should instead focus on communication between patient and provider. Some commenters suggested that the measure be modified for responsiveness of an EP or staff to patient messaging rather than the proposed percentage of patients who send a secure message.

Response: As we stated in the proposed rule, there is an expectation that the EP would respond to electronic messages sent by the patient, although we do not specify the method of response or require the EP to document his or her response for this measure. We decline to specify the method of provider response because we believe it is best left to the provider's clinical judgment to decide the course of action which should be taken in response to the patient's electronic message. An EP or staff member could decide that a follow-up telephone call or office visit is more appropriate to address the concerns raised in the electronic message. Therefore, we decline to alter the measure to include provider response.

Comment: Commenters asked for clarification as to whether the EP had to respond personally to electronic messaging or whether members of the EP's staff could respond. Commenters also asked for clarification regarding whether or not messages sent by a patient-authorized representative would be recorded in this measure.

Response: There is not an expectation that the EP must personally respond to electronic messages to the patient. Just as an EP's staff respond to telephone inquiries or conduct office visits on behalf of the EP, staff could also respond to electronic messages from the patient. We also intend for electronic messages sent by a patient-authorized representative to be included in the measure of this objective and have modified the language of the measure below accordingly.

Comment: Some commenters raised concerns regarding the security of electronic messaging, specifically citing instances where family members might have access to the patient's account or elderly patients who would not know how to use a computer and would have to give account access to a caregiver. Other commenters raised concerns regarding their liability in providing access to such information or in responding to an electronic message.

Response: We do not believe that secure electronic messaging poses greater risks to exposure of protected health information than other mediums such as telephone messaging, paper records, etc. In some cases secure electronic messaging can provide even greater protection of health information. We note that many patients grant access to health information to family members and caregivers to facilitate care, and we expect the same access to continue with secure electronic messaging. Nor do we believe that secure electronic messaging exposes providers to greater liability (for example, in areas of privacy protection or malpractice) than other mediums such as telephone, mail, paper records, etc. Previous research has demonstrated that better patient-provider communication reduces the likelihood of malpractice claims being filed.

Comment: Some commenters noted that the potential financial burden of implementing securing messaging as a part of their clinical or administrative workflow. These commenters noted that EPs are not reimbursed for the time spent responding to electronic messages and that it can be time consuming for an EP to have multiple exchanges with a patient via email.

Response: We do not believe that implementing electronic messaging imposes a significant burden on providers. While we note that in some scenarios it may be possible for an EP to receive reimbursement from private insurance payers for online messaging, we acknowledge that EPs are generally not reimbursed for time spent responding to electronic messaging. However, it is also true that EPs are generally not reimbursed for other widely used methods of communication with patients (for example, telephone). As we noted in the proposed rule, many providers have seen a reduction in time responding to inquires and less time spent on the phone through the use of electronic messaging. In addition, we note that EPs themselves do not have to respond to electronic messages personally and can delegate this task to staff, just as many EPs currently delegate telephone exchanges with patients to staff.

After consideration of the public comments, we are finalizing the meaningful use measure for EPs as ''A secure message was sent using the electronic messaging function of CEHRT by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period'' at § 495.6(j)(17)(ii) and the exclusion for EPs as ''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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period'' at § 495.6(j)(17)(iii).

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(e)(3).

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of unique patients seen by the EP during the EHR reporting period.
- *Numerator:* The number of patients or patient-authorized representatives in the denominator who send a secure electronic message to the EP that is received using the electronic messaging function of CEHRT during the EHR reporting period.
- *Threshold:* The resulting percentage must be more than 5 percent in order for an EP 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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Proposed Eligible Hospital/CAH Objective: Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

In the proposed rule, we outlined the following benefits of automatically tracking medications with eMAR: eMAR increases the accuracy of medication administration thereby increasing both patient safety and efficiency. The HIT Policy Committee has recommended the inclusion of this objective for hospitals in Stage 2, and we proposed this as a core objective for eligible hospitals and CAHs. The additional time made available for Stage 2 implementation makes possible the inclusion of some new objectives in the core set. eMAR is critically important to making care safer by reducing medication errors which may make care more affordable. eMAR has been shown to lead to significant improvements in medication-related adverse events within hospitals with associated decreases in cost. eMAR cuts

in half the adverse drug event (ADE) rates for non-timing medication errors, according to a study published in the *New England Journal of Medicine* (Poon et al., 2010, Effect of Bar-Code Technology on the Safety of Medication Administration *http://www.nejm.org/doi/abs/10.1056/NEJMsa0907115?query=NC*). A study done to evaluate cost-benefit of eMAR (Maviglia et al., 2007, Cost-Benefit Analysis of a Hospital Pharmacy Bar Code Solution *http://archinte.ama-assn.org/cgi/content/full/167/8/788*) demonstrated that associated ADE cost savings allowed hospitals to break even after 1 year and begin reaping cost savings going forward.

We proposed to define eMAR as technology that automatically documents the administration of medication into CEHRT using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding). The specific characteristics of eMAR for the EHR Incentive Programs will be further described in the ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register**.

By its very definition, eMAR occurs at the point of care so we did not propose additional qualifications on when it must be used or who must use it.

Comment: Some commenters suggested that this should be a menu objective for Stage 2.

Response: As we stated in the proposed rule, we believe that eMAR is critically important to making care safer by reducing medication errors which may also make care more affordable. eMAR has been shown to lead to significant improvements in medication-related adverse events within hospitals with associated decreases in cost. Therefore, we believe that the benefits to patient safety from eMAR warrant the inclusion of this as a Stage 2 core objective for eligible hospitals and CAHs.

After consideration of the public comments, we are finalizing the meaningful use objective for eligible hospitals and CAHs at § 495.6(l)(16)(i) as proposed.

Proposed Eligible Hospital/CAH Measure: More than 10 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 tracked using eMAR.

Comment: A number of commenters questioned whether the measure should apply to at least one instance of the administration of a dose connected with a medication order or whether each individual dose connected with a medication order should be included in the measure. Some commenters believed that a single instance of administration of a dose should constitute fulfillment of the measure, while others believed that all doses administered rather than orders administered would be a more precise and meaningful measurement.

Response: We believe that including each individual dose connected with a medication order through this measure could yield denominators that are very large. However, we believe that the benefits to patient safety from eMAR are seen when all doses of a medication order are tracked. Therefore, we clarify that we include in the numerator of this objective medication orders for which all doses are tracked using eMAR, and we are amending the measure language below to reflect this clarification. If a medication is ordered but not all doses of the medication are tracked using eMAR, then that order may not be included in the numerator of the measure.

Comment: Some commenters raised the concern that certain rural and low volume hospitals might face undue financial burden in implementing this objective and proposed an exclusion for hospitals with either a limited number of inpatient beds or a low average inpatient volume. Some commenters suggested there should be an exclusion for very small hospitals for whom eMAR could be a prohibitively expensive undertaking. Other commenters noted that the difficulties in implementing eMAR were outweighed by the significant benefits to patient safety.

Response: We agree with commenters who suggested that the potential benefits to patient safety of eMAR are significant. While we agree that certain hospitals may face challenges in implementing eMAR on a wider scale, we believe that the low threshold for this measure lessens the burden associated with implementation of eMAR for most rural and low volume hospitals. We also note that CEHRT will include eMAR capabilities, so the primary barrier to implementation for most hospitals will be workflow.

However, we are also concerned that very small hospitals may have local technical support and training issues that may make an automated eMAR solution actually less effective than other approaches. We also believe that very small hospitals will have fewer health care professionals involved in the process of medication administration and fewer patients for whom duplicative orders could present an issue, which would also make an eMAR solution less effective. Therefore, we believe these hospitals would not benefit from eMAR as much as larger facilities and are finalizing an exclusion for these hospitals. Any hospital with an average daily inpatient census of fewer than 10 patients may be excluded from meeting the measure of this objective. For purposes of this exclusion, we define an average daily inpatient census as the total number of patients admitted during the previous calendar year divided by 365 (or 366 if the previous calendar year is a leap year).

Comment: Some commenters stated that the percentage threshold of this measure should be replaced with the implementation of eMAR in one ward or unit of the hospital to limit burdensome measurement requirements. Other commenters argued that changing the measure to one ward or unit of the hospital would introduce ambiguity regarding what constitutes a ward or unit, while a percentage threshold would allow hospitals the flexibility to implement eMAR capabilities on a limited basis.

Response: We believe that the low threshold of this objective does not impose burdensome measurement requirements on hospitals, especially since we do not anticipate a significant difference in the way CEHRT will measure eMAR usage regardless of where it is implemented. We agree that limiting the measure to implementation in a single ward or unit could introduce ambiguity regarding the precise definition of ward or unit, especially since some hospitals combine the locations and workflows of certain units. We further note that the percentage threshold does allow hospitals to implement eMAR in a limited capacity, and that a hospital could potentially meet the low measure of this objective by implementing in a single ward or unit or by implementing in several smaller wards or units that combine to yield more than 10 percent of medication orders created during the EHR reporting period. We believe the percentage measure of this objective yields maximum flexibility for a hospital to implement eMAR in a way that is clinically relevant to its individual workflow.

Comment: Some commenters requested clarification on whether eMAR could be implemented solely in portions of an inpatient department or solely in portions of an emergency department in order to meet the measure, as opposed to implementing eMAR in both the inpatient and emergency departments.

Response: As stated previously, we have attempted to provide maximum flexibility for a hospital to implement eMAR in a way that is clinically relevant to its individual workflow. Therefore, we do not require that eMAR is implemented in both inpatient and emergency departments in order to meet this measure, only that more than 10 percent of medication orders created by authorized providers of either the inpatient or emergency department (POS 21 or 23) during the EHR reporting period are tracked using eMAR. Hospitals could implement eMAR in the inpatient department, the emergency department, or both departments in order to meet the threshold of this measure.

After consideration of the public comments, we modify the meaningful use measure as ''More than 10 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 for which all doses are tracked using eMAR'' for eligible hospitals and CAHs at § 495.6(l)(16)(ii) and finalize the exclusion as ''Any eligible hospital or CAH with an average daily inpatient census of fewer than 10 patients'' at § 495.6(l)(16)(iii).

We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(16).

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of medication orders created by 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 for which all doses are tracked using eMAR.
- *Threshold:* The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.
- *Exclusion:* Any hospital with an average daily inpatient census of fewer than ten (10) patients.

Proposed Eligible Hospital/CAH Objective: Generate and transmit permissible discharge prescriptions electronically (eRx)

In the proposed rule, we outlined the following benefits of electronic prescribing: 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 recognize the information and can provide decision support to promote safety and quality in the form of adverse interactions and other treatment possibilities. The CEHRT can also provide decision support that promotes 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. Transmitting the prescription electronically promotes efficiency and 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. This comparison allows for many of the same decision support functions enabled at the generation of the prescription, but bases them on potentially greater information.

We have combined the comments and responses for this objective with the measure below. After consideration of the public comments, we are finalizing the meaningful use objective for eligible hospitals and CAHs at § 495.6(m)(4)(i) as proposed.

Proposed Eligible Hospital/CAH Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and transmitted electronically using CEHRT.

Comment: Most commenters voiced support for this as a menu set item, with some commenters noting that the threshold for this measure should remain low for Stage 2 because of the difficulty of using electronic prescribing for all prescriptions, including controlled substances.

Response: We appreciate the support for this objective, and we note that the measure of the objective for eligible hospitals and CAHs for Stage 2 is set at more than 10 percent of all discharge medication orders for permissible prescriptions. We believe this sets a sufficiently low threshold that would allow most hospitals to achieve this measure and eliminates the inclusion of controlled substances, which are not included as permissible prescriptions for the purposes of this measure.

Comment: Most commenters noted that distinguishing new and altered prescriptions from refills would be unnecessarily burdensome for hospitals.

Response: Although we had initially proposed to limit this measure to only new and altered prescriptions because we believed that hospitals would not issue refill prescriptions, we agree with the commenters that distinguishing refills from new and altered prescriptions could be unnecessarily burdensome for hospitals. Therefore, we are not imposing this limitation and include new, altered, and refill prescriptions in the measure of discharge medication orders for permissible prescriptions.

Comment: Some commenters expressed concerns about patient requests for paper prescriptions instead of electronic prescriptions.

Response: We believe that the more than 10 percent of discharge medication orders threshold is sufficiently low to accommodate patient requests for paper prescriptions and still allow most, if not all, hospitals to meet the measure of this objective.

Comment: Some commenters asked whether prescriptions electronically transmitted to in-house pharmacies should be included in the measure and if the standards specified by ONC for this measure would apply to these transmissions.

Response: We are continuing the policy from Stage 1 that prescriptions transmitted electronically within an organization (the same legal entity) would be counted in the measure and would not need to use the standards specified by ONC for this objective. However, a hospital's CEHRT must meet all applicable certification criteria and be certified as having the capability of meeting external transmission requirements. In addition, the EHR that is used to transmit prescriptions within the organization would need to be CEHRT.

The hospital would include in the numerator and denominator both types of electronic transmission (those within and outside the organization) for the measure of this objective. We further clarify that for purposes of counting discharge prescriptions ''generated and transmitted electronically,'' we considered the generation and transmission of prescriptions to occur simultaneously if the prescriber and dispenser are the same person and/or are accessing the same record in an integrated EHR to create an order in a system that is electronically transmitted to an internal pharmacy.

Comment: Some commenters asked for clarification regarding whether drug-formulary checks had to be enabled for the entire EHR reporting period, as required by the Stage 1 measure.

Response: No. The Stage 1 objective for drug-formulary checks has been combined with this Stage 2 objective for generating and transmitting permissible discharge prescriptions electronically. Although the measure of the Stage 1 objective required the capability for

drug-formulary checks to be enabled for the entire reporting period, the measure of the Stage 2 objective specifies drug-formulary checks should be performed for more than 10 percent of hospital discharge medication orders for permissible prescriptions. We recognize that not every patient will have a formulary that is relevant for him or her. Therefore, we require not that the EHR check each prescription against a formulary relevant for a given patient, but rather that the EHR check each prescription for the existence of a relevant formulary. If a relevant formulary is available, then the information can be provided. We believe that this initial check is essentially an on or off function for the EHR and should not add to the measurement burden. Therefore, with this clarification of the check we are referring to, we are finalizing the drug formulary check as a component of this measure. We look forward to the day when a relevant formulary is available for every patient. We modified the measure to use the word query instead of compare.

Comment: Some commenters asked whether the measure of this objective applied to inpatient departments, emergency departments, or both.

Response: We specify that the measure of this objective applies to medication orders for patients discharged from either the inpatient (POS 21) department, the emergency department, or both the inpatient and emergency departments of an eligible hospital or CAH during the EHR reporting period.

Comment: One commenter asked for clarification of whether a patient for whom no relevant drug formularies are available could be counted in the numerator of the measure if the discharge prescription for that patient is generated and transmitted electronically. Another commenter suggested that patients for whom no relevant formularies are available should not be counted in the measure.

Response: As noted in the proposed rule, we believe that the inclusion of the comparison to at least one drug formulary enhances the efficiency of the healthcare system when clinically appropriate and cheaper alternatives may be available. In the event that a relevant formulary is unavailable for a particular patient and medication combination, a discharge prescription that is generated and electronically transmitted should still be included in the numerator of the measure. We do not agree that prescriptions for patients for whom relevant formularies are unavailable should be excluded from this measure.

Comment: Several commenters believed that the exclusion based on the availability of a pharmacy capable of receiving electronic prescriptions within 25 miles of the hospital's location was not adequate for all areas, particularly rural areas. Some commenters suggested that 10 miles is a more appropriate distance.

Response: We appreciate the commenters' concerns about this exclusion. As stated in the proposed rule, we recognize that certain areas may not have widespread availability of electronic prescribing in all pharmacies, we believe that most hospitals will be able to fulfill electronic prescriptions through an internal pharmacy. However, we agree with commenters that basing the exclusion on a 25-mile radius could place a significant burden on patients to travel to fill prescriptions, especially in rural areas. Therefore, we are finalizing a 10-mile radius at the start of the EHR reporting period. Hospitals that do not have an internal pharmacy and that are located 10 miles from a pharmacy that can receive electronic prescriptions at the start of the EHR reporting period would be able to claim the exclusion for this measure. We also believe that the low threshold of more than 10 percent of discharge prescriptions transmitted electronically would make it possible for all hospitals to meet this measure.

Comment: Some commenters requested for clarification of whether CEHRT would provide the capability to determine the availability of a pharmacy capable of receiving electronic prescriptions within 25 miles of the hospital's location.

Response: CEHRT will not provide the capability to determine whether a hospital meets the exclusion for this measure. As stated in the previous response, we are finalizing the exclusion for the availability of a pharmacy capable of receiving electronic prescriptions within 10 miles of the hospital's location. Therefore, eligible hospitals and CAHs may use their own resources to make a determination regarding the availability of a pharmacy capable of receiving electronic prescriptions within 10 miles of the hospital's location.

After consideration of the public comments, we modify the meaningful use measure for eligible hospitals and CAHs as ''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'' at § 495.6(m)(4)(ii) and we modify the exclusion for eligible hospitals and CAHs at § 495.6(m)(4)(iii) by changing the radius from 25 miles to 10 miles.

We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(10) and (b)(3).

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 Eligible Hospital/CAH Objective: Provide patients the ability to view online, download, and transmit information about a hospital admission.

In the proposed rule, we noted that studies have found that patients engaged with computer based information sources and decision support show improvement in quality of life indicators, patient satisfaction and health outcomes. (Ralston, Carrell, Reid, Anderson, Moran, & Hereford, 2007) (Gustafson, Hawkins, Bober, S, Graziano, & CL, 1999) (Riggio, Sorokin, Moxey, Mather, Gould, & Kane, 2009) (Gustafson, et al., 2001). In addition, we noted that this objective aligns with the FIPPs,[5] in affording baseline privacy protections to individuals. We stated that we believe this information is integral to the Partnership for Patents initiative and reducing hospital readmissions. While this objective does not require all of the information sources and decision support used in these studies, having a set of basic information available advances these initiatives. 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

[5] Ibid.

available. However, providers should 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. Additionally, other health information may not be accessible. Finally, we noted that providers who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

We proposed this as a core objective for hospitals for Stage 2. We also specified in the proposed rule the information that must be made available as part of the objective, although we noted hospitals could choose to provide additional information (77 FR 13730).

Comment: Some commenters suggested that this objective should be part of the menu set instead of a core objective for Stage 2. This would permit eligible hospitals and CAHs that do not believe they can meet the measure at this time to select different objectives.

Response: We do not agree that this objective should be part of the menu set. We proposed this objective as part of the core for eligible hospitals and CAHs because it is intended to replace the previous Stage 1 core objective of ''Provide patients with an electronic copy of their health information upon request'' and the Stage 1 core objective of ''Provide patients with an electronic copy of their discharge information.'' Although CEHRT will provide added capabilities for this objective, we do not believe the objective itself is sufficiently different from previous objectives to justify placing it in the menu set. Also, we believe that patient access to their discharge information is a high priority for the EHR Incentive Programs and this objective best provides that access in a timely manner.

Comment: Some commenters expressed the opinion that this objective should not be included as part of meaningful use and was more appropriately regulated under HIPAA and through the Office for Civil Rights.

Response: We do not agree that this objective should not be included in meaningful use. Although we recognize that many issues concerning the privacy and security of information online are subject to HIPAA requirements, we believe that establishing an objective to provide online access to health information is within the regulatory purview of the EHR Incentive Programs and consistent with the statutory requirements of meaningful use.

After consideration of the public comments, we are finalizing the meaningful use objective for eligible hospitals and CAHs at § 495.6(l)(8)(i) as proposed.

Proposed Eligible Hospital/CAH Measure: There are 2 measures for this objective, both of which must be satisfied in order to meet the objective.

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.

More than 10 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the EHR reporting period.

Comment: A commenter questioned how long data should be made available online before it can be removed.

Response: It is the goal of this objective to make available to the patient both current and historical health information regarding hospital discharges. Therefore, we would anticipate that the data should be available online on an ongoing basis. However, an eligible hospital or CAH may withhold or remove information from online access for purposes of meaningful use if they believe substantial harm may arise from its disclosure online.

Comment: Some commenters asked for clarification on whether online access had to be made available using CEHRT or if the information could be made available through other means (patient portal, PHR, etc.).

Response: Both of the measures for this objective must be met using CEHRT. Therefore, for the purposes of meeting this objective, the capabilities provided by a patient portal, PHR, or any other means of online access and that would permit a patient or authorized representative to view, download, or transmit their personal health information would have to be certified in accordance with the certification requirements adopted by ONC. We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register**.

Comment: Some commenters asked for clarification on how access by the patient is defined.

Response: We define access as having been given when the patient possesses all of the necessary information needed to view, download, or transmit their discharge information. This could include providing patients with instructions on how to access their health information, the Web site address they must visit for online access, a unique and registered username or password, instructions on how to create a login, or any other instructions, tools, or materials that patients need in order to view, download, or transmit their discharge information.

Comment: Some commenters suggested that patients under the age of 18 should not have the same access to the same information to which adult patients have access and requested a separate list of required elements for patients under the age of 18.

Response: An eligible hospital or CAH may decide that online access is not the appropriate forum for certain health information for patients under the age of 18. Within the confines of the laws governing guardian access to medical records for patients under the age of 18, we would defer to the eligible hospital's or CAH's judgment regarding which information should be withheld for such patients. In lieu of providing online access to patients under the age of 18, eligible hospitals or CAHs could provide online access to guardians for patients under the age of 18, in accordance with state and local laws, in order to meet the measure of this objective. Providing online access to guardians in accordance to state and local laws would be treated the same as access for patients, and guardians could then be counted in the numerator of the measure. We recognize that state and local laws may restrict the information that can be made available to guardians, and in these cases such information can be withheld and the patient could still be counted in the numerator of the measure.

Comment: Many commenters voiced objections to the second measure of this objective and the concept of providers being held accountable for patient actions. The commenters believed that while providers could be held accountable for making information available online to patients, providers could not control whether patients actually accessed their information. Many commenters also noted that the potential barriers of limited internet access, computer access, and patient engagement with health IT for certain populations (for example, rural, elderly, lower income, non-English-speaking, etc.) might make the measure impossible to meet for some providers. There were also a number of comments stating that metrics used to track views or downloads can be misleading and are not necessarily the most accurate measure of patient usage. Commenters suggested a number of possible solutions to allow providers to overcome these barriers, including

eliminating the percentage threshold of the measure or requiring providers to offer and track patient access but not requiring them to meet a percentage measure in order to demonstrate meaningful use. However, some commenters believed that the measure was a reasonable and necessary step to ensure that providers had accountability for engagement of their patients in use of electronic health information and integration of it into clinical practice. In addition, commenters pointed to the unique role that providers can play in encouraging and facilitating their patients' and their families' use of online tools.

Response: While we recognize that eligible hospitals and CAHs cannot directly control whether patients access their health information online, we continue to believe that eligible hospitals and CAHs are in a unique position to strongly influence the technologies patients use to improve their own care, including viewing, downloading, and transmitting their health information online. We believe that the eligible hospital's or CAH's ability to influence patients coupled with the low threshold of more than 10 percent of patients who view online, download, or transmit to a third party their information make this measure achievable for all eligible hospitals and CAHs.

We recognize that certain patient populations face greater challenges in online access to information. We address the potential barrier of limited internet access in the comment regarding a broadband exclusion below. We address the potential barrier to individuals with disabilities through ONC's rules requiring that EHRs meet disability accessibility standards. While we agree that excluding certain patient populations from this requirement would make the measure easier for eligible hospitals and CAHs to achieve, we do not know of any reliable method to quantify these populations for each eligible hospital and CAH in such a way that we could standardize exclusions for each population. We also decline to eliminate the percentage threshold of this measure because we do not believe that a simple yes/no attestation for this objective is adequate to encourage a minimum level of patient usage. However, in considering the potential barriers faced by these patient populations, we agree that it would be appropriate to lower the proposed threshold of this measure to more than 5 percent of unique patients who view online, download, or transmit to a third party their information. In addition, we are concerned that blanket exclusions for certain disadvantaged populations could serve to extend existing disparities in electronic access to information and violate civil rights laws. All entities receiving funds under this program are subject to civil rights laws. For more information about these laws and their requirements (see *http://www.hhs.gov/ocr/civilrights/index.html*). We believe that this lower threshold, combined with the broadband exclusion detailed in the response later in this section, will allow all eligible hospitals and CAHs to meet the measure of this objective.

Comment: Some commenters suggested making the numerator and denominator language for this measure consistent with the language used for this measure for EPs.

Response: We agree that there are some slight variations in language between the measure for EPs and the measure for hospitals. To the extent possible, we have harmonized the language between both.

Comment: Some commenters asked for clarification on how view is defined.

Response: We define view as the patient (or authorized representative) accessing their health information online.

Comment: Some commenters noted that the potential financial burden of implementing an online patient portal to provide patients online access to discharge information. These commenters noted the added time burden for staff in handling the additional patient use of online resources, which may increase costs through the hiring of additional staff, as well as the need to modify their existing workflow to accommodate potential online messages from patients. Some commenters also believed that there would be an additional cost for sharing content before standards exist for content types and formats.

Response: As noted in the proposed rule, studies have found that patients engaged with computer based information sources and decision support show improvement in quality of life indicators, patient satisfaction and health outcomes (see Rosenberg SN, Shnaiden TL, Wegh AA, Juster IA (2008) ''Supporting the patient's role in guideline compliance: a controlled study'' American Journal of Managed Care 14(11):737–44; Gustafson DH, Hawkins R, Boberg E, Pingree S, Serlin RE, Graziano F, Chan CL (1999) ''Impact of a patient-centered, computer-based health information/support system'' American Journal of Preventive Medicine 16(1):1–9; Ralston JD, Carrell D, Reid R, Anderson M, Moran M, Hereford J (2007) ''Patient web services integrated with a shared medical record: patient use and satisfaction'' Journal of the American Medical Informatics Association 14(6):798–806). We believe that the information provided as part of this measure is integral to the Partnership for Patents initiative and reducing hospital readmissions. We do not believe that implementing online access for patients imposes a significant burden, financial or otherwise, on providers. While we note that in some scenarios it may be possible for an eligible hospital or CAH to receive reimbursement from private insurance payers for online messaging, we acknowledge that eligible hospitals and CAHs are generally not reimbursed for time spent responding to electronic messaging. However, it is also true that eligible hospitals and CAHs are generally not reimbursed for other widely used methods of communication with patients (for example, telephone). In addition, it will be part of the capability of CEHRT to automatically populate most of the list of required elements to meet this measure, which significantly reduces the administrative burden of providing this information. Finally, we believe that the standards established for this objective by ONC will serve as a content standard that will allow this information to be more easily transmitted and uploaded to another certified EHR, thereby reducing the cost of sharing information.

Comment: Some commenters noted that patient engagement could occur effectively with or without online access, and patients should be encouraged to use any method (for example, telephone, internet, traditional mail) that suits them. These commenters noted that engagement offline reduces both the need and value for engagement online.

Response: We agree that patient engagement can occur effectively through a variety of media, and we also believe that electronic access to discharge information can be an important component of patient compliance and improving longitudinal care. We do not believe that offline engagement reduces the need for online access, as patients may opt to access information in a variety of ways. Because of the variety of ways that patients/families may access information, we keep the threshold for this measure low. Measuring other means of accessing health information is beyond the scope of the EHR Incentive Programs. We also note that online access to health information can enhance offline engagement—for example, patients could download information from a hospital admission

to bring with them for a consult on follow-up care—which is one of the primary goals of the EHR Incentive Programs.

Comment: Some commenters expressed concern that vendors would not be able to make these capabilities available as part of CEHRT in time for the beginning of Stage 2.

Response: Many CEHRT vendors already make patient portals available that would meet the certification criteria and standards required for this measure. Although the Stage 2 eligible hospital/CAH measure requires some additional required elements and fields capabilities, we believe vendors will be able to make these capabilities available in time for the beginning of Stage 2.

Comment: Some commenters suggested that basing the exclusion on the broadband data available from the FCC Web site (*www.broadband.gov*) was suspect since the data originates from vendors.

Response: The broadband data made available from the FCC was collected from over 3,400 broadband providers nationwide. This data was then subject to many different types of analysis and verification methods, from drive testing wireless broadband service across their highways to meeting with community leaders to receive feedback. Representatives met with broadband providers, large and small, to confirm data, or suggest changes to service areas, and also went into the field looking for infrastructure to validate service offerings in areas where more information was needed. Therefore, we believe the data is appropriate for the exclusion to this measure. We note that since publication of our proposed rule the Web site has changed to *www.broadbandmap.gov* and the speed used has changed from 4Mbps to 3Mbps. We are updating our exclusion to reflect these changes.

Comment: Some commenters believe that broadband exclusions should be based on the patients' locations instead of the providers, since county-level data may not be granular enough to capture all areas of low broadband availability within a particular region.

Response: Although we agree that a broadband exclusion based primarily on the individual locations of each patient seen would be more accurate, we do not believe that there is any method of making this determination for every patient without placing an undue burden on the provider. We continue to believe that limited broadband availability in the eligible hospital's or CAH's immediate practice area, coupled with the low threshold of this measure, adequately serves as an acceptable proxy for determining areas where online access can present a challenge for patients. Therefore, after consideration of the public comments received, we are finalizing the broadband exclusion as proposed.

Comment: Some commenters suggested that the required element of ''Problem list maintained by the hospital on the patient'' should be made consistent with the required element in the objective of the same name and changed to ''Problem list.'' Other commenters asked for clarification of ''Relevant past diagnoses known by the hospital'' and how this element differs from ''Problem list.''

Response: We agree that this language should be made standard. By ''Relevant past diagnoses known by the hospital'' we mean to indicate historical entries in the patient's problem list. Therefore, we are eliminating the ''Relevant past diagnoses'' element and modifying the problem list element to ''Current and past problem list'' in the list of required elements below.

Comment: Some commenters suggested that displaying all historical medications for each patient under the required element of ''Medication list maintained by the hospital on the patient (both current admission and historical)'' would be too burdensome for hospitals. These commenters suggested amending the required element to only the active medication list maintained by CEHRT. They also expressed confusion over the use of the term ''current admission'' since the information for this measure would be posted after the patient's discharge.

Response: We believe that just as providing a historical problem list for the patient can be useful, so too can providing a historical list of all medications. To clarify the intention of this objective, we are modifying the language in the list of required elements below to read ''Active medication list and medication history. Current admission referred to the admission and subsequent discharge that places the patient in the denominator for this measure.

Comment: Some commenters suggested that ''Laboratory test results (available at discharge)'' could result in a large number of test results that could be confusing to patients. They suggested limiting this required element to a subset of lab results of a particular type or lab results from the last 24 hours of admission.

Response: We believe that a list of all laboratory test results can be beneficial to longitudinal care, therefore, we decline to modify this required element either by type of lab result or by any time period beyond those lab test results available at discharge.

Comment: Some commenters suggested that the required element of ''Care transition summary and plan for next provider of care (for transitions other than home)'' should be made consistent with the required element in the objective of the same name and changed to ''Care plan field, including goals and instructions.'' Some commenters also suggested that care transition plans are more appropriate for providers than patients.

Response: By ''care transition summary and plan for next provider of care'' we mean for eligible hospitals and CAHs to include both the care plan field(s), including goals and instructions, and a copy of the summary of care document that hospitals must generate and provide for the core objective of ''The eligible hospital or CAH that transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.'' While we believe that the summary of care documents are best exchanged directly with the provider to whom the hospital is transitioning care or referring the patient, we also believe that providing an electronic copy with discharge information will ensure that the provider can easily access the information after the transition of referral. We have modified the language in the list of required elements below to reflect this.

After consideration of the public comments received, we are finalizing the first meaningful use measure for eligible hospitals and CAHs at § 495.6(l)(8)(ii)(A) as proposed. We are modifying the second meaningful use measure for eligible hospitals and CAHs to be ''More than 5 percent of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the EHR reporting period'' at § 495.6(l)(8)(ii)(B), and the exclusion for eligible hospitals and CAHs at § 495.6(l)(8)(iii) as ''Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the second measure.''

We further specify that in order to meet this objective and measure, an

eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(e)(1).

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:

- *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.

To calculate the percentage of the second measure for reporting on the 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 (or their authorized representatives) who view, download or transmit health information, CMS and ONC have worked together to define the following for this objective:

- *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 unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the discharge information provided by the eligible hospital or CAH.
- *Threshold:* The resulting percentage must be more than 5 percent in order for an eligible hospital or CAH to meet this measure.
- *Exclusion:* Any eligible hospital or CAH will be excluded from the second measure if it is located in a county that does not have 50 percent or more of its housing units with 3Mbps broadband availability according to the latest information available from the FCC on the first day of 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.
- Current medication list and medication history.
- Current medication allergy list and medication allergy history.
- 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.

As noted in the proposed rule, this is not intended to limit the information made available by the hospital. A hospital can make available additional information and still align with the objective. Please note that while some of the information made available through this measure is similar to the information made available in the summary of care document that must be provided following transitions of care or referrals, the list of information above is specific to the view online, download, and transmit objective. Patients and providers have different information needs and contexts, so CMS has established separate required fields for each of these objectives.

Proposed Eligible Hospital/CAH Objective: Record whether a patient 65 years old or older has an advance directive.

In our proposed rule, we noted that the HIT Policy Committee recommended making this a core objective and also requiring eligible hospitals and CAHs to either store an electronic copy of the advance directive in the CEHRT or link to an electronic copy of the advance directive. However, we proposed to maintain this objective as part of the menu set for Stage 2, and we did not propose the requirement of an electronic copy or link to the advance directive. As we stated in our Stage 1 final rule (75 FR 44345), we have continuing concerns that there are potential conflicts between storing advance directives and existing state laws. Also, we believe that because of state law restrictions, an advance directive stored in an EHR may not be actionable. Finally, we believe that eligible hospitals and CAHs may have other methods of satisfying the intent of this objective at this time, although we recognize that these workflows may change as EHR technology develops and becomes more widely adopted. Therefore, we did not propose to adopt the HIT Policy Committee's recommendations for this objective.

The HIT Policy Committee has also recommended the inclusion of this objective for EPs in Stage 2. In our Stage 1 final rule (75 FR 44345), we indicated our belief that many EPs will not record this information under current standards of practice and will only require information about a patient's advance directive in rare circumstances. We continue to believe this is the case and that creating a list of specialties or types of EPs that will be excluded from the objective will be too cumbersome and still might not be comprehensive. Therefore, we did not propose the recording of the existence of advance directives as an objective for EPs in Stage 2. However, we solicited public comment on this decision and encouraged commenters to address specific concerns regarding scope of practice and ease of compliance for EPs. And we note that nothing in this rule compels the use of advance directives.

Comment: While some commenters supported the HIT Policy Committee's recommendations, many recommended that we keep this measure as part of the menu set. We received several comments about a link or copy of the advance directives, and these commenters generally supported our proposal of not including this as part of the objective.

Response: While we appreciate the commenters support and the HITPC's reiteration of their recommendation, neither the HITPC nor other commenters provided new information that would address our concerns regarding conflicting state laws.

Comment: While most commenters agreed that this objective should not be extended to EPs at this time, a select few suggested adding it as part of the menu set.

Response: We are not extending this objective to EPs. Our belief that many EPs would not record this information under current standards of practice was supported by commenters. Also, we continue to believe that creating a list of specialties or types of EPs that would be excluded from the objective would be too cumbersome and would not be comprehensive.

After consideration of public comments, we are finalizing this objective for eligible hospitals and CAHs at § 495.6(m)(1)(i) as proposed.

Proposed Eligible Hospital/CAH Measure: More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have

an indication of an advance directive status recorded as structured data.

In the proposed rule, we explained that the calculation of the denominator for the measure of this objective is limited to unique patients age 65 or older who are admitted to an eligible hospital's or CAH's inpatient department (POS 21). Patients admitted to an emergency department (POS 23) should not be included in the calculation. As we discussed in our Stage 1 final rule (75 FR 44345), we believe that this information is a level of detail that is not practical to collect on every patient admitted to the eligible hospital's or CAH's emergency department, and therefore, have limited this measure only to the inpatient department of the hospital.

Comment: A commenter indicated that nearly 70 percent of hospitals could meet this measure in Fall 2011.

Response: Data collected from Stage 1 attestations shows that less than 15 percent of hospitals deferred this measure.

After consideration of public comments, we are finalizing this measure for eligible hospitals and CAHs at § 495.6(m)(1)(ii) as proposed. We are maintaining the exclusion for any eligible hospital or CAH that admits no patients age 65 years old or older during the EHR reporting period.

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(17).

- *Denominator:* Number of unique patients age 65 or older admitted to an eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period.
- *Numerator:* The number of patients in the denominator who have an indication of an advance directive status entered using structured data.
- *Threshold:* The resulting percentage must be more than 50 percent in order for an eligible hospital or CAH to meet this measure.
- *Exclusion:* Any eligible hospital or CAH that admits no patients age 65 years old or older during the EHR reporting period.

(f) HIT Policy Committee Recommended Objectives Discussed in the Proposed Rule Without Proposed Regulation Text

We did not propose these objectives for Stage 2 as explained at each objective, but we solicited comments on whether these objectives should be incorporated into Stage 2.

Hospital Objective: Provide structured electronic lab results to eligible professionals.

Although the HITPC recommended this as a core objective for Stage 2 for hospitals, we did not propose this objective for the following reasons as explained in the proposed rule. Although hospital labs supply nearly half of all lab results, they are not the predominant vendors for providers who do not share or cannot access their technology. Independent and office laboratories provide over half of the labs in this market. We stated that we were concerned that imposing this requirement on hospital labs would unfairly disadvantage them in this market. Furthermore, not all hospitals offer these services so it would create a natural disparity in meaningful use between those hospitals offering these services and those that do not. Finally, all other aspects of meaningful use in Stage 1 and Stage 2 focus on the inpatient and emergency departments of a hospital. This objective is not related to these departments, and in fact excludes services provided in these departments. We asked for comments on both the pros and cons of this objective and whether it should be considered for this final rule as recommended by the HITPC.

Comment: Nearly all of the commenters that supported the inclusion of this objective based their support wholly or in part on the concept that the benefits of hospitals providing structured electronic lab results outweigh the costs of doing so. They point to specific benefits, such as making it more likely that EPs will be able to meet the meaningful use measure of incorporating clinical lab-test results into CEHRT as structured data, as well as more general benefits of structured electronic results.

Response: The large number of commenters in support of this objective and the associated benefits they identified make a compelling case for inclusion. In particular, inclusion of this objective will enable EPs to incorporate laboratory test results into the CEHRT as structured data, which in turn adds to the ability of CEHRT to provide CDS and to calculate clinical quality measures. In addition, this objective will improve consistency in the market by incentivizing the use of the uniform standard for laboratory exchange transactions included in CEHRT as established in ONC's certification criteria at (ONC reference once available). However, the benefits identified are somewhat tempered by the makeup of the commenters supporting the inclusion of this objective, who are usually those who stand to benefit (EPs, patient advocates and others), whereas those who did not support inclusion are usually those who would bear the burden (hospitals and vendors). We summarize and respond to the comments in opposition later. However, due to the strong disagreements among commenters about the inclusion of this objective, and also concern for market impact discussed in the comments later, we will include it in the menu set of Stage 2 and not in the core set as recommended by the HITPC and supported by some of the commenters.

Comment: Several commenters questioned the applicability of this objective to meaningful use. Most stated that it was not applicable for several reasons. First, commenters asserted it is beyond the statutory authority of the Medicare EHR Incentive Program, which is established in sections of the statute that govern payment for hospital inpatient services, whereas laboratory services are paid under a different payment system. Second, as meaningful use is currently constrained to the inpatient and emergency departments, it would be inconsistent to expand it to include lab results for patients that are not admitted to either the inpatient or emergency department of the hospital. Third, systems used by hospitals to process and send laboratory results are not traditionally considered part of CEHRT, and including those systems in CEHRT could have many unintended consequences and costs.

Response: We believe the statute supports a definition of meaningful use that is not limited to actions taken within the inpatient department of a hospital. The meaningful use incentive payments and payment adjustments for Medicare eligible hospitals are established in sections of the Act that are under the hospital inpatient prospective payment system (IPPS) (sections 1886(n) and 1886(b)(3)(B)(ix) of the Act, respectively). However, the statutory definition of a ''meaningful EHR user'' under section 1886(n)(3) of the Act does not constrain the use of CEHRT to the inpatient department of the hospital. The definition requires in part that an eligible hospital must use CEHRT ''for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination'' (section 1886(n)(3)(A)(ii)), which the objective of providing structured electronic lab results to ambulatory providers would support. Moreover, the majority of hospital objectives for Stages 1 and 2 of meaningful use take into account actions performed in the emergency department as well as the inpatient department. In the Stage 1 final rule, we indicated that we may consider

applying the Stage 2 criteria more broadly to all hospital outpatient settings beyond the emergency department (75 FR 44322). One of the primary reasons not to include outpatient settings in meaningful use for hospitals is the potential for overlap with settings where EPs typically would use CEHRT. We believe there is minimal risk of such overlap with this objective, as it involves a function that is controlled by the hospital, and for which EPs are a recipient and not a provider of information. In regards to the third reason identified by commenters, CEHRT and meaningful use already include the ability to report electronic lab results to public health agencies, so consequences and costs of such inclusion should have already occurred. The impact of including these systems in certification is addressed in the ONC regulation published elsewhere in this issue of the **Federal Register**.

Comment: A few commenters supported this objective because they believe that hospital labs have lagged behind independent labs in providing electronic results.

Response: We agree that hospital lab reporting should be included as a menu set objective, but without actual data demonstrating lags by hospitals in laboratory exchange with ambulatory providers, we do not find this to be a compelling reason to include the objective as part of the core set.

Comment: Commenters believed this objective is inappropriate because the meaningful use regulations do not apply to commercial clinical laboratories, leading to an adverse market impact for hospitals in competition with others that process laboratory results for physician offices. The operational impacts of this objective are significant. In the absence of functional health information exchanges, hospitals would need to create and maintain separate, system-to-system interfaces with each physician office that receives laboratory results electronically, at considerable cost and effort. The transition to using standardized code sets in laboratories that must continue to function is challenging and burdensome, particularly for small hospitals.

Response: For these reasons, we include this objective and measure in the menu set. Those hospitals that see competitive benefits in providing electronic lab results to ambulatory providers may wish to select this as a menu set objective. Those who believe that building out the capability to provide electronic lab results is not beneficial in their competitive market environments can defer the objective. Similarly, those hospitals that consider the burden too high can defer this objective.

After consideration of public comments, we are including this objective in the menu set for eligible hospitals and CAHs at § 495.6(m)(6)(i) as ''Provide structured electronic lab results to ambulatory providers.''

For each objective, we outline the benefits expected from that objective. We did not include these benefits in our proposed rule and we are adding them to this final rule. Hospitals sending structured lab results electronically to EPs using CEHRT and in accordance with designated standards will directly enhance the ability of EPs to meet meaningful use objectives, including incorporating laboratory test results into the EHR as structured data, generating lists of patients with particular conditions, utilizing clinical decision support, and enhancing the ability to calculate clinical quality measures. The addition of this objective will help improve consistency in the market, in contrast to today's environment in which inconsistencies in interface requirements are hindering the delivery of structured hospital lab results to ambulatory EHRs. This objective will also benefit hospitals by creating a uniform standard for laboratory exchange transactions, which will eliminate variation, reducing interface costs and time to deploy.

Hospital Measure: Hospital labs send (directly or indirectly) structured electronic clinical lab results to the ordering provider for more than 40 percent of electronic lab orders received.

The measure for this objective recommended by the HIT Policy Committee is that 40 percent of clinical lab test results electronically sent by an eligible hospital or CAH will need to be done so using the capabilities CEHRT. This measure requires that in situations where the electronic connectivity between an eligible hospital or CAH and an EP is established, the results electronically exchanged are done so using CEHRT. To facilitate the ease with which this electronic exchange may take place, ONC proposed that for certification, ambulatory EHR technology will need to be able to incorporate lab test results formatted in the same standard and implementation specifications to which inpatient EHR technology will need to be certified as being able to create.

Comment: Some commenters who support this objective raised concerns that small hospitals might not be able to comply due to the burden involved and suggest an unspecified exclusion for them.

Response: By including this objective as a menu set item, those hospitals that view lab reporting to ambulatory practices as too burdensome can defer this measure.

Comment: Some commenters supporting the measure indicated that they would like to see hospital reference labs that are already providing electronic lab results to ordering providers ''grandfathered'' into the measure.

Response: There are two reasons that a hospital providing electronic lab results already would need special consideration. First, they are not using the standards of CEHRT where available. Second, they may not have gotten the system they use certified. As it is meaningful use of CEHRT we do not believe that we should include exceptions to the use of CEHRT in meaningful use. We do not believe that providers must ''rip and replace'' existing systems. Existing systems that support the standards of CEHRT can be certified for inclusion and those that do not support the standards can defer the objective until they upgrade to the standards of CEHRT.

Comment: Commenters expressed concern that if the objective is included in meaningful use that the threshold is unattainable. They noted that for a hospital to send electronic lab results the EP must be able to receive electronic results and that current adoption rates do not indicate that 40 percent of EPs will be able to receive electronic lab results.

Response: The measure uses a denominator of electronic lab orders received so this consideration is already built into the measure. However, we do agree with commenters that 40 percent is a high threshold for this completely new measure as it is dependent on electronic health exchange. For the final measure we reduce the threshold to 20 percent. While we considered lowering the threshold to 10 percent, the denominator limitation that the lab order must be received electronically already limits the measure to those ordering providers capable of submitting electronic orders and implies at least some electronic health information exchange has been established between the hospital and the ordering provider.

After considering the comments, we are finalizing this measure for eligible hospitals and CAHs at § 495.6(m)(6)(ii) as ''Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received.''

In order to be counted in the numerator, the hospital would need to use CEHRT to send laboratory results to the ambulatory provider in a way that has the potential for electronic incorporation of those results as structure data. Methods that have no potential for automatic incorporation such as ''portal view'' do not count in the numerator. 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 CEHRT at 45 CFR 170.314(b)(6).

- *Denominator:* The number of electronic lab orders received.
- *Numerator:* The number of structured clinical lab results sent to the ordering provider.
- *Threshold:* The resulting percentage must be greater than 20 percent.

EP Objective/Measure: Record patient preferences for communication medium for more than 20 percent of all unique patients seen during the EHR reporting period.

We proposed that this requirement is better incorporated with other objectives that require patient communication and is not necessary as a standalone objective.

Commenters were supportive of the incorporation of this objective and we continue to believe that it is better incorporated; therefore, we are finalizing this provision as proposed.

Objective/Measure: Record care plan goals and patient instructions in the care plan for more than 10 percent of patients seen during the reporting period.

We proposed that this requirement is better incorporated with other objectives that require summary of care documents and is not necessary as a standalone objective.

Commenters were supportive of the incorporation of this objective as proposed and we continue to believe that it is better incorporated; therefore, we are finalizing this provision as proposed.

Objective/Measure: Record health care team members (including at a minimum PCP, if available) for more than 10 percent of all patients seen during the reporting period; this information can be unstructured.

We proposed that this requirement is better incorporated with other objectives that require summary of care documents and is not necessary as a standalone objective.

Commenters were supportive of the incorporation of this objective as proposed and we continue to believe that it is better incorporated; therefore, we are finalizing as proposed.

Objective/Measure: Record electronic notes in patient records for more than 30 percent of office visits.

In the proposed rule, we encouraged public comment regarding the inclusion of this objective/measure. We noted that narrative entries are considered an important component of patient records and complement the structured data captured in CEHRT. We also noted our understanding that electronic notes are already widely used by providers and therefore may not need to include this as a meaningful use objective.

Comment: Commenters agreed that existing technology has the capability to capture notes in an electronic form for inclusion in the patient record. Other commenters mentioned that not all CEHRT in use currently include the capability to incorporate narrative clinical documentation.

Response: We reiterate the statement in the proposed rule regarding the important contribution of narrative clinical documentation in the patient record. In light of the comments that not all CEHRT currently has the capability to incorporate this clinical documentation, we agree to incorporate this functionality to record electronic notes as an additional menu objective for Stage 2 of meaningful use. The ONC standards and certification criteria final rule associated with this objective/measure is published elsewhere in this issue of the **Federal Register**. We believe that inclusion of electronic patient notes to the meaningful use menu objectives is another incremental step towards maximizing the potential of EHR technology.

Comment: The HIT Policy Committee commented that this objective/measure should apply to both EPs, eligible hospitals and CAHs because some certified EHRs do not have clinical documentation and because they believe that a complete record (including progress notes) is required to deliver high quality, efficient care.

Response: We agree and are adopting this objective in the menu set for Stage 2 for EPs, eligible hospitals and CAHs in order to allow providers access to the most accurate and complete patient information available electronically to support quality of care efforts across patient care settings.

Comment: A commenter suggested that if this objective/measure becomes part of the final rule it will require a clear definition of how notes are defined and who may create, edit and sign them in order to be included in the measure numerator. Other commenters requested clarification of the term electronic note and whether it would include nursing notes, flow sheets, operative reports, discharge summaries, consults, etc. in addition to basic progress notes.

Response: For this objective, we have determined that any EP as defined for the Medicare or Medicaid EHR Incentive Programs, or an authorized provider of the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) may author, edit, and provide an electronic signature for the electronic notes in order for them to be considered for this measure. We further define electronic notes as electronic progress notes for the purpose of this measure. We will rely on providers own determinations and guidelines defining when progress notes are necessary to communicate individual patient circumstances and for coordination with previous documentation of patient observations, treatments and/or results in the electronic health record.

Comment: Many commenters agreed with the inclusion of the text searchable certification requirement and agreed that portions of clinical notes are already being collected electronically. The HIT Policy Committee recommended inclusion of this measure because some certified EHRs do not have clinical documentation, and believe that the benefit of a complete patient record, including progress notes, is required to deliver high quality, efficient care. Several commenters were opposed to the inclusion of this additional measure in order to limit the number of reporting objectives.

Response: Based on the multiple reasons stated in this preamble we agree with the benefits of including the electronic progress notes measure in the menu set for the Stage 2 meaningful use objectives. We envision continued technological advances in the capture and processing of text and diagrammatic data such as research of natural language processing. We also believe there is added value in collecting both narrative data and structured data in the EHR and using that information to track key clinical conditions and communicating that information for care coordination purposes. Therefore, we are including this objective/measure to record electronic notes in the patient records for more than 30 percent of office visits or unique patients admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) as was originally recommended by the HITPC.

After consideration of public comments, we are finalizing this objective for EPs at § 495.6 (k)(6)(i) and for eligible hospitals and CAHs at § 495.6(m)(5)(i) as ''Record electronic notes in patient records.''

We are adding the measure for EPs at § 495.6(k)(6)(ii) and for eligible hospitals and CAHs at § 495.6(m)(5)(ii) of our regulations to include this new measure:

EP Menu Measure: Enter at least one electronic progress note created, edited and signed by an EP for more than 30 percent of unique patients with at least one office visit during the EHR reporting period. Electronic progress notes must be text-searchable. Non-searchable notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be included with searchable text notes under this measure.

Eligible Hospital/CAH Menu Measure: Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. Electronic progress notes must be text-searchable. Non-searchable notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be included with searchable text notes under this measure.

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 CEHRT at 45 CFR 170.314(a)(9).

To calculate the percentage, CMS and ONC have worked together to define the following for these measures:

- *Denominator:* Number of unique patients with at least one office visit during the EHR reporting period for EPs or admitted to an eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- *Numerator:* The number of unique patients in the denominator who have at least one electronic progress note from an eligible professional or authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) recorded as text-searchable data.
- *Threshold:* The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure.

TABLE B5—STAGE 2 OBJECTIVES AND MEASURES

Health outcomes policy priority	Stage 2 objectives		Stage 2 measures
	Eligible professionals	Eligible hospitals and CAHs	
CORE SET			
Improving quality, safety, efficiency, and reducing health disparities.	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	More than 60 percent of medication, 30 percent of laboratory, and 30 percent 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.
	Generate and transmit permissible prescriptions electronically (eRx).	.....	More than 50 percent of all permissible prescriptions, or all prescriptions written by the EP and queried for a drug formulary and transmitted electronically using CEHRT.
	Record the following demographics: • Preferred language • Sex • Race • Ethnicity • Date of birth	Record the following demographics: • Preferred language • Sex • Race • Ethnicity • Date of birth • Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.	More than 80 percent of all unique patients 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 demographics recorded as structured data.
	Record and chart changes in vital signs: • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0–20 years, including BMI	Record and chart changes in vital signs: • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0–20 years, including BMI	More than 80 percent of all unique patients 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 blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

TABLE B5—STAGE 2 OBJECTIVES AND MEASURES—Continued

Health outcomes policy priority	Stage 2 objectives		Stage 2 measures
	Eligible professionals	Eligible hospitals and CAHs	
	Record smoking status for patients 13 years old or older.	Record smoking status for patients 13 years old or older.	More than 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data.
	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. It is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency. 2. The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug and drug allergy interaction checks for the entire EHR reporting period.
	Incorporate clinical lab-test results into Certified EHR Technology as structured data.	Incorporate clinical lab-test results into Certified EHR Technology as structured data.	More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.
	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.
	Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder, per patient preference.	.....	More than 10 percent of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available.
		Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).	More than 10 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 for which all doses are tracked using eMAR.

TABLE B5—STAGE 2 OBJECTIVES AND MEASURES—Continued

Health outcomes policy priority	Stage 2 objectives		Stage 2 measures
	Eligible professionals	Eligible hospitals and CAHs	
Engage patients and families in their health care.	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 (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. 2. More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download, or transmit to a third party their health information.
		Provide patients the ability to view online, download, and transmit information about a hospital admission.	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. 2. More than 5 percent of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period.
	Provide clinical summaries for patients for each office visit.	.....	Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits.
	Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.	Use Certified EHR Technology 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 percent of all unique patients with office visits seen by the EP during the EHR reporting period. More than 10 percent 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 Certified EHR Technology.
	Use secure electronic messaging to communicate with patients on relevant health information.	.....	A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period.

TABLE B5—STAGE 2 OBJECTIVES AND MEASURES—Continued

Health outcomes policy priority	Stage 2 objectives		Stage 2 measures
	Eligible professionals	Eligible hospitals and CAHs	
Improve care coordination	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 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).
	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 provides a summary of care record for more than 50 percent of transitions of care and referrals. 2. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either—(a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. 3. An EP, eligible hospital or CAH must satisfy one of the two following criteria: (A) Conducts one or more successful electronic exchanges of a summary of care document, as part of which is counted in ''measure 2'' (for EPs the measure at § 495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs the measure at § 495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was developed designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or (B) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.
Improve population and public health.	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

TABLE B5—STAGE 2 OBJECTIVES AND MEASURES—Continued

Health outcomes policy priority	Stage 2 objectives		Stage 2 measures
	Eligible professionals	Eligible hospitals and CAHs	
		Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to public health agencies for the entire EHR reporting period.
		Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.
Ensure adequate privacy and security protections for personal health information.	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	Protect electronic health information created or maintained by the Certified EHR Technology 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 encryption/security 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.
MENU SET			
Improving quality, safety, efficiency, and reducing health disparities.	.....	Record whether a patient 65 years old or older has an advance directive.	More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.
	Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.	Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.	More than 10 percent of all tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through Certified EHR Technology.
	Record patient family health history as structured data.	Record patient family health history as structured data.	More than 20 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.
		Generate and transmit permissible discharge prescriptions electronically (eRx).	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 Certified EHR Technology.

TABLE B5—STAGE 2 OBJECTIVES AND MEASURES—Continued

Health outcomes policy priority	Stage 2 objectives		Stage 2 measures
	Eligible professionals	Eligible hospitals and CAHs	
	Record electronic notes in patient records.	Record electronic notes in patient records.	Enter at least one electronic progress note created, edited and signed by an eligible professional for more than 30 percent of unique patients with at least one office visit during the EHR reporting period.
			Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. Electronic progress notes must be text-searchable. Non-searchable notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be included with searchable text notes under this measure.
		Provide structured electronic lab results to ambulatory providers.	Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received.
Improve Population and Public Health.	Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.	.....	Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.
	Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.	.....	Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period.
	Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.	.....	Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

B. Reporting on Clinical Quality Measures Using Certified EHR Technology by Eligible Professionals, Eligible Hospitals, and Critical Access Hospitals

The following sections address CQMs reporting requirements using CEHRT. These include: EHR technology certification requirements; criteria for CQM selection; time periods for reporting CQMs; issues related to specifications for CQMs and transmission formats; reporting options and CQMs for EPs; reporting methods for EPs; reporting options and CQMs for eligible hospitals and CAHs; and reporting methods for eligible hospitals and CAHs.

1. Time Periods for Reporting CQMs

This section addresses the reporting periods and submission periods as they relate to reporting CQMs only. For a summary of the reporting and submission periods proposed for CQMs, please refer to Table 5 in the Stage 2 proposed rule (77 FR 13742).

We proposed that the reporting period for CQMs, which is the period during which data collection or measurement for CQMs occurs, would continue to track with the EHR reporting periods for the meaningful use objectives and measures:

- EPs: January 1 through December 31 (calendar year).
- Eligible Hospitals and CAHs: October 1 through September 30 (federal fiscal year).
- EPs, eligible hospitals, and CAHs in their first year of meaningful use for Stage 1, any continuous 90-day period within the calendar year (CY) or federal fiscal year (FY), respectively.

To avoid a payment adjustment, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding any payment adjustment year would have to ensure that their 90-day EHR reporting period ends at least 3 months before the end of the CY or FY, and that all submission is completed by October 1 or July 1, respectively. For more information on payment adjustments, see section II.D. of this final rule.

The submission period is the time during which EPs, eligible hospitals, and CAHs may submit CQM information. We proposed the submission period for CQM data generally would be the 2 months immediately following the end of the EHR reporting period as follows:

- EPs: January 1 through February 28.
- Eligible Hospitals and CAHs: October 1 through November 30.
- EPs, eligible hospitals, and CAHs in their first year of Stage 1: Anytime after the end of their 90-day EHR reporting period until the end of the 2 months immediately following the end of the CY or FY, respectively. However, for purposes of avoiding the payment adjustments, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must submit their CQM data no later than October 1 (EPs) or July 1 (eligible hospitals) of such preceding year.

Comment: Several commenters stated that the first year of a new stage for reporting CQMs should only require a 90-day or 180-day reporting period instead of a 365-day reporting period.

Response: We agree that vendors, EPs, eligible hospitals, and CAHs may need more time to develop, test, and implement EHR technology certified to the 2014 Edition EHR certification criteria and to be able to meet the CQM reporting requirements that we proposed beginning in 2014. Therefore, for the reasons discussed in this section, we are modifying the reporting periods for CQMs in 2014 to match the EHR reporting periods that we are finalizing for 2014. By using 3-month quarters as the reporting periods in 2014 for providers that are beyond their first year of demonstrating meaningful use instead of requiring a full year as proposed, we allow vendors and health care providers as much as 9 months more time to program, develop, and implement CEHRT, and meet the requirements for meaningful use in 2014. We note that the 3-month quarter reporting period is only applicable for 2014. For 2015 and subsequent years, we are finalizing our proposal of a full year reporting period for EPs, eligible hospitals and CAHs that are beyond their first year of demonstrating meaningful use. We have selected 3-month quarters rather than any continuous 90-day period to promote more ready comparisons of data. This is particularly important for eligible hospitals and CAHs since many of the CQMs that we are finalizing for 2014 and subsequent years are also used in the CMS Hospital IQR Program. We have indicated our desire to transition the CMS Hospital IQR Program to collecting EHR-based quality data. Having data from hospitals for comparable quarter timeframes as used for the CMS Hospital IQR Program will be beneficial for comparing chart abstracted data with data derived from CEHRT and will facilitate data collection mode for potential future usage for Hospital Compare public reporting and the CMS Hospital Value Based Purchasing programs.

After consideration of the public comments received, we are finalizing the reporting and submission periods as follows. The reporting period for CQMs generally will be the same as an EP's, eligible hospital's, or CAH's respective EHR reporting period for the meaningful use objectives and measures, with the exceptions discussed later in this section. Please note that Medicare EPs who choose to report CQMs through the options we are finalizing that rely on other CMS programs (namely, Option 2—PQRS (see section II.B.6.c. of this final rule) and the group reporting options—Physician Quality Reporting System (PQRS) and Accountable Care Organizations (ACOs) (see section II.B.6.d. of this final rule) would be subject to the reporting periods for CQMs established for those programs. As an example using CY 2014, for Medicare EPs who choose to submit CQMs under Option 2 (PQRS EHR Reporting Option) for purposes of satisfying the CQM reporting component of meaningful use, the reporting periods for the PQRS EHR reporting that fall within CY 2014 would apply. Medicaid EPs and eligible hospitals must submit CQM data for a reporting period that is the same as their EHR reporting period using the reporting methods and submission periods specified by their state Medicaid agency.

In 2013, the reporting period for CQMs will continue to be an EP's, eligible hospital's or CAH's respective EHR reporting period. The submission period will be the 2 months immediately following the end of the CY or FY, respectively (EPs: January 1 through February 28, 2014; eligible hospitals and CAHs: October 1 through November 30, 2013). EPs, eligible hospitals and CAHs in their first year of meaningful use may submit CQM data anytime after the end of their 90-day EHR reporting period until the end of the 2 months immediately following the end of the CY or FY, respectively.

Beginning in 2014 and in subsequent years, for EPs, eligible hospitals and CAHs that are in their first year of meaningful use, the reporting period for CQMs will be their respective 90-day EHR reporting period, and they must submit CQM data by attestation. The submission period will be anytime after the end of their respective 90-day EHR reporting period until the end of the 2 months immediately following the end of the CY or FY, respectively. However, for purposes of avoiding a payment adjustment, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must submit their CQM data no later than October 1 (EPs) or July 1 (eligible hospitals) of such preceding year. We note that these deadlines do not apply to CAHs. For more details on submission deadlines specific to CAHs, please refer to section II.D.4. of this final rule.

Beginning in 2014 and in subsequent years, EPs, eligible hospitals and CAHs that are beyond their first year of meaningful use must electronically submit CQM data unless the Secretary lacks the capacity to accept electronic submission. In the unlikely event that the Secretary does not have the capacity to accept electronic submission, then consistent with sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii) of the Act, we would continue to accept attestation as a method of reporting CQMs. We would inform the public of this fact by publishing a notice in the **Federal Register** and providing instructions on how CQM data should be submitted to us. For additional details on the reporting methods for EPs, please refer to sections II.B.6.c. and II.B.6.d. of this final rule, and for the reporting methods for eligible hospitals and CAHs, please refer to section II.B.8.b. of this final rule. The reporting periods for CQMs in 2014 for EPs, eligible hospitals, and CAHs that are beyond their first year of meaningful use are as follows:

- EPs, eligible hospitals and CAHs may report CQM data for the full CY or FY 2014, respectively, if desired. Alternatively, they may report CQM data for the 3-month quarter(s) that is/are their respective EHR reporting period.

++ For EPs, the 3-month quarters are as follows:
—January 1, 2014 through March 31, 2014
—April 1, 2014 through June 30, 2014
—July 1, 2014 through September 30, 2014
—October 1, 2014 through December 31, 2014
++ For eligible hospitals and CAHs, the 3-month quarters are as follows:
—October 1, 2013 through December 31, 2013
—January 1, 2014 through March 31, 2014
—April 1, 2014 through June 30, 2014
—July 1, 2014 through September 30, 2014

In all cases of electronic submission, the submission period will be the 2 months immediately following the end of the CY or FY, respectively. This submission period will apply regardless of whether an EP, eligible hospital or CAH reports CQM data for the full CY or FY, respectively, or only for a 3-month quarter:

• EPs: January 1, 2015 through February 28, 2015.
• Eligible Hospitals and CAHs: October 1, 2014 through November 30, 2014.

The reporting periods for CQMs in 2015 and in subsequent years for EPs, eligible hospitals, and CAHs that are beyond their first year of meaningful use will be the full CY or FY, respectively. For EPs, we expect to accept a single annual submission. For eligible hospitals and CAHs, we expect to align with the submission frequency of the Hospital IQR program for electronic reporting of CQMs.

We summarize the reporting and submission periods beginning with CY/FY 2014 for EPs, eligible hospitals, and CAHs reporting CQMs via attestation in Table 5 and reporting CQMs electronically in Table 6.

TABLE 5—REPORTING AND SUBMISSION PERIODS FOR EPS, ELIGIBLE HOSPITALS AND CAHS IN THEIR FIRST YEAR OF MEANINGFUL USE SUBMITTING CQMS VIA ATTESTATION BEGINNING WITH CY/FY 2014

Provider type	Reporting period for first year of meaningful use (Stage 1)	Submission period for first year of meaningful use (Stage 1)*
EP	90 consecutive days	Anytime immediately following the end of the 90-day reporting period, but no later than February 28 of the following calendar year.
Eligible Hospital/CAH	90 consecutive days	Anytime immediately following the end of the 90-day reporting period, but no later than November 30 of the following fiscal year.

*For purposes of avoiding a payment adjustment, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must submit their CQM data no later than October 1 (EPs) or July 1 (eligible hospitals) of such preceding year.

TABLE 6—REPORTING AND SUBMISSION PERIODS FOR EPS, ELIGIBLE HOSPITALS AND CAHS BEYOND THEIR FIRST YEAR OF MEANINGFUL USE SUBMITTING CQMS ELECTRONICALLY BEGINNING WITH CY/FY 2014

Provider type	Optional reporting period in 2014*	Reporting period for subsequent years of meaningful use (stage 1 and subsequent stages)	Submission period for subsequent years of meaningful use (stage 1 and subsequent stages)*
EP	Calendar year quarter: January 1–March 31 April 1–June 30 July 1–September 30 October 1–December 31	1 calendar year (January 1–December 31).	2 months following the end of the reporting period (January 1–February 28).
Eligible Hospital/CAH	Fiscal year quarter October 1–December 31 January 1–March 31 April 1–June 30 July 1–September 30	1 Fiscal year (October 1–September 30).	2 months following the end of the reporting period (October 1–November 30).

*NOTE: The optional quarter reporting periods have the same submission period as a full year reporting period for electronic submission.

2. EHR Technology Certification Requirements for Reporting of CQMs

ONC adopts certification criteria for EHR technology and proposed a 2014 Edition of certification criteria in a proposed rule (77 FR 13832). As such, we proposed to require that CEHRT, as defined by ONC, must be used by EPs, eligible hospitals, and CAHs to satisfy their CQM reporting requirements (77 FR 13743). We proposed that CQM reporting methods could include the following:

• Aggregate reporting methods (EPs, eligible hospitals, and CAHs):
++ Attestation
++ Electronic submission
• Patient-level reporting methods:
++ The PQRS EHR reporting option, the group reporting options for PQRS, the Medicare SSP or Pioneer ACOs (note: these are reporting methods for EPs)
++ The manner similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs.

For the attestation and aggregate electronic reporting methods, we proposed that EPs, eligible hospitals, and CAHs must only submit CQMs that their EHR technology had been certified to ''incorporate and calculate'' (45 CFR 170.314(c)(2) in ONC's rule). For example, if an EP's CEHRT was certified to calculate CQMs #1 through #9, and the EP submitted CQMs #1 through #8 and #25, the EP would not have met the meaningful use requirement for reporting CQMs because his/her CEHRT was not certified to calculate CQM #25. For the attestation and aggregate electronic reporting methods, we proposed that CEHRT must be certified to the ''reporting'' certification criterion proposed for adoption by ONC at 45 CFR 170.314(c)(3) and which focused on

EHR technology's capability to create and transmit a standard aggregate XML-based file that CMS can electronically accept.

Comment: Most commenters supported the requirement that EHR technology certified to the 2014 Edition EHR certification criteria should be able to capture, accurately calculate and transmit CQM data. Many of these commenters pointed out EHR technology certified to the 2011 Edition EHR certification criteria did not produce accurate results and was not explicitly tested and certified for accurate CQM calculation. As a result of experiences in Stage 1, some commenters recommended requiring that EHR technologies be able to calculate all measures finalized by CMS in order to be certified rather than requiring only one CQM to be certified, as was proposed by ONC to satisfy the Base EHR definition. Others supported EHR technology's output of data to another product for calculation or output in the Quality Reporting Data Architecture (QRDA) format. Many commenters also supported consistency among EHR technologies based on certification and adequate testing of the systems during certification, including use of test data. One commenter recommended closer oversight of vendors by ONC and a remediation process for vendors who do not properly implement CEHRT.

Many commenters stated that the specific XML-based format required by CMS for CQM reporting should be incorporated into ONC's certification criteria. One commenter suggested that all vendors focus on codified data collection and provide complete CCD extractions to another system (such as PopHealth) and allow that system to manage the calculations and data tables as well as provide the extraction of data for a QRDA report, stating that this method would save time and money because it would not require testing each individual EHR product. Another commenter supported the use of CQM definitions that include standards for technical and electronic specifications that allow for interoperability across EHRs and consistent use among end users.

Response: Comments on EHR technology certification requirements are outside the scope of this final rule and are addressed in ONC's Standards and Certification Criteria (S&CC) final rule published elsewhere in this issue of the **Federal Register**. ONC has addressed the CQM requirements for the Base EHR definition, the standards necessary for the submission of CQM data to CMS, and has made other conforming revisions to the proposed certification criteria in response to public comments received.

Comment: Several commenters stated that it was unrealistic to expect the transition to EHR technology certified to the 2014 Edition EHR certification criteria to be feasible for all EPs and all eligible hospitals and CAHs at the same time. These commenters explained that EHR vendors would need to develop, test, distribute upgraded products, and provide user support for a large number of clients in a short amount of time. Furthermore, EPs, eligible hospitals, and CAHs would need to devote time and resources as well as have qualified staff to purchase and implement the upgraded technology, including testing the system and training staff, which may include designing new clinical workflows. The commenters requested a more reasonable approach to transitioning to the upgraded technology that would ensure proper implementation and avoid compromising patient safety.

Response: We acknowledge that the transition to upgraded EHR technology will be a challenge for all parties involved. Due to several interrelated factors addressed by ONC and CMS to relieve regulatory burden in our respective final rules, we have respectively included certain new flexibilities for EPs, eligible hospitals, and CAHs in order to allow for a more reasonable transition to the upgraded technology. ONC has decided to finalize a more flexible CEHRT definition for the EHR reporting periods in FY/CY 2013, which would permit EPs, eligible hospitals, and CAHs to use EHR technology that has been certified only to the 2014 Edition EHR certification criteria.

For EPs, eligible hospitals, and CAHs that seek to use EHR technology certified only to the 2014 Edition EHR certification criteria in FY/CY 2013, we note that EHR technology certified to these criteria reflect the new set of CQMs we adopt in this rule for reporting beginning with FY/CY 2014. We also note that the reporting requirements in FY/CY 2013 are otherwise the same as for FY/CY 2011 and 2012, including reporting on the CQMs that were finalized in the July 28, 2010 Stage 1 final rule. For EPs, the reporting schema for CY 2013 will remain 3 core or alternate core CQMs, and 3 additional CQMs, as explained in section II.B.5.b. of this final rule. We note that EHR technology certified to the 2014 Edition certification criteria will exclude the three CQMs that we are removing from the list of EP CQMs for reporting beginning in CY 2014 (NQF 0013, 0027, 0084). NQF 0013 is in the list of core CQMs in the Stage 1 final rule, but just as in the case where one of the core CQMs would not apply to an EP's scope of practice or unique patient population, EPs can select one CQM from the list of alternate core CQMs to replace NQF 0013. Therefore, in order to meet the CQM reporting criteria for meaningful use in CY 2013, EPs who seek to use EHR technology certified only to the 2014 Edition EHR certification criteria could only select from CQMs that are included in both the Stage 1 and Stage 2 final rules. For eligible hospitals and CAHs, the reporting schema for FY 2013 will remain all 15 of the CQMs finalized for reporting in FYs 2011 and 2012 because all CQMs that were included in the Stage 1 final rule are also included in the Stage 2 final rule.

Comment: Most commenters stated that CQM exceptions (allowable reason for non-performance of a quality measure for patients that meet the denominator criteria and do not meet the numerator criteria) should be incorporated into the CQM certification requirements. Many commenters also stated that EPs should not be penalized if it is later determined that a vendor has not met the certification requirement as it would be burdensome and expensive to then purchase additional certified modules and modify workflows after an existing EHR is determined to be non-certified. The same commenters believed that EPs should have an exemption from CQM reporting requirements of meaningful use until measures have been tested and vendors have shown they have met the certification requirements.

Some commenters requested delaying implementation of CQMs that require information from Labor and Delivery information systems until they are certified. One commenter stated that EHR technology should be based on the 2011 Edition EHR certification criteria. Another commenter stated that very few vendors are providing QI measure data integrity and error-checking algorithms, citing the information in FAQ 10839 which includes that CMS does not require providers to record all clinical data in their CEHRT but that providers should report the CQM data exactly as it is generated as output from CEHRT.

Response: We do not agree with the suggestion that EHR technology should based on the 2011 Edition EHR certification criteria. The 2014 Edition EHR certification criteria are significantly enhanced compared to 2011 Edition and we believe that it is important for EPs, eligible hospitals and CAHs to adopt, implement, and use

EHR technology based on the updated certification criteria. We expect that the enhancements in the 2014 Edition certification criteria will address the accuracy of outputs from CEHRT.

We agree generally with the rest of the comments. All CQMs included in this final rule will have electronic specifications available at or around the time of publication. Certification requirements are outside the scope of this rule. We refer readers to ONC's S&CC final rule published elsewhere in this issue of the **Federal Register** for information of certification requirements for items such as CQM exceptions. We discuss the testing of CQM specifications in section II.B.4. of this final rule. We encourage EPs, eligible hospitals and CAHs to refer to the Certified HIT Products List when selecting an EHR product (*http://oncchpl.force.com/ehrcert*). We also encourage EPs, eligible hospitals, and CAHs to discuss their intent to participate in the EHR Incentive Programs with their vendors, and for vendors to communicate intentions related to certification of a product with EPs, eligible hospitals or CAHs.

After consideration of the public comments received, we are finalizing the proposals related to EHR technology certification requirements for reporting of CQMs subject to the discussion earlier. They include:

- The data reported to CMS for CQMs must originate from an EP's, eligible hospital's, or CAH's CEHRT that has been 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).
- For attestation and the aggregate electronic reporting methods, the only CQMs that can be reported are those for which an EP's, eligible hospital's, or CAH's CEHRT has been certified to ''import and calculate'' in accordance with 45 CFR 170.314(c)(2).
- In FY/CY 2013, if an EP, eligible hospital, or CAH seeks to use EHR technology certified only to the 2014 Edition EHR certification criteria for reporting CQMs, they can only report those CQMs that are included in both the Stage 1 and Stage 2 final rules. For EPs, this would exclude the option of reporting NQF 0013, 0027, 0084 from the CQMs in the Stage 1 final rule. Since NQF 0013 is a core CQM in the Stage 1 final rule, EPs would select one of the alternate core CQMs to replace it. All 15 CQMs for eligible hospitals and CAHs in the Stage 1 final rule are included in the Stage 2 final rule.

3. Criteria for Selecting CQMs

We solicited comment on a wide-ranging list of 125 potential CQMs for EPs and 49 potential CQMs for eligible hospitals and CAHs. We stated that we expected to finalize only a subset of these proposed CQMs. We discussed several criteria that we used to select the proposed CQMs.

In the proposed rule, we stated our commitment to align quality measurement and reporting among our programs (for example, IQR, PQRS, CHIPRA, ACO programs). We noted that our alignment efforts focus on several fronts including using the same measures for different programs, standardizing the measure development and electronic specification processes across CMS programs, coordinating quality measurement stakeholder involvement efforts, and identifying ways to minimize multiple submission requirements and mechanisms. In the proposed rule, we gave the example that we are working toward allowing CQM data submitted via CEHRT by EPs, eligible hospitals and CAHs to apply to other CMS quality reporting programs. A longer-term vision would be hospitals and clinicians reporting through a single, aligned mechanism for multiple CMS programs. We stated our belief that the alignment options proposed for PQRS/EHR Incentive Program would be a first step toward such a vision.

Comment: There was strong support for aligning CQMs and reporting mechanisms across multiple quality reporting programs as well as alignment with the goals of the National Quality Strategy and the HIT Policy Committee recommendations. However, some commenters addressed utility of the CQMs within the EHR Incentive Program as follows:

- Removal of measures that are not included under other quality reporting programs.
- Alignment in other areas such as specifications, reporting methods and to whom measures are reported.
- Concern that the penalties that will be applied in 2015, given the many problems that were encountered implementing Stage 1 CQMs.
- Administrative burden required by multiple submission requirements and multiple reporting mechanisms. Where possible, one commenter encouraged CMS to promote and/or mandate similar action for state, accreditation body, and private payer reporting.

Response: We appreciate the comments received and have made every effort to accommodate the concerns by aligning quality reporting for EPs with the PQRS EHR Reporting Option and establishing an infrastructure for eligible hospitals and CAHs that could be used by IQR and other hospital reporting programs to electronically report CQMs.

We continue to explore how data intermediaries and state Medicaid Agencies could participate in and further enable these quality measurement and reporting alignment efforts, while meeting the needs of multiple Medicare and Medicaid programs (for example, ACO programs, Dual Eligible initiatives, Medicaid shared savings efforts, CHIPRA and Affordable Care Act measure sets). Through these efforts, we intend to lessen provider burden and harmonize with our data exchange priorities.

In addition to statutory requirements for EPs (see section II.B.5.a. of this final rule), eligible hospitals (see sections II.B.7.a. of this final rule), and CAHs (see section II.B.7.a. of this final rule), we relied on other criteria to select the proposed CQMs for EPs, eligible hospitals, and CAHs such as measures that can be technically implemented within the capacity of the CMS infrastructure for data collection, analysis, and calculation of reporting and performance rates. This includes measures that are ready for implementation, such as those with developed specifications for electronic submission that have been used in the EHR Incentive Program or other CMS quality reporting initiatives, or that will be ready soon after the expected publication of the final rule in 2012. This also includes measures that can be most efficiently implemented for data collection and submission.

Comment: There were several comments on infrastructure regarding quality measures, the selection of quality measures, challenges of implementing EHRs and the lack of coordination between measure developers and software vendors. These comments included the following:

- CQMs require data that is not coded in a structured format within the EHRs and thus require significant resources and effort, including specialized coding and training, in order to build CQMs within the EHR systems that can produce accurate results.
- CMS should only include measures which have been sufficiently field tested and validated. The National Qualify Forum's (NQF) Quality Data Model (QDM) and Measure Authoring Tool (MAT) have not been sufficiently tested to ensure valid and accurate EHR CQM calculations.
- A general lack of communication between vendors and measure stewards.

There were also several comments providing additional recommendations for selecting quality measures, including CQMs that:

- Can be automatically abstracted from an EHR.
- Rely on data that is considered viable and accurate.
- Definitively support quality care improvement.
- Align with current quality programs.

Response: The CQMs that we are finalizing for reporting beginning with 2014 have either undergone feasibility testing in EHR systems and clinical settings or were finalized in the Stage 1 final rule for reporting in 2011 and 2012 and specifications have been updated based on experiences with reporting those CQMs. In addition, ONC's 2014 Edition certification criteria explicitly require that the data elements be captured for certification (see 45 CFR 170.314(c), as discussed in ONC's final rule). We have taken into account the recommendations of commenters in our selection of the CQMs finalized for reporting beginning in 2014, and we are finalizing measures that align with current clinical quality programs as well as definitively support quality care improvements.

Comment: Commenters pointed out the limitations of current CQMs in addressing longitudinal patient care management and population health.

Response: We are finalizing CQMs for EPs, eligible hospitals, and CAHs that will have electronic specifications available at or around the time of publication of the final rule and also meet the selection criteria described in this rule. We agree with the importance of the clinical quality measurement goals mentioned by the commenters and are working with measure stewards and measure developers to create a broader set of electronic CQMs that would address these goals.

We also identified the following as criteria used in selecting CQMs:

- CQMs that can be technically implemented within the capacity of the CMS infrastructure for data collection, analysis, and calculation of reporting and performance rates. This includes CQMs that are ready for implementation, such as those with developed specifications for electronic submission that have been used in the EHR Incentive Program or other CMS quality reporting initiatives, or that will be ready soon after the expected publication of the final rule in 2012. This also includes CQMs that can be most efficiently implemented for data collection and submission.
- CQMs that support CMS and HHS priorities for improved quality of care for people in the United States, which are based on the March 2011 report to the Congress, ''National Strategy for Quality Improvement in Health Care'' (National Quality Strategy, NQS) (*http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf*) and the Health Information Technology Policy Committee's (HITPC's) recommendations (*http://healthit.hhs.gov/portal/server.pt?open=512&objID=1815&parentname=CommunityPage&parentid=7&mode=2&in_hi_userid=11113&cached=true*).
- CQMs that address known gaps in quality of care, such as measures in which performance rates are currently low or for which there is wide variability in performance, or that address known drivers of high morbidity and/or cost for Medicare and Medicaid.
- CQMs that address areas of care for different types of EPs (for example, Medicare- and Medicaid-eligible physicians, and Medicaid-eligible nurse-practitioners, certified nurse-midwives, dentists, physician assistants).

In an effort to align the CQMs used within the EHR Incentive Program with the goals of CMS and HHS, the NQS, and the HITPC's recommendations, we have assessed all proposed CQMs against six domains based on the NQS's six priorities, which were further developed by the HITPC Workgroups, as follows:

- *Patient and Family Engagement.* These are CQMs that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level as well as the population level through greater involvement of patients and families in decision making, self care, activation, and understanding of their health condition and its effective management.
- *Patient Safety.* These are CQMs that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.
- *Care Coordination.* These are CQMs that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families in order to improve appropriate and timely patient and care team communication.
- *Population and Public Health.* These are CQMs that reflect the use of clinical and preventive services and achieve improvements in the health of the population served and are especially focused on the leading causes of mortality. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.
- *Efficient Use of Healthcare Resources.* These are CQMs that reflect efforts to significantly improve outcomes and reduce errors. These CQMs also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.
- *Clinical Processes/Effectiveness.* These are CQMs that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

We solicited comments on these domains, and whether they would adequately align with and support the breadth of CMS and HHS activities to improve quality of care and health outcomes.

Comment: Many commenters supported the NQS initiative. Many commenters stated that the domains were imprecise and some CQMs can be placed in multiple domains. Some commenters recommended that the Care Coordination domain include pre- and post-acute care providers and that the CQMs be carefully assigned to the appropriate domains.

Response: We appreciate the supportive comments with respect to the NQS. We agree with commenters that certain CQMs do not fit in only a single domain. When we considered CQMs for selection, we also considered to what extent a domain is already represented in the meaningful use objectives and measures, which use performance thresholds. For example, in the area of care coordination, to be a meaningful EHR user, a provider must provide a summary of care record for more than 50 percent of their transitions of care and referrals. In addition, in the area of patient and family engagement, to be a meaningful EHR user a provider must make patients' health information available to them and potentially their caregivers and families and is responsible for ensuring that at least 5 percent of their patients or their

caregivers and families actually access that information. For these reasons, we are relaxing the requirement to report CQMs in each domain as discussed in section II.B.5.c. of this final rule for EP reporting requirements and II.B.7.c. of this final rule for eligible hospital and CAH reporting requirements.

We stated in the proposed rule that we also considered the recommendations of the Measure Applications Partnership (MAP) for inclusion of CQMs. The MAP is a public-private partnership convened by the National Quality Forum (NQF) for the primary purpose of providing input to HHS on selecting performance measures for public reporting. The MAP published draft recommendations in their Pre-Rulemaking Report on January 11, 2012 (*http://www.qualityforum.org/map/*), which includes a list of, and rationales for, all the CQMs that the MAP did not support. The MAP did not review the CQMs for 2011 and 2012 that were previously adopted for the EHR Incentive Program in the Stage 1 final rule. We stated in the proposed rule that we included some of the CQMs not supported by the MAP in Tables 7 (EPs) and 8 (eligible hospitals and CAHs) to ensure alignment with other CMS quality reporting programs, address recommendations by other Federal advisory committees such as the HITPC, and support other quality goals such as the Million Hearts Campaign. We also stated that we included some CQMs to address specialty areas that may not have had applicable CQMs in the Stage 1 final rule.

We stated in the proposed rule that we anticipated that only a subset of these CQMs would be finalized. We stated that in considering which measures to finalize, we would take into account public comment on the CQMs themselves and the priorities listed previously. We also stated that we intended to prioritize CQMs in order to align with and support to the extent possible the measurement needs of CMS program activities related to quality of care, delivery system reform, and payment reform, especially the following:

- Encouraging the use of outcome measures, which provide foundational data needed to assess the impact of these programs on population health.
- Measuring progress in preventing and treating priority conditions, including those affecting a large number of CMS beneficiaries or contributing to a large proportion of program costs.
- Improving patient safety and reducing medical harm.
- Capturing the full range of populations served by CMS programs.

Comment: Several commenters support the inclusion of CQMs recommended by the MAP. A commenter supported CQMs which are both MAP evaluated and NQF endorsed. Another commenter raised concern that CMS did not have enough time to consider the MAP recommendations as the CQMs published in the proposed rule differ from those recommended by the MAP. Some commenters were concerned that limiting the CQMs to MAP-supported and/or NQF-endorsed CQMs would discourage CQM innovation and the creation of novel CQMs and those that cover more specialties.

Response: We carefully considered the MAP recommendations and took NQF endorsement status into consideration when making our CQM selections for reporting beginning with 2014. In order to align with other quality reporting programs and address recommendations by other Federal advisory committees, such as the HITPC, as well as consider CQMs endorsed by other multistakeholder groups, we considered CQMs that were not supported by the MAP. After consideration of the public comments received, we are finalizing the policies on criteria for selecting CQMs as proposed.

4. CQM Specification

We stated in the proposed rule that we do not intend to use notice and comment rulemaking as a means to update or modify CQM specifications. In general, it is the role of the measure steward to make changes to a CQM in terms of the initial patient population, numerator, denominator, and potential exclusions. We recognized that it may be necessary to update CQM specifications after they have been published to ensure their continued relevance, accuracy, and validity. Measure specifications 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 would be described in full through supplemental updates to the electronic specifications for EHR submission provided by CMS. We stated that measures would be tracked on a version basis as updates to those CQMs are made, and we would require EPs, eligible hospitals, and CAHs to submit the versions of the CQMs as identified on our Web site.

We stated in the proposed rule that the complete CQM specifications would be posted on our Web site (*https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp*) at or around the time of the final rule. In order to assist the public in considering the proposed CQMs, we published tables titled ''Proposed CQMs for 2014 CMS EHR Incentive Programs for Eligible Professionals'' and ''Proposed CQMs for 2014 CMS EHR Incentive Programs for Eligible Hospitals and CAHs'' on this Web site. These tables contain additional information for the EP, eligible hospital, and CAH CQMs, respectively, which may not be found on the NQF Web site. We noted that some of the CQMs were still being developed and that the additional descriptions provided in the tables may still change before the final rule is published. We noted that the titles and descriptions for the CQMs included in these tables were updated by the measure stewards and therefore may not match the information provided on the NQF Web site.

We proposed that, under certain circumstances, it may be necessary to remove a CQM from the EHR Incentive Programs between rulemaking cycles. We stated in the proposed rule that when there is reason to believe the continued collection of a CQM as it is currently specified raises potential patient safety concerns and/or is no longer scientifically valid, we would take immediate action to remove the CQM from the EHR Incentive Programs and not wait for the next rulemaking cycle. Likewise, we stated if a CQM undergoes a substantive change by the measure steward between rulemaking cycles such that the measure's intent has changed, we would remove the measure immediately from the EHR Incentive Programs until the next rulemaking cycle when we could propose the revised CQM for public comment. Under this proposed policy, we would promptly remove such CQMs from the set of CQMs available for EPs or eligible hospitals and CAHs to report under the EHR Incentive Programs, confirm the removal or propose the revised CQM, in the next EHR Incentive Programs rulemaking cycle, and notify providers (EPs, eligible hospitals, and CAHs) and the public of our decision to remove the CQM(s) through the usual communication channels (memos, email notification, web site postings).

Comment: Numerous commenters indicated the importance of having CQM specifications and implementation guides as soon as possible. Several commenters pointed out that CQMs without electronic specifications should be re-tooled as eMeasures prior to inclusion in meaningful use.

Response: We will provide complete CQM specifications at or around the time of the publication of this final rule on our Web site (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Quality Measures/Electronic Specifications.html*). All of the CQMs that we are finalizing will be fully specified.

Comment: Many commenters noted that more than 6 months is needed to deploy and adequately test upgrades that may affect clinician workflows and patient safety. Other commenters stated that software developers need at least 18 to 24 months to alter their systems and allow for installation of software to complete process updates, development, testing, error checks, training, and roll-out before the reporting periods begin. Multiple commenters requested notification and a scheduled approach to making changes to CQM specifications. Commenters suggested that CMS post the CQMs and updates in one place for easy reference.

Response: We understand health care providers and software developers need sufficient time to accommodate CQM specification updates. However, we must balance this with our policy priority for CQMs to remain consistent with clinical practice guidelines and any new scientific data related to efficacy. To address the timing concerns mentioned by commenters, we expect to make the updated specifications, which will be tracked on a version basis, publicly available through our Web site (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/ElectronicSpecifications.html*) approximately 6 months in advance of the beginning of the CY and FY for EPs and hospitals, respectively. We will make every effort to have updated specifications made available earlier and ensure that measure updates are limited in scope. In the event that we remove CQMs between rulemakings, we will post this information on the same Web site and notify the public through listserv and any additional communication channels that may be appropriate.

Comment: Many commenters stated that CQM specifications should not have to be updated in CEHRT during the period for which the EHR product is certified. Some commenters pointed out the burden and complexity of supporting multiple versions of the CQMs concurrently (that is, the specifications authorized for use within the current reporting period, and the updated specifications intended for implementation in the following reporting period).

Response: CQM specifications are updated to maintain alignment with current clinical guidelines and ensure that the CQM remains relevant and actionable within the clinical care setting. We believe the benefits of having the ability to update specifications more frequently than the rulemaking cycle for the EHR Incentive Programs outweighs the burden and complexity identified by commenters.

As a result of aligning with other quality reporting programs (for example, PQRS), the CQMs and specifications are being used in multiple programs. If we do not have the ability to update specifications annually, then our respective programs may no longer align. Furthermore, without having the ability to update the specifications at least annually, the CQMs could become obsolete and would not adequately reflect current best practices. The majority of the administrative changes expected in the annual specification updates would reflect updates that vendors would routinely push to their clients' EHR technologies (for example, drug code updates).

We did not receive any comments on our proposed policy to remove CQMs between rulemaking cycles under certain circumstances.

After consideration of the public comments received, we are finalizing the following policies on CQM specifications. Updates to CQM specifications may be provided annually approximately 6 months in advance of the FY/CY for hospitals and EPs, respectively. Providers will not be required to use the updated specifications for purposes of submitting the CQMs for the EHR Incentive Program unless specified in future rulemaking. We note that EPs choosing to submit CQMs through another quality reporting program (for example, PQRS) would need to use the updated specifications if required by the other program. We are finalizing the policy on removing CQMs between rulemaking cycles under certain circumstances as proposed. In the event that one or more CQMs are removed between rulemakings, the number of CQMs that an EP, eligible hospital, or CAH must report would be reduced by the number of CQMs removed. For example, if one EP CQM was removed from the set of CQMs finalized for EPs in Table 7, EPs would only be required to submit 8 CQMs instead of 9. Likewise, if a hospital CQM is removed from the set of CQMs finalized in Table 8, eligible hospitals and CAHs would only be required to submit 15 CQMs instead of 16. The requirement that the CQMs submitted cover at least 3 domains will remain the same unless all CQMs for a particular domain have been eliminated. EPs that are not affected by such a removal of a CQM between rulemakings and could report on other CQMs are expected to continue reporting on 9 CQMs. Likewise, eligible hospitals and CAHs that are not affected and could report on other CQMs are expected to continue reporting on 16 CQMs.

5. CQMs for EPs

(a) Statutory and Other Considerations

Sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C) of the Act provide for the reporting of CQMs by EPs as part of demonstrating meaningful use of CEHRT. For further explanation of the statutory requirements, we refer readers to the discussion in our proposed and final rules for Stage 1 (75 FR 1870 through 1902 and 75 FR 44380 through 44435, respectively).

Under sections 1848(o)(1)(D)(iii) and 1903(t)(8) of the Act, the Secretary must seek, to the maximum extent practicable, to avoid duplicative requirements from federal and state governments for EPs to demonstrate meaningful use of CEHRT under Medicare and Medicaid. Therefore, to meet this requirement, we continued our practice from Stage 1 of proposing CQMs that would apply for both the Medicare and Medicaid EHR Incentive Programs, as listed in sections II.B.5.b. and II.B.5.c. of this final rule.

Section 1848(o)(2)(B)(iii) of the Act requires that in selecting CQMs for EPs, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under subsection (k)(2)(C) (that is, reporting under the PQRS). Consistent with that requirement, we proposed to select CQMs for EPs for the EHR Incentive Programs that align with other quality reporting programs mentioned in the proposed rule (77 FR 13745). We stated in the proposed rule that when a CQM is included in more than one CMS quality reporting program and is reported using CEHRT, we would seek to avoid requiring EPs to report the same CQM to separate programs through multiple transactions or mechanisms.

Section 1848(o)(2)(B)(i)(I) of the Act requires the Secretary to give preference to CQMs endorsed by the entity with a contract with the Secretary under section 1890(a) (namely, the NQF). We proposed CQMs for EPs for 2013, 2014, and 2015 (and potentially subsequent years) that reflect this preference,

although we note that the Act does not require the selection of NQF endorsed CQMs for the EHR Incentive Programs. CQMs listed in this final rule that do not have an NQF identifying number are not NQF endorsed, but are included in this final rule with the intent of eventually obtaining NQF endorsement of those CQMs determined to be critical to our program.

We stated our intent to increase the total number of CQMs for EPs to include areas such as behavioral health, dental care, long-term care, special needs populations, and care coordination. We proposed new pediatric CQMs, an obstetric CQM, behavioral/mental health CQMs, CQMs related to HIV medical visits and antiretroviral therapy, two oral health CQMs, as well as other CQMs that address NQS goals. Although we did not propose additional CQMs in the areas of long-term and post-acute care due to the lack of electronic specifications, we stated that we would continue to develop or identify CQMs for these areas for future years. We received public comments related to statutory and other considerations. We have responded to those comments in later sections of this final rule, including comments related to form and manner and the clinical areas covered by specific CQMs (see sections II.B.6.c. or II.B.6.d. of this final rule).

(b) CQMs for EPs for CY 2013

We proposed that for the EHR reporting periods in CY 2013, EPs must submit data for the CQMs that were finalized in the Stage 1 final rule for CYs 2011 and 2012 (75 FR 44398 through 44411, Tables 6 and 7). We stated that we expected to post updates to the CQMs' electronic specifications on the EHR Incentive Program Web site at least 6 months prior to the start of CY 2013. As required by the Stage 1 final rule, EPs must report on 3 core or alternate core CQMs, plus 3 additional CQMs. We referred readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those CQMs (75 FR 44398 through 44411).

We received no public comments and are finalizing these proposals for EPs for CY 2013. We have posted updates to the CQM specifications on the EHR Incentive Program Web site (*https://www.cms.gov/apps/ama/license.asp?file=/QualityMeasures/Downloads/QMEPSupplemental.zip*) and note that they will be optional with respect to CY 2013 reporting.

(c) CQMs and Reporting Options for EPs Beginning with CY 2014

(i) Reporting Options

We proposed two reporting options that would begin in CY 2014 for Medicare and Medicaid EPs, as described as follows: Options 1 and 2. We proposed the CQMs listed in Table 8 of the proposed rule (77 FR 13749 through 13757) for all EPs (Medicare and Medicaid) for the EHR reporting periods in CYs 2014, 2015, and potentially subsequent years, regardless of whether an EP is in Stage 1 or Stage 2 of meaningful use. We stated that the policies and CQMs proposed for CYs 2014 and 2015 would continue to apply in CY 2016 and subsequent years until a new rule is published. Therefore, we referred to CQMs that apply ''beginning with'' or ''beginning in'' CY 2014. We stated that for Medicaid EPs, although the reporting method for CQMs may vary by state, the set of CQMs from which to select would be the same as for Medicare EPs. We stated that Medicare EPs who are in their first year of Stage 1 may report CQMs by attestation.

For Option 1, we proposed two alternatives (Options 1a and 1b), but stated that we intended to finalize only a single method. We proposed that Medicare EPs who participate in both the PQRS EHR reporting option and the EHR Incentive Program may choose Option 2 instead of Option 1.

- Option 1a: We proposed that EPs would select and report 12 CQMs from those listed in Table 8 of the proposed rule (77 FR 13749 to 13757), including at least 1 CQM from each of the 6 domains, which are described in section II.B.3. of this final rule. EPs would select the CQMs that best apply to their scope of practice and/or unique patient population. If an EP's CEHRT does not contain patient data for at least 12 CQMs, then the EP must report the CQMs for which there is patient data and report the remaining required CQMs as ''zero denominators'' as displayed by the EPs CEHRT. If there are no CQMs applicable to the EP's scope of practice or unique patient populations, EPs must still report 12 CQMs even if zero is the result in either the numerator and/or the denominator of the CQM. If all applicable CQMs have a value of zero from their CEHRT, then EPs must report any 12 of the CQMs. We noted one advantage of this approach is that EPs can choose CQMs that best fit their practice and patient populations. However, because of the large number of CQMs to choose from, this approach would result in fewer EPs reporting on any given CQM, and likely only a small sample of patient data represented in each CQM. We proposed that EPs would submit the CQM data in an XML-based format on an aggregate basis reflective of all patients without regard to payer.
- Option 1b: We proposed that EPs would report 11 ''core'' CQMs listed in Table 6 of the proposed rule (77 FR 13746 to 13747), plus 1 ''menu'' CQM from Table 8 of the proposed rule (77 FR 13749 to 13757). We noted that the ''core'' CQM set reflected the national priorities outlined in section II.B.3. of the proposed rule. EPs would select 1 CQM to report from the ''menu'' set based on their respective scope of practice and/or unique patient population. We explained one advantage of this approach is that quality data would be collected on a smaller set of CQMs, so the resulting data for each CQM would represent a larger number of patients and therefore could be more accurate. However, this approach could mean that more CQMs are reported with zero denominators (if they are not applicable to certain practices or populations), making the data less comprehensive. We stated that the policy on reporting ''zeros'' in the numerator and/or denominator of a CQM, as discussed previously under Option 1a, would also apply for Option 1b.
- Option 2: Submit and satisfactorily report CQMs under the PQRS's EHR Reporting Option.

We proposed that Medicare EPs who participate in both the PQRS EHR reporting option and the EHR Incentive Program may choose Option 2 instead of Option 1. In order to streamline quality reporting options for EPs participating in both programs, we proposed that Medicare EPs who submit and satisfactorily report PQRS CQMs under the PQRS's EHR reporting option using CEHRT would satisfy the CQM reporting requirement under the Medicare EHR Incentive Program. We referred readers to 42 CFR 414.90 and the CY 2012 Medicare PFS final rule with comment period (76 FR 73314) for more information about the existing requirements of the PQRS and stated that EPs who choose this Option 2 would be required to comply with any changes to the requirements of the PQRS that may apply in future years.

Comment: Many commenters preferred Option 1a instead of 1b since it offers more flexibility and a larger selection of CQMs, especially for specialties including surgery, otolaryngology, urology, and psychiatry. However, they also indicated that it would be difficult to report 1 CQM from each of the 6 domains that apply to their scope of practice and/or unique patient population.

Other commenters supported Option 1b over 1a as long as it limits the number of CQMs to those that vendors would be required to support. A few commenters suggested removing the ''one menu CQM'' requirement entirely.

Many commenters suggested a modification of Options 1a and 1b to require reporting a specific number of core CQMs (fewer than the 11 proposed) and a specific number of menu CQMs (more than 1 as proposed) along with some changes to the domain requirement. Many commenters suggested a reporting option requiring EPs to report 6 clinically relevant CQMs covering at least 2 domains, and if no CQMs are clinically relevant for an EP, they must demonstrate zeros in the denominator for 6 CQMs covering at least 2 domains. A few commenters suggested requiring up to 9 CQMs covering a range of 2 to 4 domains. One commenter also advocated for the retention of all three reporting options (1a, 1b, and 2) so that EPs could select the one most appropriate to their practice.

Response: We agree that a modified approach for Option 1 would provide a more optimal reporting schema for most EPs. In our modified approach, we included the positive and minimized the negative components of each of the two proposed options where possible. The Option 1 that we are finalizing (as explained in detail later) decreases the number of CQMs that EPs must select to report, decreases the total number of domains required to be covered among the selected CQMs, recommends but does not require reporting from a ''core'' set of CQMs, and offers specialist EPs the flexibility to select CQMs that are applicable to their scope of practice.

We note the following CQMs in the finalized recommended core sets for adults and children were included in the proposed core set: NQF 0018, 0022, 0024, 0028, 0418, and TBD—Closing the referral loop: receipt of specialist report.

Comment: We also received many comments on Option 2. Numerous commenters supported Option 2, including the submission of CQM data via the PQRS program and receiving credit for both PQRS and meaningful use. However, some of these commenters indicated that not all EPs qualify to participate in PQRS. Another concern was that the patient population reported differs between the two programs in that PQRS requires reporting on Medicare patients only, whereas meaningful use reflects all patients without regard to payer.

Response: For the reporting of CQMs, we are finalizing Option 2 as proposed in order to reduce reporting burden on EPs who participate in both programs and attain the goal of alignment with the PQRS EHR reporting option. EPs who do not participate in PQRS may submit CQMs for the EHR Incentive Program using Option 1. Regardless of whether an EP chooses Option 1 or Option 2 for CQM reporting, we note that all EPs must also report the meaningful use objectives and measures through attestation, as well as meet all other meaningful use requirements.

We acknowledge that under the PQRS, only Medicare patient information is submitted. In general, our preference is to measure quality at the all patient level, based on samples of all patient data (that is, patients that meet the denominator criteria of each reported CQM). We believe this provides a better assessment of overall care quality rendered by EPs. However, although meaningful use reflects all patients without regard to payer, we believe Option 2 is appropriate because it is a step in the direction of the longer-term goal of a single, aligned mechanism for multiple CMS programs.

After consideration of the public comments received, and for the reasons discussed earlier, we are finalizing two reporting options beginning with CY 2014 for EPs in all stages of meaningful use. These options will continue to apply in the event that we have not engaged in another round of rulemaking by CY 2016.

Option 1: Report 9 CQMs covering at least 3 domains.

Medicare and Medicaid EPs selecting this reporting option will be required to submit a total of 9 CQMs covering at least 3 domains from Table 7. We expect EPs would select the CQMs that best apply to their scope of practice and/or unique patient population. For this reporting option, CQMs will be submitted on an aggregate basis reflective of all patients without regard to payer. We are not requiring the submission of a core set of CQMs, but we identify two recommended core sets, one for adults and one for children, that we encourage EPs to report to the extent those CQMs are applicable to an EP's scope of practice and patient population. If an EP's CEHRT does not contain patient data for at least 9 CQMs covering at least 3 domains, then the EP must report the CQMs for which there is patient data and report the remaining required CQMs as ''zero denominators'' as displayed by the EP's CEHRT. If there are no CQMs applicable to the EP's scope of practice and patient population, EPs must still report 9 CQMs even if zero is the result in either the numerator or the denominator of the measure. If all applicable CQMs have a value of zero from their CEHRT, then EPs must report any 9 CQMs from Table 7.

Option 2: Submit and satisfactorily report CQMs under the PQRS's EHR Reporting Option.

Under this option, Medicare EPs who participate in both the PQRS and the Medicare EHR Incentive Program will satisfy the CQM reporting component of meaningful use if they submit and satisfactorily report PQRS CQMs under the PQRS's EHR reporting option using CEHRT. EPs choosing to report under this option for purposes of the Medicare EHR Incentive Program will be subject to the reporting periods established for the PQRS EHR reporting option, which may be different from their EHR reporting period for the meaningful use objectives and measures. For example, in CY 2014, an EP who is beyond his or her first year of meaningful use will have a 3-month quarter EHR reporting period for the meaningful use objectives and measures, but the reporting periods for the PQRS EHR reporting option that fall within CY 2014 would apply for purposes of reporting CQMs. We emphasize that EPs who are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year cannot choose this Option 2 for reporting CQMs for the EHR Incentive Program. For purposes of avoiding a payment adjustment, they must submit their CQM data by attestation no later than October 1 of such preceding year. For more information on the requirements of the PQRS, we refer readers to 42 CFR 414.90 and the CY 2013 Medicare PFS proposed rule (77 FR 44805 through 44988). EPs who choose this option to satisfy the CQM reporting component of meaningful use under the Medicare EHR Incentive Program will be required to comply with any changes to the PQRS that may apply in future years.

(ii) CQMs

We proposed to remove three CQMs beginning with CY 2014 for EPs at all stages of meaningful use for the following reasons:

- NQF # 0013—The measure steward did not submit this CQM to the NQF for continued endorsement. We included other CQMs that address high blood pressure and hypertension in Table 8 in the proposed rule.
- NQF #0027—We determined this CQM is very similar to NQF #0028 a and b; therefore, to avoid duplication, we proposed to only retain NQF # 0028 a and b.
- NQF #0084—The measure steward did not submit this CQM to the NQF for continued endorsement. Additionally,

CMS has decided to remove this CQM because there are other FDA-approved anticoagulant therapies available in addition to Warfarin. We proposed to replace this measure, pending availability of electronic specifications, with NQF #1525—Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

We did not receive public comments and are finalizing the elimination of measures NQF #0013, NQF #0027, and NQF #0084 beginning with CY 2014 for EPs at all stages of meaningful use. We proposed to replace NQF #0084 with NQF #1525, which was determined to contain data elements that were difficult to capture in EHRs after additional feasibility testing. Therefore, we are implementing an Adverse Drug Events CQM to replace NQF #0084:

Title: ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range.

Description: Average percentage of time in which individuals with atrial fibrillation who are on chronic anticoagulation have International Normalized Ratio (INR) test results within the therapeutic range during the measurement period.

For a list of all the CQMs proposed for EPs to report for the EHR Incentive Programs beginning with CY 2014, please refer to Table 8 in the Stage 2 proposed rule (77 FR 13749 to 13757). We stated that we expected to finalize only a subset of the CQMs listed in Table 8 based on public comments and the priorities discussed in section II.B.3. of the proposed rule.

We noted that some of these CQMs had not yet been submitted for consensus endorsement consideration or were under review for endorsement consideration by the NQF. We stated that we expect that any measure proposed in Table 8 for inclusion beginning with CY 2014 would be submitted for endorsement consideration by the measure steward. Because measure specifications may need to be updated more frequently than our expected rulemaking cycle will allow for, we stated that we would provide updates to the specifications at least 6 months prior to the beginning of the calendar year for which the measures would be required, and we expected to update specifications annually.

Comment: Many commenters indicated support for CMS's efforts to include CQMs that are broadly applicable across primary care and specialist EPs. However, many commenters also stated that most of the proposed CQMs apply to primary care practices and preventive medicine and requested more CQMs that apply to specialist practices or to adjust the reporting requirements to match the number of clinically available CQMs for nonprimary care EPs. Another commenter requested pediatricians be excluded from having to report on CQMs for patients older than 18 years old rather than having to demonstrate zero denominators on a population that does not apply to them.

Many commenters stated that there were too many CQMs, citing issues with implementation of such a large set of measures as well as diluting the impact of quality measurement. Some of these commenters believed that CMS should focus on a smaller set of CQMs to refine for accuracy in implementation. They also did not believe that they should have to build CQMs into their CEHRT if those CQMs did not apply to their scope of practice because those CQMs would only yield zero denominators. Some suggested alternatives to building out all CQMs included allowing EPs to attest to having a low denominator, such as 25 or fewer patients, or for CMS to assign the primary care or specialty fields that each CQM applies to, whereby EPs whose field is not listed for a particular CQM would be exempt from reporting that CQM.

Many of the proposed EP CQMs received support from the public. Some commenters gave feedback on specific proposed CQMs, including questions on the feasibility of reporting the CQM, issues with specific requirements of the CQM, and preferences for preventative CQMs. A few commenters did not support finalizing CQMs that were not NQF endorsed. We also received suggestions for additional CQMs that were not included in the list of 125 proposed EP CQMs. A few commenters expressed concern about the lack of transparency in the development of the CQMs.

Response: We stated in the Stage 2 proposed rule that we would be finalizing a subset of the proposed CQMs. We convened a Quality Measures Task Force (QMTF), which is made up of stakeholders from across the Department and includes representation from different quality reporting programs. Through the QMTF and with senior leadership, we considered public comments, feasibility of the electronic specifications to be captured in EHRs, and the goals stated in section II.B.3. of this final rule when selecting the finalized list of EP CQMs. By including such a large representation of stakeholders, we believe that we have prioritized CQMs that align with other programs, which includes CQMs that are not used in other programs currently but could be implemented in other programs as they include more electronically specified CQMs in their respective CQM lists. This will move us closer to our longer-term goal of having a single, aligned mechanism for CQM reporting.

Since the measure stewards are responsible for any information that affects the requirements of the CQM, we have shared the feedback on specific CQMs with the respective measure stewards. Consideration of both evidence and expert consensus are integral parts of the NQF's measure endorsement process. More information on this Consensus Development Process is available on the NQF Web site: *http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx.* Although we give preference to CQMs that have been endorsed by NQF, section 1848(o)(2)(B)(i)(I) of the Act does not require the selection of NQF-endorsed CQMs for the EHR Incentive Program. Please refer to section II.B.3. of this final rule for the discussion on criteria for inclusion of a CQM.

We appreciate the commenters' suggestions for additional CQMs that apply to specialties that may not have been as represented in the measure set as primary care or preventative medicine. Although we cannot in this final rule select CQMs that were not proposed in the proposed rule, we will consider the suggested CQMs for future inclusion. As for the commenters' request to adjust the reporting requirements or exclude certain specialties from reporting certain CQMs, we believe that our policy on allowing ''zero denominators'' to be reported allows specialists to meet the CQM reporting requirements of meaningful use and is a continuation of our policy from the Stage 1 final rule.

Comment/Response: Table 7 summarizes the public comments received on specific proposed EP CQMs and the CMS rationale (that is, our response to the CQM-specific comment(s)) for finalizing or not finalizing the CQM for reporting beginning with CY 2014.

TABLE 7—SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	Rationale
NQF 0002	No comments	No comments	Yes	Addresses efficient use of resources; alignment with other programs.
NQF 0004	Supports measure	Privacy concerns; concerned that it could be difficult to implement.	Yes	Addresses high priority agency goals and aligns with other quality reporting programs. We retained NQF 0004 in order to represent the important issue of alcohol or other drug dependence treatment in our measure set. We also believe that through our collaboration with ONC, we have addressed the issues associated with data collection.
NQF 0018	Public comment supports measure.	No comments	Yes	Supports high priority goals (controlling high blood pressure).
NQF 0022	No comments	Measure is not supported by evidence.	Yes	Addresses patient safety. NQF requires clinical evidence supporting a measure in order to achieve NQF endorsement.
NQF 0024	Support for measure but evidence only for overweight, obese, or underweight children and not ideal weight.	Contains data elements that are difficult to capture as structured data.	Yes	Supports high priority goals (weight assessment, nutrition, physical activity for children); received strong public support. Based on industry standards, CMS is collaborating with other federal agencies and private organizations to standardize data elements.
NQF 0028	Support for measure	Concerns about capturing discrete data.	Yes	Supports high priority goals (tobacco use cessation); alignment with other programs.
NQF 0031	No comments	Does not align with current clinical guidelines for frequency of screening.	Yes	This CQM is currently NQF endorsed.# This is a high priority prevention measure for breast cancer.
NQF 0032	No comments	Does not align with current clinical guidelines for frequency of screening.	Yes	This CQM is currently NQF endorsed# and will be updated for consistency with clinical guidelines as discussed earlier in this section. This is a high priority prevention measure for cervical cancer.
NQF 0033	No comments	Does not align with current clinical guidelines for frequency of screening.	Yes	This CQM is currently NQF endorsed# and will be updated for consistency with clinical guidelines as discussed earlier in this section. This is a high priority prevention measure.
NQF 0034	No comments	Does not align with current clinical guidelines.	Yes	This CQM is currently NQF endorsed# and will be updated for consistency with clinical guidelines as discussed earlier in this section. This is a high priority prevention measure.

TABLE 7—SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	Rationale
NQF 0036	No comments	Duplicative of other measures (duplicate measure not included).	Yes	Addresses high priority agency goals and aligns with other quality reporting programs. Some aspects of this measure may be considered duplicative of other CQMs, however we believe that there are unique aspects of this CQM that are important to measure.
NQF 0038	Supports measures to reduce rate of Hepatitis B.	No comments	Yes	Supports public health goals.
NQF 0041	Support for measure	No evidence to support influenza vaccinations for all patients; Concerns about capturing discrete data and accounting for alternative delivery locations.	Yes	This CQM is currently NQF endorsed.# This is a high priority prevention measure. Delivery of the vaccine should be captured in the EHR even if it was delivered in an alternate location.
NQF 0043	Support for measure	Concerns about capturing discrete data and accounting for alternative delivery locations.	Yes	Alignment with PQRS/ACOs/NCQA–PCMH Accreditation. This is a high priority prevention measure. Delivery of the vaccine should be captured in the EHR even if it was delivered in an alternate location. Passed feasibility testing for the data elements needed.
NQF 0052	Support with suggestions for improvements.	No comments	Yes	Addresses efficient use of resources.
NQF 0055	No comments	Inconsistent with evidence	Yes	This CQM is currently NQF endorsed.# This is a high priority prevention measure.
NQF 0056	Support for measure	Concerns about ability to collect discrete data.	Yes	Supports high priority goals (diabetes); alignment with other programs. Passed feasibility testing for the data elements needed.
NQF 0059	Support for measure	No comments	Yes	Supports high priority goals (diabetes); alignment with other programs.
NQF 0060	Support for measure	Concern that this measure is untested in a pediatric population.	Yes	Supports high priority goals (diabetes, pediatric population).
NQF 0062	Supports measure	No comments	Yes	Supports high priority goals (diabetes); alignment with other programs.
NQF 0064	Supports measure as a way to monitor overuse and non-evidence based therapies.	No comments	Yes	Supports high priority goals (diabetes); alignment with other programs.
NQF 0068	Support for measure	No comments	Yes	Supports high priority goals (heart disease); alignment with other programs.
NQF 0069	No comments	No comments	Yes	Addresses efficient use of resources; alignment with other programs.
NQF 0070	Support for measure	No comments	Yes	Supports high priority goals (heart disease); alignment with other programs.
NQF 0075	Support for measure	Denominator is complex and ability to capture prior year data is questioned.	Yes	Supports high priority goals (heart disease); alignment with other programs. We are also collaborating very closely with the ONC to ensure that these data are captured within CEHRT.

TABLE 7—SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	Rationale
NQF 0081	Support for measure	No comments	Yes	Supports high priority goals (heart disease); alignment with other programs.
NQF 0083	Support for measure	No comments	Yes	Supports high priority goals (heart disease); alignment with other programs.
NQF 0086	Support for measure	Does not advance quality of care.	Yes	This CQM is currently NQF endorsed.#
NQF 0088	Supports measure	Concerned about ability to transmit data between providers.	Yes	Supports high priority goals (diabetes); alignment with other programs. Data is not required to be electronically transmitted between providers.
NQF 0089	Supports measure	Does not advance quality of care; Concerned about ability to transmit data between providers.	Yes	This CQM is currently NQF endorsed.# Communication between eye specialist and the physician who manages diabetes care is important. Data is not required to be electronically transmitted between providers.
NQF 0101	Support for measure	Concerns about ability to collect discrete data.	Yes	Addresses patient safety. Passed feasibility testing for the data elements required.
NQF 0104	Support for measure	Duplicative of other measures; Concerns about ability to collect discrete data.	Yes	Supports public health goals; alignment with other programs. Duplicative measures have not been finalized. Takes initial steps toward collecting discrete data.
NQF 0105	Support for measure	Concerns about suggesting pharmacotherapy over other treatment options.	Yes	This CQM is currently NQF endorsed.#
NQF 0108	No comments	No comments	Yes	Addresses pediatric population.
NQF 0110	Support for measure	Concerns about complexity and confidentiality; Concerns about ability to collect discrete data.	Yes	We are collaborating very closely with the ONC to ensure that these data are captured within CEHRT.
NQF 0384	Support for measure	Concerns about ability to collect discrete data.	Yes	Addresses patient engagement; alignment with other programs.
NQF 0385	Supports measure	Concerns about ability to collect discrete data.	Yes	Addresses high priority agency goals and aligns with other quality reporting programs.
NQF 0387	Support for measure	Concerns about ability to collect discrete data.	Yes	Addresses high priority agency goals and aligns with other quality reporting programs.
NQF 0389	Support for measure	Concerns about complexity; Concerns about ability to collect discrete data.	Yes	We are collaborating very closely with the ONC to ensure that these data are captured within CEHRT.
NQF 0403	Support for measure	Concerns about ability to document AIDS status.	Yes	Addresses high priority agency goals and aligns with other quality reporting programs.
NQF 0405	Support for measure	Concerns about agreement with current clinical guidelines.	Yes	This CQM is currently NQF endorsed# and will be updated for consistency with clinical guidelines as discussed earlier in this section.
TBD (proposed as NQF 0407—HIV/AIDS RNA Control).	Support for measure	Concerns about ability to collect discrete data.	Yes	Alignment with other programs. This CQM will be updated for consistency with the clinical guidelines as discussed earlier in this section.

TABLE 7—SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	Rationale
NQF 0418	Support for assessment of depression.	Concern that patient refusal of screening could count against EP; Concerns about ability to collect discrete data.	Yes	Supports public health goals; alignment with other programs. We also recognize that patients may refuse the treatments measured within this CQM, but there are no performance thresholds established for the EHR Incentive Program.
NQF 0419	Support for measure with concerns about ability to capture discrete data.	Too check-boxy and does not advance quality of care.	Yes	This CQM is currently NQF endorsed.[#]
NQF 0421	Support for measure	Too check-boxy and does not advance quality of care; Concerns about ability to collect discrete data.	Yes	Supports public health goals. Alignment with PQRS/ACOs/UDS. This CQM is currently NQF endorsed.[#] Passed feasibility testing for the data elements needed.
NQF 0564	Supports measure that targets high priority condition to Medicare population and will add substantial value to the clinical quality measure set.	No comments	Yes	Addresses patient safety; alignment with other programs.
NQF 0565	Supports measure that targets high priority condition to Medicare population and will add substantial value to the clinical quality measure set.	No comments	Yes	Alignment with other programs.
NQF 0608	No comments	No comments	Yes	Addresses high priority agency goals.
NQF 0710	Supports measure concept but concerned metric is too high.	Privacy concerns	Yes	Addresses high priority agency goals. To protect patient confidentiality and adhere to HIPAA requirements, CMS and all contractors for CMS are held to maintaining and abiding by the IT Security Policy in the transmission of electronic data.
NQF 0712	Supports measure	Privacy concerns; Concerns about ability to collect discrete data.	Yes	Addresses high priority agency goals and takes initial steps towards collecting accurate discrete data. To protect patient confidentiality and adhere to HIPAA requirements, CMS and all contractors for CMS are held to maintaining and abiding by the IT Security Policy in the transmission of electronic data.
TBD (proposed as 1335 Children dental).	Supports measure	Concerns about collecting data via EHR and required changes to workflow; Concerns about ability to collect discrete data.	Yes	Addresses child health and dental measures not previously included in program. We are collaborating very closely with the ONC to ensure that these data are captured within CEHRT.
NQF 1365	Support for measure	Concerns about ability to collect discrete data.	Yes	Supports public health goals; alignment with other programs. Duplicative measures have not been finalized. Takes initial steps toward collecting discrete data.

TABLE 7—SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	Rationale
NQF 1401	No comments	Concerns about linking measure to age of child when measure relates to maternal depression and ability to capture discrete data.	Yes	Addresses public health goals. We are collaborating very closely with the ONC to ensure that these data are captured within CEHRT.
TBD (proposed as 1419 Primary caries prevention).	Support if revised to clarify numerator and denominator.	Concerns about whether measure reflects standard of care for medical providers.	Yes	Addresses child health and dental measures not previously included in program. Received strong public support. The CQM is currently NQF endorsed for medical providers.[#]
TBD (LDL)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data.	Yes	Addresses high priority goal (high cholesterol); Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (Fasting LDL)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data.	Yes	Addresses high priority goal (high cholesterol); Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (Dementia)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data.	Yes	Addresses high priority agency goals and takes initial steps towards collecting accurate discrete data; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (Hypertension)	No comments	No comments	Yes	Addresses high priority goal (hypertension).
TBD (Closing referral loop)	Supports as an example of a core measure.	Concerns about ability to capture data exchange; not NQF endorsed.	Yes	Addresses care coordination; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (FSA knee)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data.	Yes	Addresses functional status assessment and patient engagement; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (FSA hip)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data.	Yes	Addresses functional status assessment and patient engagement; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.

TABLE 7—SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	Rationale
TBD (FSA complex)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data.	Yes	Addresses functional status assessment and patient engagement; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (ADE)	Supports	Not NQF endorsed; Concerns about ability to collect discrete data.	Yes	Addresses patient safety; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (HBP followup)	No comments	Measure focuses on limited population; not NQF endorsed.	Yes	Addresses high priority goals (hypertension); Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
NQF 0001	Supports measure	Does not advance quality of care; Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0012	Measure could be adapted to use EHRs to create more accurate quality measures.	No comments	No	Measure no longer supported by measure steward.
NQF 0014	No comments	Does not advance quality of care.	No	Measure no longer supported by measure steward.
NQF 0045	No comments	Measure is untested in part of population age range; focus on communications instead of outcomes.	No	Difficulty ensuring accurate and standard data collected.
NQF 0046	Supports measure	Concerns about ability to collect discrete data.	No	Difficulty ensuring accurate and standard data collected.
NQF 0047	Supports measure	Measure is complicated; concern about lack of look back period.	No	Difficulty ensuring accurate and standard data collected.
NQF 0048	Supports measure with suggested changes.	No comments	No	Difficulty ensuring accurate and standard data collected.
NQF 0050	Supports measure	Does not advance quality of care; Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0051	Supports measure	Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0058	No comments	Definition of condition too restrictive.	No	Concur with public comment that acute bronchitis is too restrictive for an antibiotic overuse CQM. Seek to limit measure set to reduce burden.
NQF 0061	Support for measure	No comments	No	Redundant with other measures assessing condition (e.g., NQF 0018).
NQF 0066	Support for measure	Measure contains two diagnoses and should separated into two measures; Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0067	Support for measure	Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0073	Support for measure and suggestion to adapt to further exploit EHRs.	No comments	No	Redundant with other measures assessing condition (e.g., NQF 0018).

TABLE 7—SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	Rationale
NQF 0074	Support for measure	Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0097	Support for measure	Measure does not advance quality of care, too ''check boxy,'' reconciling across care settings; Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0098	Support for measure	Measure is vague; ability to capture discrete data; need standardized tool for assessment; no evidence interventions support outcomes.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0100	Support for measure	No evidence interventions support outcomes; Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0102	Support for measure	Concerns about ability to collect discrete data and calculate measure.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0103	Support for measure; harmonize with other measures.	Does not advance quality of care; privacy issues; Concerns about ability to collect discrete data.	No	Concur with concerns in public comments.
NQF 0106	Support for measure	Measure is too complex; concerns about ability to collect discrete data.	No	Concur with concerns in public comments that the measure is too complex; and agree with the concerns about ability to collect discrete data.
NQF 0107	No comments	Duplicative of other measures	No	Concur with concerns in public comments that it is duplicative of other measures.
NQF 0112	Support for measure	Measure is too complex; privacy issues; vague; concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0239	Support for measure	Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
Former NQF 0246	Support for measure	Does not advance quality of care; not NQF endorsed; Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0271	Support for measure	Questions if appropriate for ambulatory setting; Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0312	Support for measure	Measure is vague	No	Difficulty ensuring accurate and standard data collected.
NQF 0321	Support for measure	No comments	No	Complexity associated with collecting discrete data.
NQF 0322	Support for measure	Measure is vague; concerns about ability to capture discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0323	Support for measure	Interoperability concerns	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0382	Support for measure	Concerns about ability to capture numerator data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0383	Support for measure	Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0388	Support for measure	Concerns about ability to collect discrete data.	No	Measure retired by steward.

TABLE 7—SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	Rationale
NQF 0399	Support for measure	No comments	No	Seek to limit measure set to reduce burden.
NQF 0400	Support for measure	No comments	No	Seek to limit measure set to reduce burden.
NQF 0401	Support for measure	Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0406	Support for measure	Concerns about keeping up-to-date with changing guidelines.	No	Concur with concerns from public comments with concerns about keeping up-to-date with changing guidelines.
NQF 0507	Support for measure	Does not advance quality of care.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0508	Support for measure	Inability to capture screening results as discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0510	Support for measure	Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0513	Support for measure	Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0519	Support for measure	Does not advance quality of care; Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0561	Support for measure; supports care coordination and alignment with PQRS.	Does not advance quality of care; Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0562	Support for measure	Concerns about ability to collect discrete data; important measure of overuse.	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0575	Support for measure with reasonable target regarding potential adverse effects of tight diabetes control.	No comments	No	Concur with concerns in public comments regarding potential adverse effects of tight diabetes control.
NQF 0711	Supports measure concept but concerned metric is too high.	Potentially duplicative; privacy issues.	No	Concur with concerns in public comments about potentially duplicative measure; and privacy issues.
NQF 1525	Support for measure	Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Risk Assessment for Falls).	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Plan of Care for Falls)	Support for measure	Not NQF endorsed; questions evidence base for plan of care for falls.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (ADK: BP Mgmt)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (ADK: ESA)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Wound Wet to Dry)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Dementia Staging)	Support for measure	Not NQF endorsed; does not advance quality of care. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.

TABLE 7—SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	Rationale
TBD (Dementia FSA)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Dementia Safety)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Dementia Driving)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Dementia Caregiver)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Wound Compression)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (RA: FSA)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Glaucoma)	No comments	Not NQF endorsed	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Wound Diabetic)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data.	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Hypertension: BPM)	No comments	Not NQF endorsed; questions appropriateness due to narrow population.	No	Prefer CQMs on the topic of hypertension with NQF endorsement.

[#] NQF endorsement includes a consensus development process that takes into account clinical guidelines and scientific evidence. NQF describes its consensus development process at *http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx*.

After consideration of the public comments received and the CQM selection criteria discussed, we are finalizing the list of 64 CQMs for EPs included in Table 7. We note that the CQMs that do not have a CQM number in Table 7 are those that are not NQF endorsed. EPs will identify these CQMs by the eMeasure ID and version number that will be included in the CQM specifications that will be made available on our Web site.

We also note that three of the CQMs listed with a CQM number of TBD in Table 7 were proposed with NQF numbers but are changed to ''TBD'' in this final rule as follows:

- NQF 0407 is now HIV/AIDS: RNA control for Patients with HIV
- NQF 1335 is now Children who have dental decay or cavities
- NQF 1419 is now Primary Caries Prevention Intervention as Part of Well/Ill Child Care as Offered by Primary Care Medical Providers

NQF 0407 referenced antiretroviral therapy as the means for RNA control. This CQM is scheduled for NQF review and, due to changing clinical guidelines regarding therapies, significant change in this measure is expected. Due to the nature of HIV/AIDS, the virus mutates frequently, necessitating frequent changes in clinical guidelines with respect to treatments. By respecifying the CQM to remove antiretroviral therapy as the specific treatment and only focus on the outcome of RNA control, the intent of this CQM remains the same. The respecified CQM will be submitted to NQF for endorsement. NQF 1335 was endorsed as population-based CQMs rather than individual provider-level CQMs and will be respecified to include individual provider reporting, and NQF 1419 was endorsed at the individual provider level but only for primary care physicians and will be respecified to include dental providers. Both will undergo additional testing, and the results for each CQM will be submitted to NQF to determine whether the respecification warrants a new NQF number. However, the intent of each of these CQMs will remain the same as proposed.

The CQMs finalized in the recommended core sets are included in Table 7 and are denoted with a ''*'' for adult populations (9 CQMs) and ''**'' for pediatric populations (9 CQMs). We believe this approach supports the NQS and provides flexibility for specialists whose scope of practice may not be adequately represented in the proposed core CQM set. Controlling blood pressure has been and continues to be a high priority goal in many national health initiatives, including the Million Hearts campaign. Therefore, we emphasize the importance of reporting NQF #0018 as a primary recommended core CQM. We will monitor reporting on NQF #0018 and consider ways to increase its reporting. This may include, through future rulemaking, requiring EPs in relevant specialties such as primary care and cardiovascular care to report this CQM. We note that the designation of being recommended for

the adult population or pediatric population does not limit an EP from reporting the CQM only for those populations as long as the patients still fit the criteria to be included in the measure (for example, the CQM numbered ''TBD—Closing the referral loop: receipt of specialist report'' is designated as a recommended core CQM for adult populations, but it can apply to pediatric populations as well).

TABLE 8—CQMS FINALIZED FOR MEDICARE AND MEDICAID EPS BEGINNING WITH CY 2014

CQM No.	CQM title and description	Measure steward and contact information	Other quality measure programs that use the same CQM***	New CQM	Domain
NQF 0002**	Title: Appropriate Testing for Children with Pharyngitis. Description: Percentage of children 2–18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance (NCQA) Contact information: *www.ncqa.org.*	EHR PQRS, CHIPRA.		Efficient Use of Healthcare Resources.
NQF 0004	Title: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment. Description: Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, HEDIS, state use, ACA 2701, NCQA–PCMH Recognition.		Clinical Process/Effectiveness.
NQF 0018*	Title: Controlling High Blood Pressure Description: Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement =period.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, UDS.		Clinical Process/Effectiveness.
NQF 0022*	Title: Use of High-Risk Medications in the Elderly Description: Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two different high-risk medications.	NCQA *Contact Information: www.ncqa.org.*	PQRS	New	Patient Safety
NQF 0024**	Title: Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents. Description: Percentage of patients 3–17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	NCQA *Contact information: www.ncqa.org.*	EHR PQRS, UDS		Population/Public Health.
NQF 0028*	Title: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. Description: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI *Contact Information: cpe@ama-assn.org.*	EHR PQRS, ACO, Group Reporting PQRS, UDS.		Population/Public Health.
NQF 0031	Title: Breast Cancer Screening Description: Percentage of women 40–69 years of age who had a mammogram to screen for breast cancer.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, ACA 2701, HEDIS, state use, NCQA–PCMH Recognition.		Clinical Process/Effectiveness.
NQF 0032	Title: Cervical Cancer Screening Description: Percentage of women 21–64 years of age, who received one or more Pap tests to screen for cervical cancer.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, ACA 2701, HEDIS, state use, NCQA–PCMH Recognition, UDS.		Clinical Process/Effectiveness.
NQF 0033**	Title: Chlamydia Screening for Women Description: Percentage of women 16–24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, CHIPRA, ACA 2701, HEDIS, state use, NCQA–PCMH Recognition.		Population/Public Health.

TABLE 8—CQMS FINALIZED FOR MEDICARE AND MEDICAID EPS BEGINNING WITH CY 2014—Continued

CQM No.	CQM title and description	Measure steward and contact information	Other quality measure programs that use the same CQM***	New CQM	Domain
NQF 0034	Title: Colorectal Cancer Screening Description: Percentage of adults 50–75 years of age who had appropriate screening for colorectal cancer.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, NCQA–PCMH Recognition.		Clinical Process/Effectiveness.
NQF 0036**	Title: Use of Appropriate Medications for Asthma Description: Percentage of patients 5–64 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement period.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS		Clinical Process/Effectiveness.
NQF 0038**	Title: Childhood Immunization Status Description: Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, UDS		Population/Public Health.
NQF 0041	Title: Preventative Care and Screening: Influenza Immunization. Description: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA–PCPI *Contact Information: cpe@ama-assn.org.*	EHR PQRS, ACO, Group Reporting PQRS.		Population/Public Health.
NQF 0043	Title: Pneumonia Vaccination Status for Older Adults. Description: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, NCQA–PCMH Recognition.		Clinical Process/Effectiveness.
NQF 0052*	Title: Use of Imaging Studies for Low Back Pain Description: Percentage of patients 18–50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS		Efficient Use of Healthcare Resources.
NQF 0055	Title: Diabetes: Eye Exam Description: Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0056	Title: Diabetes: Foot Exam Description: Percentage of patients aged 18–75 years of age with diabetes who had a foot exam during the measurement period.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0059	Title: Diabetes: Hemoglobin A1c Poor Control Description: Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0% during the measurement period.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS, UDS.		Clinical Process/Effectiveness.
NQF 0060	Title: Hemoglobin A1c Test for Pediatric Patients Description: Percentage of patients 5–17 years of age with diabetes with an HbA1c test during the measurement period.	NCQA Contact Information: *www.ncqa.org.*		New	Clinical Process/Effectiveness.
NQF 0062	Title: Diabetes: Urine Protein Screening Description: The percentage of patients 18–75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0064	Title: Diabetes: Low Density Lipoprotein (LDL) Management. Description: Percentage of patients 18–75 years of age with diabetes whose LDL–C was adequately controlled (<100 mg/dL) during the measurement period.	NCQA *Contact Information: www.ncqa.org.*	PQRS, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0068	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic. Description: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antithrombotic during the measurement period.	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS.		Clinical Process/Effectiveness.

TABLE 8—CQMS FINALIZED FOR MEDICARE AND MEDICAID EPS BEGINNING WITH CY 2014—Continued

CQM No.	CQM title and description	Measure steward and contact information	Other quality measure programs that use the same CQM***	New CQM	Domain
NQF 0069 **	Title: Appropriate Treatment for Children with Upper Respiratory Infection (URI). Description: Percentage of children 3 months–18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	NCQA Contact Information: *www.ncqa.org.*	PQRS, NCQA–PCMH Recognition.	New	Efficient Use of Healthcare Resources.
NQF 0070	Title: Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%). Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have a prior MI or a current or prior LVEF <40% who were prescribed beta-blocker therapy.	AMA–PCPI *Contact Information: cpe@ama-assn.org.*	EHR PQRS, NCQA–PCMH Recognition.		Clinical Process/Effectiveness.
NQF 0075	Title: Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control. Description: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had a complete lipid profile performed during the measurement period and whose LDL–C was adequately controlled (<100 mg/dL).	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, ACO, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0081	Title: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD). Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	AMA–PCPI *Contact Information: cpe@ama-assn.org.*	EHR PQRS, Group Reporting PQRS, NCQA–PCMH Recognition.		Clinical Process/Effectiveness
NQF 0083	Title: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD). Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	AMA–PCPI *Contact Information: cpe@ama-assn.org.*	EHR PQRS, ACO, Group Reporting PQRS.		Clinical Process/Effectiveness.
NQF 0086	Title: Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation. Description: Percentage of patients aged 18 years and older with a diagnosis of POAG who have an optic nerve head evaluation during one or more office visits within 12 months.	AMA–PCPI *Contact Information: cpe@ama-assn.org.*	EHR PQRS		Clinical Process/Effectiveness.
NQF 0088	Title: Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy. Description: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	AMA–PCPI *Contact Information: cpe@ama-assn.org.*	EHR PQRS		Clinical Process/Effectiveness.
NQF 0089	Title: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care. Description: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	AMA–PCPI *Contact Information: cpe@ama-assn.org.*	EHR PQRS		Clinical Process/Effectiveness.

TABLE 8—CQMS FINALIZED FOR MEDICARE AND MEDICAID EPS BEGINNING WITH CY 2014—Continued

CQM No.	CQM title and description	Measure steward and contact information	Other quality measure programs that use the same CQM***	New CQM	Domain
NQF 0101	Title: Falls: Screening for Future Fall Risk Description: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: *www.ncqa.org.*	PQRS, ACO, Group Reporting PQRS.	New	Patient Safety.
NQF 0104	Title: Major Depressive Disorder (MDD): Suicide Risk Assessment. Description: Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of MDD who had a suicide risk assessment completed at each visit during the measurement period.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Clinical Process/Effectiveness.
NQF 0105	Title: Anti–depressant Medication Management Description: Percentage of patients 18 years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	NCQA *Contact Information: www.ncqa.org.*	EHR PQRS, HEDIS, state use, ACA 2701.		Clinical Process/Effectiveness.
NQF 0108**	Title: ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication. Description: Percentage of children 6–12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	NCQA Contact Information: *www.ncqa.org.*		New	Clinical Process/Effectiveness.
NQF 0110	Title: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use. Description: Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use.	Center for Quality Assessment and Improvement in Mental Health (CQAIMH) Contact Information: *www.cqaimh.org; cqaim-h@cqaimh.org.*	NCQA–PCMH Recognition.	New	Clinical Process/Effectiveness.
NQF 0384	Title: Oncology: Medical and Radiation—Pain Intensity Quantified. Description: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	AMA–PCPI Contact Information: *cpe@ama-assn.org.*	PQRS	New	Patient and Family Engagement.
NQF 0385	Title: Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients. Description: Percentage of patients aged 18 through 80 years with Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period.	AMA–PCPI *Contact Information:* cpe@ama-assn.org;*American Society of Clinical Oncology (ASCO): www.asco.org*; National Comprehensive Cancer Network (NCCN): *www.nccn.org.*	EHR PQRS		Clinical Process/Effectiveness.
NQF 0387	Title: Breast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer. Description: Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.	AMA–PCPI *Contact Information: cpe@ama-assn.org; ASCO: www.asco.org; NCCN: www.nccn.org.*	EHR PQRS		Clinical Process/Effectiveness.

TABLE 8—CQMS FINALIZED FOR MEDICARE AND MEDICAID EPS BEGINNING WITH CY 2014—Continued

CQM No.	CQM title and description	Measure steward and contact information	Other quality measure programs that use the same CQM***	New CQM	Domain
NQF 0389	Title: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients. Description: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	AMA–PCPI *Contact Information: cpe@ama-assn.org.*	EHR PQRS		Efficient Use of Healthcare Resources.
NQF 0403	Title: HIV/AIDS: Medical Visit Description: Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 60 days between each visit.	AMA–PCPI Contact Information: *cpe@ama-assn.org;* NCQA Contact Information: www.ncqa.org.		New	Clinical Process/Effectiveness.
NQF 0405	Title: HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) Prophylaxis. Description: Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis.	AMA–PCPI Contact Information: *cpe@ama-assn.org*; NCQA Contact Information: www.ncqa.org.	PQRS, NCQA–PCMH Recognition.	New	Clinical Process/Effectiveness.
TBD (proposed as NQF 0407).	Title: HIV/AIDS: RNA control for Patients with HIV Description: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 60 days between each visit, whose most recent HIV RNA level is <200 copies/mL.	NCQA Contact Information: www.ncqa.org.	PQRS	New	Clinical Process/Effectiveness.
NQF 0418***	Title: Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan. Description: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare and Medicaid Services (CMS) 1–888–;734–6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139; Quality Insights of Pennsylvania (QIP) Contact Information: www.usqualitymeasures.org.	EHR PQRS, ACO, Group Reporting PQRS.	New	Population/Public Health.
NQF 0419*	Title: Documentation of Current Medications in the Medical Record. Description: Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list *must* include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND *must* contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare and Medicaid Services (CMS) 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*; QIP Contact Information: www.usqualitymeasures.org.	PQRS, EHR PQRS	New	Patient Safety.
NQF 0421*	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up. Description: Percentage of patients aged 18 years and older with a calculated BMI in the past six months or during the current reporting period documented in the medical record AND if the most recent BMI is *outside of normal parameters,* a follow-up plan is documented within the past six months or during the current reporting period. Normal Parameters: Age 65 years and older BMI ≥23 and <30. Age 18–64 years BMI ≥18.5 and <25.	Centers for Medicare and Medicaid Services (CMS) 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139;* QIP Contact Information: www.usqualitymeasures.org.	EHR PQRS, ACO, Group Reporting PQRS, UDS.		Population/Public Health.
NQF 0564	Title: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures. Description: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	AMA–PCPI Contact Information: *cpe@ama-assn.org*; NCQA Contact Information: *www.ncqa.org.*	PQRS	New	Patient Safety.

TABLE 8—CQMS FINALIZED FOR MEDICARE AND MEDICAID EPS BEGINNING WITH CY 2014—Continued

CQM No.	CQM title and description	Measure steward and contact information	Other quality measure programs that use the same CQM***	New CQM	Domain
NQF 0565	Title: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery. Description: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	AMA–PCPI Contact Information: *cpe@ama-assn.org*; NCQA Contact Information: *www.ncqa.org*.	PQRS	New	Clinical Process/Effectiveness.
NQF 0608	Title: Pregnant women that had HBsAg testing Description: This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy.	Ingenix Contact Information: www.ingenix.com.		New	Clinical Process/Effectiveness.
NQF 0710	Title: Depression Remission at Twelve Months Description: Adult patients age 18 and older with major depression or dysthymia and an initial PHQ–9 score >9 who demonstrate remission at twelve months defined as PHQ–9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ–9 score indicates a need for treatment.	Minnesota Community Measurement (MNCM) Contact Information: *www.mncm.org; info@mncm.org*.		New	Clinical Process/Effectiveness.
NQF 0712	Title: Depression Utilization of the PHQ–9 Tool Description: Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ–9 tool administered at least once during a 4 month period in which there was a qualifying visit.	MNCM Contact Information: *www.mncm.org; info@mncm.org*.		New	Clinical Process/Effectiveness.
TBD **	Title: Children who have dental decay or cavities Description: Percentage of children ages 0–20, who have had tooth decay or cavities during the measurement period.	Maternal and Child Health Bureau, Health Resources and Services Administration *http://mchb.hrsa.gov/*.		New	Clinical Process/Effectiveness.
NQF 1365	Title: Child and Adolescent Major Depressive Disorder: Suicide Risk Assessment. Description: Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	AMA–PCPI Contact Information: *cpe@ama-assn.org*.		New	Patient Safety.
NQF 1401	Title: Maternal depression screening Description: The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life.	NCQA *Contact Information: www.ncqa.org*.		New	Population/Public Health.
TBD	Title: Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists. Description: Percentage of children, age 0–20 years, who received a fluoride varnish application during the measurement period.	University of Minnesota Contact Information: *www.umn.edu*.		New	Clinical Process/Effectiveness.
TBD	Title: Preventive Care and Screening: Cholesterol—Fasting Low Density Lipoprotein (LDL–C) Test Performed. Description: Percentage of patients aged 20 through 79 years whose risk factors have been assessed and a fasting LDL–C test has been performed.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*; QIP *Contact Information: www.usqualitymeasures.org*.	EHR PQRS	New	Clinical Process/Effectiveness.
TBD	Title: Preventive Care and Screening: Risk-Stratified Cholesterol—Fasting Low Density Lipoprotein (LDL–C). Description: Percentage of patients aged 20 through 79 years who had a fasting LDL–C test performed and whose risk-stratified fasting LDL–C is at or below the recommended LDL–C goal.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*; QIP *Contact Information:* www.usqualitymeasures.org.	EHR PQRS	New	Clinical Process/Effectiveness.
TBD	Title: Dementia: Cognitive Assessment Description: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period.	AMA–PCPI Contact Information: *cpe@ama-assn.org*.	PQRS	New	Clinical Process/Effectiveness.

TABLE 8—CQMS FINALIZED FOR MEDICARE AND MEDICAID EPS BEGINNING WITH CY 2014—Continued

CQM No.	CQM title and description	Measure steward and contact information	Other quality measure programs that use the same CQM***	New CQM	Domain
TBD	Title: Hypertension: Improvement in blood pressure Description: Percentage of patients aged 18–85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.		New	Clinical Process/Effectiveness.
TBD*	Title: Closing the referral loop: receipt of specialist report. Description: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.		New	Care Coordination.
TBD	Title: Functional status assessment for knee replacement. Description: Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.		New	Patient and Family Engagement.
TBD	Title: Functional status assessment for hip replacement. Description: Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.		New	Patient and Family Engagement.
TBD*	Title: Functional status assessment for complex chronic conditions. Description: Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.		New	Patient and Family Engagement.
TBD	Title: ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range. Description: Average percentage of time in which individuals with atrial fibrillation who are on chronic anticoagulation have International Normalized Ratio (INR) test results within the therapeutic range during the measurement period.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*.		New	Patient Safety.
TBD	Title: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. Description: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	CMS 1–888–734–6433 or *http://questions.cms.hhs.gov/app/ask/p/21,26,1139*; QIP *Contact Information: www.usqualitymeasures.org*.	PQRS, EHR PQRS, Group Reporting PQRS, ACO.	New	Population/Public Health.

* Recommended Adult Core CQMs for EPs.
** Recommended Pediatric Core CQMs for EPs.
*** PQRS = Physician Quality Reporting System.
EHR PQRS = Physician Quality Reporting System's Electronic Health Record Reporting Option.
CHIPRA = Children's Health Insurance Program Reauthorization Act.
HEDIS = Healthcare Effectiveness Data and Information Set.
ACA 2701 = Affordable Care Act section 2701.
NCQA–PCMH = National Committee for Quality Assurance—Patient Centered Medical Home.
Group Reporting PQRS = Physician Quality Reporting System's Group Reporting Option.
UDS = Uniform Data System (Health Resources Services Administration).
ACO = Accountable Care Organization (Medicare Shared Savings Program).

6. Reporting Methods for CQMs for EPs

(a) Reporting Methods for Medicaid EPs

For Medicaid EPs, we stated in the proposed rule that states are, and will continue in Stage 2 to be, responsible for determining whether and how electronic reporting 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 stated that we anticipate that whatever means states have deployed for capturing Stage 1 CQMs electronically would be similar for reporting in CY 2013. However, we note that subject to our prior approval, this is within the states' purview. Beginning in CY 2014, we proposed that the states would establish the method and requirements, subject to CMS prior approval, for the electronic capture and reporting of CQMs from CEHRT.

Comment: Commenters suggested unified Medicaid CQM reporting to reduce the burden on EPs operating in multiple states.

Response: For the purposes of the Medicaid EHR Incentive Program, EPs report CQMs to the state making the EHR incentive payment. However, data from all practice locations that are equipped with CEHRT will be used for reporting CQMs, even if the practice locations are in different states.

After consideration of the public comments received, we are finalizing the policies for electronic reporting of CQMs for Medicaid EPs as proposed. As part of certification for EHR technology, ONC is including testing for data capture, CQM calculation, and electronic submission. For CQMs, this includes certification criteria for the QRDA Category I (QRDA–I) and QRDA Category III (QRDA–III) transmission formats. We expect the states that have electronic reporting options for CQMs might choose to adopt QRDA–I for patient-level data and/or QRDA–III for aggregate data as the form in which EPs would report CQM data. By adopting the same QRDA–I and/or QRDA–III that

CMS is requiring for CQM reporting, the states would be able to leverage the development of the specifications by CMS and the industry as well as the testing done by ONC for certification of EHR technology. This would reduce the burden on EHR vendors to implement and test different specifications.

(b) Reporting Methods for Medicare EPs in CY 2013

In the Stage 2 proposed rule, we did not propose any reporting methods for Medicare EPs in 2013. However, in the CY 2013 Medicare PFS proposed rule (77 FR 44988), we proposed that EPs may continue to report by attestation CQM results as calculated by CEHRT, as they did for 2011 and 2012. For further explanation of reporting CQMs by attestation, please see the Stage 1 final rule (75 FR 44430 through 44434). We also proposed in the CY 2013 Medicare PFS proposed rule (77 FR 44988) to continue the voluntary electronic reporting pilot for CQMs (the PQRS—Medicare EHR Incentive Pilot) for 2013, which we had previously established for 2012. We expect to finalize in the CY 2013 Medicare PFS final rule the reporting methods that would apply in 2013 for EPs participating in the Medicare EHR Incentive Program.

(c) Reporting Methods for Medicare EPs Beginning With CY 2014

Under section 1848(o)(2)(A)(iii) of the Act, EPs must submit information on the CQMs selected by the Secretary ''in a form and manner specified by the Secretary'' as part of demonstrating meaningful use of CEHRT. We proposed that Medicare EPs who are in their first year of Stage 1 may report CQMs through attestation for a continuous 90-day EHR reporting period. We proposed that Medicare EPs who choose Option 1 for reporting CQMs would submit through an aggregate reporting method, which would require the EP to log into a CMS-designated portal and submit through an upload process data produced as output from their CEHRT in an XML-based format specified by CMS. We proposed that Medicare EPs who choose to report CQMs as described in Option 2 would submit in accordance with the requirements of the PQRS program.

Comment: We received several comments on the proposal to use an XML-based format for transmitting aggregate results. Those commenters were generally in favor of using an aggregate XML and that the technical structure aligns with the PQRS registry reporting option. One commenter noted that the aggregate-level standard QRDA–III is not currently mature. Some commenters indicated a preference that the aggregate reporting method should only require submission of one data file instead of multiple files, citing that submitting multiple files is onerous and may not be manageable due to the number of files EPs would need to upload.

Response: We acknowledge that there is currently no consensus standard for the electronic transmission of aggregate results of CQMs. However, the 2014 Edition certification criteria adopt the QRDA–III specification. As a result, we expect to be able to receive data submitted using the QRDA–III specification.

We proposed to consider an ''interim submission'' option for Medicare EPs who are in their first year of Stage 1 and who participate in PQRS. Under this option, EPs would submit the PQRS CQM data for a continuous 90-day EHR reporting period, and the data must be received no later than October 1 to meet the requirements of the EHR Incentive Program. We proposed that the EP would report the remainder of his/her CQM data by the deadline specified for PQRS in order to meet the requirements of the PQRS program. We solicited public comment on this potential option.

Comment: Many commenters indicated the proposed interim submission option for Medicare EPs in their first year of Stage 1 is unclear and would involve a prohibitive amount of effort. The commenters also suggested removing this option. Other commenters supported the interim submission option.

Response: This option was intended to accommodate Medicare EPs who are demonstrating meaningful use for the first time in 2014 and want to choose Option 2 (the PQRS EHR reporting option) for reporting CQMs. As proposed, however, it would require two submissions. We agree with the commenters that the ''interim submission option'' is complex and potentially burdensome. We are not finalizing the interim submission option.

After consideration of the public comments received, we are finalizing the following reporting methods for Medicare EPs beginning in CY 2014:

- Option 1: Aggregate reporting through a CMS-designated electronic transmission method using CEHRT.

The format required for aggregate reporting will be the QRDA–III, which is an XML-based format. The electronic transmission method for aggregate reporting differs from reporting via attestation in that the QRDA–III report would be generated by the EPs CEHRT and transmitted electronically rather than the aggregate results manually input into the Registration and Attestation system. EPs who are in their first year of Stage 1 must report CQMs under Option 1 through attestation (please refer to the Stage 1 final rule for an explanation of reporting CQMs through attestation (75 FR 44430 through 44434)). Consistent with section 1848(o)(2)(B)(ii) of the Act, in the unlikely event that the Secretary does not have the capacity to receive CQM data electronically, EPs who are beyond the first year of Stage 1 may continue to report aggregate CQM results through attestation.

- Option 2: Patient-level reporting via PQRS through the transmission methods established for the PQRS EHR-based reporting mechanisms and using CEHRT.

Please refer to 42 CFR 414.90 and the CY 2013 Medicare PFS proposed rule (77 FR 44988) for more information on the PQRS.

(d) Group Reporting Option for Medicare and Medicaid EPs Beginning With CY 2014

For Stage 1, EPs were required to report the CQMs on an individual basis and did not have an option to report the CQMs as part of a group practice. Under section 1848(o)(2)(A) of the Act, the Secretary may provide for the use of alternative means for EPs furnishing covered professional services in a group practice (as defined by the Secretary) to meet the requirements of meaningful use. Beginning with CY 2014, we proposed three group reporting options to allow EPs within a single group practice to report CQM data on a group level. We proposed that all three methods would be available for Medicare EPs, while only the first one would be possible for Medicaid EPs, at states' discretion.

We proposed each of these options as an alternative to reporting CQM data as an individual EP under the proposed options and reporting methods discussed earlier in this rule. These group reporting options would only be available for reporting CQMs for purposes of the EHR Incentive Program and only if all EPs in the group are beyond the first year of Stage 1. EPs would not be able to use these group reporting options for any of the other meaningful use objectives and associated measures in the EHR Incentive Programs.

The three group reporting options that we proposed for EPs are as follows:

- Two or more EPs, each identified with a unique NPI associated with a group practice identified under one tax

identification number (TIN) may be considered an EHR Incentive Group for the purposes of reporting CQMs for the Medicare EHR Incentive Program. This group reporting option would only be available for electronic reporting of CQMs and would not be available for those EPs in their first year of Stage 1. The CQMs reported under this option would represent all EPs within the group. EPs who choose this group reporting option for CQMs would have to individually satisfy the objectives and associated measures for their respective stage of meaningful use. We proposed that states may also choose this option to accept group reporting for CQMs, based upon a predetermined definition of a ''group practice,'' such as sharing one TIN.

• Medicare EPs participating in the Medicare SSP and the testing of the Pioneer ACO model who use CEHRT to submit ACO measures in accordance with the requirements of the Medicare SSP would be considered to have satisfied their CQM reporting requirement as a group for the Medicare EHR Incentive Program. The Medicare SSP does not require the use of CEHRT. However, all CQM data would have to be extracted from CEHRT in order for the EP to qualify for the Medicare EHR Incentive Program if an EP intends to use this group reporting option. EPs would have to individually satisfy the objectives and associated measures for their respective stage of meaningful use, in addition to submitting CQMs as part of an ACO. EPs who are part of an ACO but do not enter the data used for reporting the CQMs (which excludes the survey tool or claims-based measures that are collected to calculate the quality performance score in the Medicare SSP) into CEHRT would not be able to meet meaningful use requirements. For more information about the requirements of the Medicare SSP, see 42 CFR 425 and the November 2, 2011 final rule (76 FR 67802). EPs who use this group reporting option for the Medicare EHR Incentive Program would be required to comply with any changes to the Medicare SSP that may apply in the future. EPs would be required to be part of a group practice (that is, two or more EPs, each identified with a unique NPI associated with a group practice identified under one TIN) to be able to use this group reporting option.

• Medicare EPs who satisfactorily report PQRS CQMs using CEHRT under the PQRS Group Practice Reporting Option (GPRO), would be considered to have satisfied their CQM reporting requirement as a group for the Medicare EHR Incentive Program. For more information about the PQRS GPRO, see 42 CFR 414.90 and the CY 2012 Medicare PFS final rule (76 FR 73314) and CY 2013 Medicare PFS proposed rule (77 FR 44805 through 44807). EPs who use this group reporting option for the Medicare EHR Incentive Program would be required to comply with any changes to the PQRS GPRO that may apply in the future and would have to individually satisfy the objectives and associated measures for their respective stage of meaningful use.

Comment: We received numerous comments on the proposed group reporting options. Generally, most commenters supported including group reporting. Many commenters indicated group reporting options are consistent with the intent of many of the measures and would promote a more patient focused healthcare experience. A commenter requested clarification regarding whether group reporting was confined to CQMs or other objectives in meaningful use as well. Other commenters requested more detail on how new EPs or EPs leaving group practices might affect reporting and validation. Commenters indicated the requirement that only EPs beyond Stage 1 be able to use this option be eliminated because new providers join practices frequently. A commenter requested that new members of a practice be able to report at the same level that the group is currently reporting. Many commenters requested greater specificity in the final rule and clarification whether all EPs under the same TIN need to submit as a group, or if some can submit as a group and others individually. A commenter recommended that not all EPs under the same TIN should have to have access to CEHRT at all group practice locations. Other commenters stated that the proposed option for group reporting is complex and suggested the files submitted contain only data related to providers within the group or practice that have met the measures. A commenter indicated that the addition of multiple reporting options has made it exceedingly difficult for providers already presented with multiple reporting options across state and federal programs.

Response: We agree with commenters as to the benefits of reporting and measurement at the group level. We believe it can lessen the complexity and burden of reporting and also promote a greater patient focus. Group level reporting can avoid the need for multiple professionals in the same practice to report the same information on single patient that they may each treat. It can promote team work and the recognition that quality care often depends on interplay of multiple professionals rather that solely on a particular individual professional. Therefore, we agree that we should include the option of group reporting of CQMs for the EHR Incentive Program.

With respect to applicability to measures other than CQMs, as proposed the group reporting options in section II.B.6.d. of the proposed rule (77 FR 13758) would apply only to CQM reporting and not to other meaningful use objectives and associated measures. EPs reporting CQMs under a group reporting option must still attest to the meaningful use objectives and associated measures individually or through the batch reporting process we are finalizing in section II.C.1.c of this final rule to successfully demonstrate meaningful use.

As for the three options for group reporting we proposed, we agree with the potential for complexity of group reporting under which different individuals within a group would be treated differently, such as the proposed requirement that all EPs in the group must be beyond their first year of meaningful use. We believe that this would be complex and difficult to operationalize, so we are not finalizing this requirement. We note that for the group reporting option under PQRS and for professionals participating in the Medicare SSP and the testing of the Pioneer ACO model, all individuals within a group are treated as being part of the group for the purposes of quality reporting.

As a result, for the Medicare EHR Incentive Program, we are finalizing the following two group reporting options for the purposes of CQM reporting:

• Medicare EPs participating in the Medicare SSP and the testing of the Pioneer ACO model who use CEHRT to submit ACO CQMs in accordance with the requirements of the Medicare SSP would be considered to have satisfied their CQM reporting requirement as a group for the Medicare EHR Incentive Program.

• Medicare EPs who satisfactorily report PQRS CQMs using CEHRT under the PQRS GPRO would be considered to have satisfied their CQM reporting requirement as a group for the Medicare EHR Incentive Program. Under the CY 2013 Medicare PFS proposed rule, additional group reporting options are proposed. We note that the proposed claims and registry options for GPRO, which do not involve the use of CEHRT, would not satisfy the CQM reporting requirement for the EHR Incentive Program. However, the options for GPRO involving the use of CEHRT, which include submissions from

CEHRT directly to CMS or through a data intermediary to CMS, could satisfy the CQM reporting requirement for the EHR Incentive Program. Under the PQRS GPRO, CQM submission is at the group level, not at the level of any individual EP that is part of the group. Each individual EP who is a member of the group would meet the CQM reporting requirement for the EHR Incentive Program if the group meets the requirements for PQRS, with the exception of the EPs in the group who are in their first year of demonstrating meaningful use as noted later in this section.

We do not finalize any additional requirements beyond those of the programs themselves for group reporting, with the exception that the group must use CEHRT in connection with submitting CQMs. Although a group may include EPs that are demonstrating meaningful use for the first time, we emphasize that these EPs cannot use either of these group reporting options for reporting CQMs for the EHR Incentive Program. CQM data collected by EPs that are part of a group and are in their first year of demonstrating meaningful use could still be part of the group's collective data submission. However, for purposes of avoiding a payment adjustment, EPs who are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must individually submit their CQM data by attestation no later than October 1 of such preceding year. We encourage EPs who would like to use the group reporting options beginning in 2014 to become meaningful EHR users in 2013. Please see section II.D.2. of this final rule for more details on payment adjustments.

For the Medicaid EHR Incentive Program, the states will have the option to allow group reporting of CQMs through an update to their State Medicaid HIT plan, which must describe how they would address the issue of EPs who switch group practices during an EHR reporting period.

7. CQMs for Eligible Hospitals and Critical Access Hospitals

(a) Statutory and Other Considerations

Sections 1886(n)(3)(A)(iii) and 1903(t)(6)(C) of the Act provide for the reporting of CQMs by eligible hospitals and CAHs as part of demonstrating meaningful use of CEHRT. For further explanation of the statutory requirements, we refer readers to the discussion in our Stage 1 proposed and final rules (75 FR 1870 through 1902 and 75 FR 44380 through 44435, respectively).

Section 1886(n)(3)(B)(i)(I) of the Act requires the Secretary to give preference to CQMs that have been selected for the purpose of applying section 1886(b)(3)(B)(viii) of the Act (that is, measures that have been selected for the Hospital Inpatient Quality Reporting (IQR) Program) or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (namely, the NQF). We proposed CQMs for eligible hospitals and CAHs for 2013, 2014, and 2015 (and potentially subsequent years) that reflect this preference, although we note that the Act does not require the selection of such CQMs for the EHR Incentive Programs. CQMs listed in this final rule that do not have an NQF identifying number are not NQF endorsed.

Under section 1903(t)(8) of the Act, the Secretary must seek, to the maximum extent practicable, to avoid duplicative requirements from federal and state governments for eligible hospitals and CAHs to demonstrate meaningful use of CEHRT under Medicare and Medicaid. Therefore, to meet this requirement, we proposed to continue our practice from Stage 1 of proposed CQMs that would apply for both the Medicare and Medicaid EHR Incentive Programs.

In accordance with CMS and HHS quality goals as well as the HHS National Quality Strategy recommendations, the hospital CQMs that we proposed beginning with FY 2014 can be categorized into the following six domains, which are described in section II.B.3. of this final rule:

- Patient & Family Engagement.
- Patient Safety.
- Care Coordination.
- Population & Public Health.
- Efficient Use of Healthcare Resources.
- Clinical Process/Effectiveness.

The selection of CQMs we proposed for eligible hospitals and CAHs was based on statutory requirements, the HITPC's recommendations, alignment with other CMS and national hospital quality measurement programs such as the Joint Commission, the Medicare Hospital Inpatient Quality Reporting (IQR) Program and Hospital Value-Based Purchasing (HVBP) Program, the National Quality Strategy (NQS), and other considerations discussed in sections II.B.7.b. and II.B.7.c. of the proposed rule.

Section 1886(n)(3)(B)(iii) of the Act requires that in selecting measures for eligible hospitals and CAHs, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required. In consideration of the importance of alignment with other measure sets that apply to eligible hospitals and CAHs, we analyzed the Hospital IQR Program, hospital CQMs used by state Medicaid agencies, and the Joint Commission's hospital CQMs when selecting the proposed CQMs to be reported under the EHR Incentive Program. Furthermore, as we noted in the proposed rule, we placed emphasis on those CQMs that are in line with the NQS and the HITPC's recommendations.

Comment: Many commenters supported alignment of measure sets and reporting methods with other quality reporting programs and agency goals, such as Hospital IQR Program, HVBP, and NQS. These commenters commended CMS's intentions to reduce duplicative requirements between programs, prevent hospitals from calculating both electronic and paper-based reports for the same CQMs, avoid confusion and move towards a single, aligned quality reporting mechanism. However, several commenters requested that we provide a timeline for these alignment efforts as well as additional clarification regarding how we intend to pursue and achieve alignment across quality report programs and what this means operationally for eligible hospitals and CAHs. One commenter requested that we also align with the Center for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) to make hospital acquired infections (HAI) a national healthcare priority. Other commenters requested that we seek alignment and accuracy in other areas of quality measurement, including electronic specifications, data reporting methodologies, and vendor certification requirements. One commenter also urged that we continuously align electronic specifications for all CQMs across quality reporting programs as measure stewards update and maintain their CQMs.

Response: We appreciate the supportive comments regarding alignment. Our principal goals in alignment of the Hospital IQR, and the Medicare and Medicaid EHR Incentive Programs are to: (1) Provide a single set of CQMs for hospital reporting; (2) to the extent possible, avoid duplicate reporting by hospitals by using a single submission for multiple purposes as appropriate; and (3) transition from manual chart abstraction to automated extraction and electronic reporting based on the use of EHR technology.

In the FY 2012 Inpatient Prospective Payment Systems/Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) proposed rule (76 FR 25893), we stated our intention to explore mechanisms for Hospital IQR Program data collection using EHRs, and gave FY 2015 as an example of when hospitals might be able to switch to EHR-based reporting of manually chart-abstracted Hospital IQR measures. The CQMs we are finalizing beginning in 2014 for reporting under the EHR Incentive Program are electronically specified versions of current IQR chart abstracted CQMs. The 2015 target date would allow for at least 1 year of electronic submission of CQMs through the EHR Incentive Program prior to our targeted date to begin EHR-based reporting for IQR. We must assess any data collection mode differences between EHR-based reporting and chart abstracted measures using a diverse and robust sample of hospitals before proposing in rulemaking to use EHR data collection in the Hospital IQR program. Among other factors, our ability to transition to EHR-based reporting for IQR will depend on whether EHR-based reporting is accurate and reliable. Our goal would be to phase out manual chart abstraction for hospital reporting.

We did not propose the IQR CQMs on HAI for the EHR Incentive Program. Hospitals may electronically submit HAI information to the CDC, although this is not required. Information of electronic submission through the NHSN can be found at *http://www.cdc.gov/nhsn/CDA_eSurveillance.html*. NHSN data is based on surveillance data rather than chart abstraction. We will consider the NHSN measures for the EHR Incentive Program in future years.

(b) CQMs for Eligible Hospitals and CAHs for FY 2013

For the EHR reporting periods in FY 2013, we proposed to require that eligible hospitals and CAHs submit information on each of the 15 CQMs that were finalized for FYs 2011 and 2012 in the Stage 1 final rule (75 FR 44418 through 44420). We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those CQMs (75 FR 44411 through 44422).

We did not receive any public comments on our proposals, and we are finalizing the CQMs for FY 2013 as proposed.

(c) CQMs for Eligible Hospitals and CAHs Beginning With FY 2014

(i) Reporting Options

We proposed to require eligible hospitals and CAHs to report 24 CQMs from a menu of 49 CQMs beginning with FY 2014, including at least 1 CQM from each of the following 6 domains, which are discussed in section II.B.3. of this final rule:

- Patient and Family Engagement.
- Patient Safety.
- Care Coordination.
- Population and Public Health.
- Efficient Use of Healthcare Resources.
- Clinical Process/Effectiveness.

For the remaining CQMs, we proposed that eligible hospitals and CAHs would select and report CQMs that best apply to their patient mix. We solicited comments on the number of CQMs and the appropriateness of the CQMs and domains for eligible hospitals and CAHs.

Comment: A few commenters stated that the requirement to report 24 CQMs was too difficult and adds to the administrative burden placed on eligible hospitals and CAHs, especially rural hospitals. Many commenters suggested that CQM reporting requirement beginning with 2014 remain at 15 CQMs due to the number of issues experienced by hospitals when implementing the Stage 1 CQMs, although other commenters stated that requiring up to 18 CQMs would be reasonable. A few commenters noted that CQMs were not evenly distributed among the 6 domains, making the requirement to report at least one CQM from each domain difficult for some hospitals. One commenter recommended that if a domain did not have at least 4 CQMs eligible hospitals and CAHs should not be required to report that domain. Multiple commenters stated that eligible hospitals and CAHs in Stage 1 in FY 2014 may have difficulty meeting the CQM requirement beginning in 2014 and recommend that the Stage 1 CQMs meet the requirements for those hospitals. Alternatively, the commenters recommended that if the CQMs beginning in 2014 are required, that the number of CQMs being reported be reduced for the eligible hospitals and CAHs in Stage 1 beginning in FY 2014. One commenter stated that CQM requirements failed to align with other meaningful use objectives.

Response: We acknowledge that increasing the number of CQMs required to be reported from 15 in 2011, 2012, and 2013 to 24 beginning in 2014 increases implementation burden on hospitals. We have stated our intention to implement EHR-based reporting of CQMs in other quality reporting programs, such as the Hospital IQR Program. One purpose of our proposal to increase the number of CQMs reported electronically for the EHR Incentive Program is to create an electronic reporting infrastructure that we can also use for other quality reporting programs. We also acknowledge that the requirement of reporting 24 CQMs for hospitals in their first year of Stage 1 in 2014 is a significant increase from the reporting requirement for hospitals that entered Stage 1 before 2014. We also acknowledge the difficulty in meeting the requirement to report at least 1 CQM in each of the 6 domains. For these reasons, we have finalized a policy that decreases the number of CQMs required from the proposal and decreases the total number of domains required to be covered among the selected CQMs.

After consideration of the public comments received and for the reasons discussed previously, we are finalizing the following policy on reporting requirements for CQMs for eligible hospitals and CAHs beginning in 2014:

Eligible hospitals and CAHs must report a total of 16 CQMs covering at least 3 domains from Table 8. We expect eligible hospitals and CAHs will select measures that best apply to their patient mix. As we proposed, if an eligible hospital's or CAH's CEHRT does not contain patient data for at least 16 CQMs covering at least 3 domains, then the eligible hospital or CAH must report the CQMs for which there is patient data and report the remaining required CQMs as ''zero denominators'' as displayed by their certified EHR technology. In the unlikely event that there are no CQMs applicable to the eligible hospital's or CAH's patient mix, eligible hospitals or CAHs must still report 16 CQMs even if zero is the result in either the numerator or the denominator of the measure. If all CQMs have a value of zero from their CEHRT, then eligible hospitals or CAHs must select any 16 CQMs from Table 8 to report. We stated in the proposed rule that our experience from Stage 1 in implementing the current set of 15 CQMs in specialty and low volume eligible hospitals illuminated several challenges. For example, children's hospitals rarely see patients 18 years or older. One of the exceptions to this generality is individuals with sickle cell disease. National Institutes of Health Guidelines (NIH Publication 02–2117) list the conditions under which thrombolytic therapy cannot be recommended for adults or children with sickle cell disease. This, plus the

fact that children's hospitals have on average two or fewer cases of stroke per year, have created workflow, cost, and clinical barriers to demonstrating meaningful use as it relates to the CQMs for stroke and VTE.

We proposed to consider whether a case number threshold would be appropriate, given the apparent burden on hospitals that very seldom have the types of cases addressed by certain CQMs such that hospitals that do not have enough cases to exceed the threshold would be exempt from reporting those CQMs. We solicited comments on what the numerical range of threshold should be, how hospitals would demonstrate to CMS or state Medicaid agencies that they have not exceeded this threshold, whether it should apply to only certain hospital CQMs (and if so, which ones), and the extent of the burden on hospitals if a case number threshold is not adopted given that they are allowed to report ''zeroes'' for the measures. We solicited comments on limiting the case threshold exemption to only children's, cancer hospitals, and a subset of hospitals in the Indian Health System as they have a much narrower patient base than acute care and critical access hospitals. We requested comments on whether such thresholds should be established for 2013, noting that the issue could be mitigated beginning in 2014 by our proposal to establish a larger menu set of CQMs from which hospitals would select.

Comment: Many commenters noted that the implementation of a case number threshold for CQM reporting would help reduce the burden placed on hospitals that very seldom have cases in the denominator of certain CQMs. However, commenters suggested differing mechanisms by which to implement a case number threshold. Many commenters suggested that we use Medicare claims data from the year prior to a hospital's CQM submission or another historical data source to determine whether a hospital should be exempt from reporting certain CQMs. Another commenter suggested that the simplest option would be to continue to allow hospitals to report zeroes in the denominators for CQMs. A few commenters requested that we implement a case number threshold for all hospital types, not just specialty hospitals or CAHs, since some acute care hospitals do not provide a full range of services. Another commenter suggested that we work with children's hospitals and CAHs and other types of hospitals with unique patient populations to ensure that meaningful use requirements are feasible for them. Some commenters stated that low volume eligible hospitals and CAHs would not know at the beginning of a reporting period which CQMs would not meet a case number threshold and therefore should not have to select the CQMs in advance based on this criterion. This commenter suggested that the hospitals select the CQMs to report that are most appropriate for their patient populations. One commenter requested that a case number threshold be implemented for all CQM reporting for FY 2013.

In terms of a specific case number threshold, one commenter suggested five or fewer cases per month as an appropriate threshold number to exempt any type of hospital from reporting a CQM. This same commenter also suggested that if a hospital does not have a least one CQM in a domain with a denominator greater than five, then that hospital should be exempt from reporting on that entire domain. Another commenter suggested exempting eligible hospitals and CAHs from reporting a CQM if the relevant patient population comprised less than 10 percent of their discharges. Other commenters suggested that children's hospitals be excluded from all CQMs that are only applicable to patients 18 years of age or older. Another commenter recommended that we set a case number threshold of 30 cases and require hospitals to validate this exemption through attestation. Other commenters did not suggest a specific case number threshold, but requested that we empirically derive this value and that it be aligned with values across quality reporting programs.

Response: We recognize the potential cost and work flow challenges when hospitals have a low volume of cases per year that apply to a particular CQM. We note that under the Hospital IQR Program, we do not require a hospital that has 5 or fewer inpatient discharges (Medicare and non-Medicare combined) in a topic area during a quarter in which data must be submitted to submit patient-level data for that topic area for the quarter (76 FR 51641). For the Hospital IQR Program, the hospital is still required to submit its aggregate population and sample size counts for Medicare and non-Medicare discharges for the topic areas each quarter, and hospitals that qualify for this exception for a particular topic can still elect to voluntarily submit their patient-level data. In order to align with the Hospital IQR Program, we will adopt a similar policy for all eligible hospitals and CAHs participating in the EHR Incentive Program, whereby hospitals with 5 or fewer inpatient discharges per quarter or 20 or fewer inpatient discharges per year (Medicare and non-Medicare combined) as defined by a CQM's denominator population would be exempted from reporting on that CQM.

After consideration of the public comments received and for the reasons discussed earlier, we are finalizing the following policy on case threshold exemptions for eligible hospitals and CAHs in all stages of meaningful use beginning in FY 2014. However, eligible hospitals and CAHs that are demonstrating meaningful use for the first time must submit their CQMs through attestation and will not be able to qualify for this exemption. The burden of submitting the aggregate population and sample size counts in order to qualify for the exemption would be at least equal to the effort required to obtain and attest to the calculated CQM data.

Eligible hospitals and CAHs that have 5 or fewer discharges per quarter in the same quarter as their reporting period in FY 2014, or 20 or fewer discharges per full FY reporting period beginning in FY 2015, for which data is being electronically submitted (Medicare and non-Medicare combined) as defined by the CQM's denominator population are exempted from reporting the CQM. For example, if the CQM's denominator population is ischemic stroke patients greater than or equal to 18 years of age, then the threshold would be 5 or fewer ischemic stroke patients aged 18 years or older discharged from the hospital in the quarter for which data is being submitted (the hospital's FY 2014 3-month quarter reporting period). To be eligible for the exemption, hospitals must submit their aggregate population and sample size counts for Medicare and non-Medicare discharges for the CQM for the reporting period no later than the 2-month submission period of October 1 through November 30 immediately following the reporting period (please see section II.B.1. of this final rule for a description of reporting and submission periods). Hospitals will report this information in the same manner as for the Hospital IQR Program (76 FR 51639 through 51641). Please refer to the QualityNet Web site (*www.qualitynet.org*) and the CMS/Joint Commission Specifications Manual for National Hospital Inpatient Quality Measures, located on the QualityNet Web site, for technical information about data submission requirements. Hospitals that do not seek an exemption under the EHR Incentive Program do not have to submit aggregate population and sample size counts for any CQMs for the purposes of the EHR Incentive Program.

(ii) Clinical Quality Measures

We proposed CQMs in Table 9 of the Stage 2 proposed rule (77 FR 13760 to 13763) that would apply for all eligible hospitals and CAHs beginning with FY 2014, regardless of whether an eligible hospital or CAH is in Stage 1 or Stage 2 of meaningful use. The set of 49 CQMs that we proposed included the current set of 15 CQMs that were finalized for FYs 2011 and 2012 in the Stage 1 final rule.

The CQM titles and descriptions in Table 8 reflect the most current updates, as provided by the measure stewards who are responsible for maintaining and updating the measure specifications, and therefore may not reflect the title and/or description as presented on the NQF Web site.

Comment: Many commenters requested that we finalize fewer than 49 CQMs. The most common reasons given for reducing the complete list of CQMs included limitations of the vendors to program and deploy systems and for hospitals to effectively implement those systems, especially among resource-limited organizations.

Several commenters recommended that CQMs that are suspended from the Hospital IQR program, not NQF endorsed, only apply to certain regions of the country or not electronically specified should not be considered for CQM reporting beginning in 2014. Additionally, some commenters suggested that no new CQMs be added until CEHRT can produce accurate calculations of the existing CQMs. A few commenters stated that increasing the number of CQMs in such a narrow timeframe would be challenging for organizations in terms of designing, creating, and implementing new workflows, building, testing and modifying configurations to ensure proper discrete data capture, and training staff. One of these commenters requested a phased-in approach for calculating CQMs through EHRs and requested that we do not add any new manually abstracted CQMs in other CMS quality reporting programs.

One commenter stated that it was unclear if mid-cycle modifications of measures would require hospitals to resubmit data and recommended that if a measure were modified or deleted mid-cycle that hospitals not have to modify measures selected.

Response: Some of the CQMs that were proposed but not finalized were not submitted by the measure stewards for continued NQF endorsement (NQF 0136 Heart Failure (HF)-1 Detailed Discharge Instructions, NQF 0481 First Temperature Measured within One Hour of Admission to the NICU, and NQF 0482 First NICU Temperature <36 degrees C). We are not finalizing NQF 0143 and NQF 0144, both related to pediatric asthma, for CQM reporting beginning in 2014 because hospital performance on these measures in the IQR program is at or near 100 percent. While pediatric asthma is a priority for CMS, we recognize that there are greater opportunities to improve care than in measuring the provision of relievers and systemic corticosteroids, which are now common practice. Our future quality measurement and improvement efforts will focus on other aspects of the clinical care for children with asthma, targeting for inclusion in CQM reporting with Stage 3 rulemaking. We have also taken into consideration the ability of the eligible hospitals and CAHs to report CQMs from CEHRT when selecting the set of CQMs for reporting beginning in 2014.

CQM specifications will be updated on an annual basis. We will not require resubmission of data as a result of these updates. If we remove a CQM from the program, we would not require data to be submitted on any additional CQMs nor would this affect data submitted prior to removal of the CQM. See section II.B.4. of this final rule for additional details on this policy.

Comment: Some commenters requested denominator definitions such as elective delivery vs. delivery based on a physician's order, and clarification on age ranges. A few commenters requested that some of the measure stewards listed in Table 9 of the proposed rule be corrected.

Response: Clarifications on denominator definitions will be provided in the electronic specifications that will be posted on or about the publication of the final rule. Any further clarification needed should be addressed to the measure steward. The measure stewards listed incorrectly in Table 9 of the proposed rule were corrected (the correction notice can be found at 77 FR 23195 through 23196).

Comment/Response: Table 9 summarizes the public comments received on specific proposed eligible hospital and CAH CQMs and the CMS rationale (that is, our response to the CQM-specific comment(s)) for finalizing or not finalizing the CQM for reporting beginning with FY 2014.

TABLE 9—SUMMARY OF ELIGIBLE HOSPITAL AND CAH CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	CMS rationale
ED Throughput: NQF 0495, 0497, 0496.	Many supported continuing with Stage 1 CQMs, instead of requiring additional CQMs for Stage 2 (ED-1&2). ED throughput measures are required by the Joint Commission.	Few stated factors affecting results are outside control of ED, difficult to implement without workflow changes and CPOE implemented hospital-wide, & may reflect negatively on hospitals routinely receiving complex patients. One commenter noted may not correlate with improved outcomes.	Yes	Continues with Stage 1 CQM reporting for ED-1&2, aligns with IQR/OQR/HVBP, retooled measures passed reliability, validity, & feasibility testing.
Stroke-2,3,4,5,6,8: NQF 0435, 0436, 0437, 0438, 0439, 0440.	Many supported continuing with Stage 1 CQMs, instead of requiring additional CQMs for Stage 2.	Few stated that it is difficult to capture certain data elements within current clinical workflows, and recommends delay to Stage 3 after further e-specification testing is completed.	Yes	Continues with Stage 1 CQM reporting, aligns with IQR/HVBP, retooled measures passed reliability, validity, & feasibility testing.

TABLE 9—SUMMARY OF ELIGIBLE HOSPITAL AND CAH CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	CMS rationale
Stroke-10: NQF 0441	Many supported continuing with Stage 1 CQMs, instead of requiring additional CQMs for Stage 2.	A commenter stated that this is a poor care coordination measure but provided no reasons.	Yes	Continues with Stage 1 CQM reporting, aligns with IQR/HVBP, retooled measures passed reliability, validity, & feasibility testing.
VTE-1,2,3,4,5,6: NQF 371, 0372, 0373, 0374, 0375, 0376.	Many supported continuing with Stage 1 CQMs, instead of requiring additional CQMs for Stage 2.	Few stated that it is difficult to capture certain data elements within current clinical workflows, one recommended delay to Stage 3 after further e-specification testing is completed.	Yes	Continues with Stage 1 CQM reporting, aligns with IQR/HVBP, retooled measures passed reliability, validity, & feasibility testing.
AMI-1, 3, 5: NQF 0132, 0137, 0160.	One commenter supported AMI-3, but for Stage 3 once CPOE is more widely implemented & e-specifications can be published in a timely manner to allow for inclusion of new guidelines. Inclusion will help tracking compliance.	Many stated these measures should not be finalized since they have been suspended from IQR, are not recommended by the MAP, are difficult to implement without CPOE implemented hospital-wide & one commenter stated it is difficult to capture unless an eMAR is implemented. AMI-1 & 5 are not included in CMS programs.	No	Suspended from IQR, thus not supportive of program alignment.
AMI-2, 7a: NQF 0142, 0164	A few commenters support including these measures for Stage 3 to allow for additional time for testing & implementation. AMI-2 is required by the Joint Commission. Inclusion will help tracking compliance.	One commenter requested delay to Stage 3 until CPOE is more widely implemented. One commenter noted AMI-2 is topped out.	Yes	Aligns with IQR/HVBP, which both consider it an important CQM on post-discharge AMI prevention for hospitals to report. Retooled measure passed reliability, validity, & feasibility testing.
AMI-8a,10: NQF 0163, 0639	N/A	One commenter stated it is difficult to capture certain data elements within current clinical workflows; one commenter stated it is difficult to capture if CPOE is not widely implemented.	Yes	Aligns with IQR/HVBP, retooled measure passed reliability, validity, & feasibility testing.
PN-3b: NQF 0148	One commenter supports including this measure for Stage 3 to allow additional time for testing & implementation. A few commenters support this measure if e-specifications are available in a timely manner. This is required by the Joint Commission.	Delay to Stage 3 after further e-specification testing is completed.	No	Retired from NQF endorsement.
PN-6: NQF 0147	N/A	One commenter states data collection is difficult due to absent decision support algorithm.	Yes	Aligns with IQR/HVBP, retooled measure passed reliability, validity, & feasibility testing.
Elective Delivery Prior to 39 Weeks: NQF 0469.	A commenter supports the inclusion of this safety-related CQM.	Not required in IQR, a commenter was concerned that labor and delivery applications are not part of certification.	Yes	Aligns with IQR, Medicaid Adult Core, & Strong Start programs, retooled measure passed reliability, validity, & feasibility testing.
Exclusive Breast Feeding at Discharge: NQF 0480.	Many commenters support this, noting that it will help improve maternity care practices and create an awareness of quality of care issues. A commenter supported this measure, but for Stage 3 once labor and delivery applications are part of certification.	Not required in IQR, highly subjective measure, specific to California only and not well vetted, and contains data elements difficult to capture.	Yes	Aligns with Medicaid reporting initiatives. Measure passed reliability, validity, & feasibility testing.

TABLE 9—SUMMARY OF ELIGIBLE HOSPITAL AND CAH CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM—Continued

CQM No.	Commenters support finalization	Commenters do not support finalization	Finalized	CMS rationale
Home Management Plan of Care, CAC-3: NQF 0338.	A commenter supports this measure, but not until documentation for peri-operative, intra-operative and anesthesia are parts of certification.	Not required in IQR, not supported by the MAP, and overly burdensome.	Yes	Aligns with Medicaid reporting initiatives. Measure passed reliability, validity, & feasibility testing.
Healthy Term Newborn: NQF 0716.	A commenter supports this measure. A commenter supports this measure, but for Stage 3 once labor and delivery applications are part of certification.	Not required in IQR	Yes	Aligns with Medicaid reporting initiatives. Measure passed reliability, validity, & feasibility testing.
Hearing Screening: NQF 1354	One commenter supports this measure if e-specifications are available in a timely manner.	Not required in IQR	Yes	Aligns with Medicaid reporting initiatives. Measure passed reliability, validity, & feasibility testing.
SCIP INF-1,2,9: NQF 0527, 0528, 0453.	A commenter supports these measures, but not until documentation for peri-operative, intra-operative and anesthesia are parts of certification. Inclusion will help tracking compliance.	N/A	Yes	Aligns with IQR/HVBP, retooled measure passed reliability, validity, & feasibility testing.
SCIP INF-3,4,6: NQF 0529, 0300, 0301.	A commenter supports this measure, but not until documentation for peri-operative, intra-operative and anesthesia are parts of certification. SCIP-INF-3 is required by the Joint Commission..	Not required in IQR and not recommended by the MAP. One commenter noted SCIP INF-6 may not correlate with improved outcomes.	No	SCIP-INF-3 reflects a limited patient population, keeps the total number of Stage 2 measure options reasonable. SCIP-INF-4 is being reworked by the steward. SCIP-INF-6 is suspended from reporting in IQR.
HF-1: NQF 0136	One commenter supported	One commenter did not support since being retired from NQF endorsement.	No	Retired from NQF endorsement.
First Temperature within 1 hour in NICU > 36° and <36°: NQF 0481, 0482.	One commenter supported if e-specifications are published in a timely manner.	A few commenters stated it is not required in IQR and not recommended by MAP.	No	Retired from NQF endorsement.
Global Immunizations Pneumonia & Influenza; NQF 1653, 1659.	N/A	A few commenters stated these are not consistent with current guidelines.	No	Required in IQR but not for HVBP, and keeps the total number of Stage 2 measure options reasonable.
Proportion of Infants 22-29 weeks old treated with Surfactant: NQF 0484.	N/A	Contains data elements difficult to capture.	No	Retired from NQF endorsement.

All hospital CQMs finalized in this rule are NQF-endorsed. NQF endorsement includes a consensus development process that takes into account clinical guidelines and scientific evidence. NQF describes its consensus development process at *http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx*.

After consideration of the public comments received and the measure selection criteria discussed, we are finalizing the list of 29 CQMs for eligible hospitals and CAHs included in Table 10.

TABLE 10—CQMS FINALIZED FOR ELIGIBLE HOSPITALS AND CAHS BEGINNING WITH FY 2014

NQF No.	Title	Measure steward and contact information	Other quality measure programs that use the same CQM ***	New CQM	Domain
0495	Title: Emergency Department (ED)-1 Emergency Department Throughput—Median time from ED arrival to ED departure for admitted ED patients. Description: Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department.	CMS/Oklahoma Foundation for Medical Quality (OFMQ) Qualitynet.org and click on "Questions & Answers".	IQR		Patient and Family Engagement.

TABLE 10—CQMS FINALIZED FOR ELIGIBLE HOSPITALS AND CAHS BEGINNING WITH FY 2014—Continued

NQF No.	Title	Measure steward and contact information	Other quality measure programs that use the same CQM ***	New CQM	Domain
0497	Title: ED-2 Emergency Department Throughput—admitted patients—Admit decision time to ED departure time for admitted patients. Description: Median time (in minutes) from admit decision time to time of departure from the emergency department for emergency department patients admitted to inpatient status.	CMS/OFMQ Qualitynet.org and click on ''Questions & Answers''.	IQR	.....	Patient and Family Engagement.
0435	Title: Stroke-2 Ischemic stroke—Discharged on anti-thrombotic therapy. Description: Ischemic stroke patients prescribed antithrombotic therapy at hospital discharge.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	.....	Clinical Process/Effectiveness.
0436	Title: Stroke-3 Ischemic stroke—Anticoagulation Therapy for Atrial Fibrillation/Flutter. Description: Ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	.....	Clinical Process/Effectiveness.
0437	Title: Stroke-4 Ischemic stroke—Thrombolytic Therapy. Description: Acute ischemic stroke patients who arrive at this hospital within 2 hours (120 minutes) of time last known well and for whom IV t-PA was initiated at this hospital within 3 hours (180 minutes) of time last known well.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	.....	Clinical Process/Effectiveness.
0438	Title: Stroke-5 Ischemic stroke—Antithrombotic therapy by end of hospital day two. Description: Ischemic stroke patients administered antithrombotic therapy by the end of hospital day two.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	.....	Clinical Process/Effectiveness.
0439	Title: Stroke-6 Ischemic stroke—Discharged on Statin Medication. Description: Ischemic stroke patients with LDL greater than or equal to 100 mg/dL, or LDL not measured, or, who were on a lipid-lowering medication prior to hospital arrival are prescribed statin medication at hospital discharge.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	.....	Clinical Process/Effectiveness.
0440	Title: Stroke-8 Ischemic or hemorrhagic stroke—Stroke education. Description: Ischemic or hemorrhagic stroke patients or their caregivers who were given educational materials during the hospital stay addressing all of the following: activation of emergency medical system, need for follow-up after discharge, medications prescribed at discharge, risk factors for stroke, and warning signs and symptoms of stroke.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	.....	Patient & Family Engagement.
0441	Title: Stroke-10 Ischemic or hemorrhagic stroke—Assessed for Rehabilitation. Description: Ischemic or hemorrhagic stroke patients who were assessed for rehabilitation services.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	.....	Care Coordination.
0371	Title: Venous Thromboembolism (VTE)-1 VTE prophylaxis. Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	.....	Patient Safety.

TABLE 10—CQMS FINALIZED FOR ELIGIBLE HOSPITALS AND CAHS BEGINNING WITH FY 2014—Continued

NQF No.	Title	Measure steward and contact information	Other quality measure programs that use the same CQM ***	New CQM	Domain
0372	Title: VTE-2 Intensive Care Unit (ICU) VTE prophylaxis. Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	.....	Patient Safety.
0373	Title: VTE-3 VTE Patients with Anticoagulation OverlapTherapy. Description: This measure assesses the number of patients diagnosed with confirmed VTE who received an overlap of parenteral (intravenous [IV] or subcutaneous [subcu]) anticoagulation and warfarin therapy. For patients who received less than five days of overlap therapy, they must be discharged on both medications or have a reason for discontinuation of overlap therapy. Overlap therapy must be administered for at least five days with an international normalized ratio (INR) greater than or equal to 2 prior to discontinuation of the parenteral anticoagulation therapy, discharged on both medications or have a reason for discontinuation of overlap therapy.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Clinical Process/Effectiveness.
0374	Title: VTE-4 VTE Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram). Description: This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Clinical Process/Effectiveness.
0375	Title: VTE-5 VTE discharge instructions ..... Description: This measure assesses the number of patients diagnosed with confirmed VTE that are discharged to home, home care, court/law enforcement, or home on hospice care on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Patient and Family Engagement.
0376	Title: VTE-6 Incidence of potentially preventable VTE. Description: This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present at admission) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.	The Joint Commission *www.jointcommission.org* and click on ''Contact Us''.	IQR	New	Patient Safety.
0142	Title: AMI-2-Aspirin Prescribed at Discharge for AMI. Description: Acute myocardial infarction (AMI) patients who are prescribed aspirin at hospital discharge.	CMS/OFMQ *www.qualitynet.org* and click on ''Questions & Answers''.	IQR	New	Clinical Process/Effectiveness.
0469	Title: PC-01 Elective Delivery Prior to 39 Completed Weeks Gestation. Description: Patients with elective vaginal deliveries or elective cesarean sections at >= 37 and <39 weeks of gestation completed.	The Joint Commission (TJC) *www.jointcommission.org* and click on ''Contact Us''.	TJC	.....	Clinical Process/Effectiveness.

TABLE 10—CQMS FINALIZED FOR ELIGIBLE HOSPITALS AND CAHS BEGINNING WITH FY 2014—Continued

NQF No.	Title	Measure steward and contact information	Other quality measure programs that use the same CQM ***	New CQM	Domain
0164	Title: AMI-7a—Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival. Description: Acute myocardial infarction (AMI) patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving fibrinolytic therapy during the hospital stay and having a time from hospital arrival to fibrinolysis of 30 minutes or less.	CMS/OFMQ *www.qualitynet.org* and click on "Questions & Answers".	IQR, HVBP	New	Clinical Process/Effectiveness.
0163	Title: AMI-8a—Primary PCI Received Within 90 Minutes of Hospital Arrival. Description: Acute myocardial infarction (AMI) patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving primary PCI during the hospital stay with a time from hospital arrival to PCI of 90 minutes or less.	CMS/OFMQ *www.qualitynet.org* and click on "Questions & Answers".	IQR, HVBP	New	Clinical Process/Effectiveness.
0639	Title: AMI-10 Statin Prescribed at Discharge ..... Description: Acute Myocardial Infarction (AMI) patients who are prescribed a statin at hospital discharge.	CMS/OFMQ *www.qualitynet.org* and click on "Questions & Answers".	IQR	New	Clinical Process/Effectiveness.
0147	Title: PN-6—Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients. Description: Immunocompetent patients with Community-Acquired Pneumonia who receive an initial antibiotic regimen during the first 24 hours that is consistent with current guidelines.	CMS/OFMQ *www.qualitynet.org* and click on "Questions & Answers".	IQR, HVBP	New	Efficient Use of Healthcare Resources.
0527	Title: SCIP-INF-1 Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision. Description: Surgical patients with prophylactic antibiotics initiated within one hour prior to surgical incision. Patients who received Vancomycin or a Fluoroquinolone for prophylactic antibiotics should have the antibiotics initiated within 2 hours prior to surgical incision. Due to the longer infusion time required for Vancomycin or a Fluoroquinolone, it is acceptable to start these antibiotics within 2 hours prior to incision time.	CMS/OFMQ *www.qualitynet.org* and click on "Questions & Answers".	IQR, HVBP	New	Patient Safety.
0528	Title: SCIP-INF-2-Prophylactic Antibiotic Selection for Surgical Patients. Description: Surgical patients who received prophylactic antibiotics consistent with current guidelines (specific to each type of surgical procedure).	CMS/OFMQ *www.qualitynet.org* and click on "Questions & Answers".	IQR, HVBP	New	Efficient Use of Healthcare Resources.
0453	Title: SCIP-INF-9—Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero. Description: Surgical patients with urinary catheter removed on Postoperative Day 1 or Postoperative Day 2 with day of surgery being day zero.	CMS/OFMQ *www.qualitynet.org* and click on "Questions & Answers".	IQR, TJC	New	Patient Safety.
0496	Title: ED-3—Median time from ED arrival to ED departure for discharged ED patients. Description: Median time from emergency department arrival to time of departure from the emergency room for patients discharged from the emergency department.	CMS/OFMQ *www.qualitynet.org* and click on "Questions & Answers".	OQR	New	Care Coordination.
0338	Title: Home Management Plan of Care (HMPC) Document Given to Patient/Caregiver. Description: An assessment that there is documentation in the medical record that a Home Management Plan of Care (HMPC) document was given to the pediatric asthma patient/caregiver.	The Joint Commission (TJC) *www.jointcommission.org* and click on "Contact Us".	state use	New	Patient & Family Engagement.

TABLE 10—CQMS FINALIZED FOR ELIGIBLE HOSPITALS AND CAHS BEGINNING WITH FY 2014—Continued

NQF No.	Title	Measure steward and contact information	Other quality measure programs that use the same CQM ***	New CQM	Domain
0480	Title: Exclusive Breast Milk Feeding ..... Description: Exclusive breast milk feeding during the newborn's entire hospitalization.	The Joint Commission (TJC) *www.jointcommission.org* and click on "Contact Us".	state use	New	Clinical Process/Effectiveness.
0716	Title: Healthy Term Newborn ..... Description: Percent of term singleton live births (excluding those with diagnoses originating in the fetal period) who DO NOT have significant complications during birth or the nursery care.	California Maternal Quality Care Collaborative *www.cmqcc.org* and click on "Contact Us".	state use	New	Patient Safety.
1354	Title: EHDI-1a—Hearing screening prior to hospital discharge. Description: This measure assesses the proportion of births that have been screened for hearing loss before hospital discharge.	CDC *www.cdc.gov* and click on "Contact CDC".	state use	New	Clinical Process/Effectiveness.

*** IQR = Inpatient Quality Reporting.
TJC = The Joint Commission.
HVBP = Hospital Value-Based Purchasing.
OQR = Outpatient Quality Reporting.

8. Reporting Methods for Eligible Hospitals and Critical Access Hospitals

(a) Reporting Methods in FY 2013

In the Stage 2 proposed rule, we did not propose any reporting methods for Medicare eligible hospitals and CAHs in 2013. However, in the CY 2013 OPPS proposed rule (77 FR 45188), we stated that eligible hospitals and CAHs may continue to report by attestation CQM results as calculated by CEHRT, as they did for 2011 and 2012. For further explanation of reporting CQMs by attestation, please see the Stage 1 final rule (75 FR 44430 through 44434). We also proposed in the CY 2013 OPPS proposed rule (77 FR 45188) to continue for 2013 the voluntary electronic reporting pilot for CQMs (the Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs), which we had previously established for 2012. We expect to finalize in the CY 2013 Hospital OPPS final rule the reporting methods that would apply in 2013 for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program.

(b) Reporting Methods Beginning With FY 2014

Under section 1886(n)(3)(A)(iii) of the Act, eligible hospitals and CAHs must submit information on the CQMs selected by the Secretary ''in a form and manner specified by the Secretary'' as part of demonstrating meaningful use of CEHRT. We proposed that Medicare eligible hospitals and CAHs would select one of the following two options for submitting CQMs electronically.

- Option 1: Submit the selected 24 CQMs through a CMS-designated portal.

We proposed that CQM data would be submitted in an XML-based format on an aggregate basis reflective of all patients without regard to payer. This method would require eligible hospitals and CAHs to log into a CMS-designated portal and submit through an upload process data that is based on specified structures produced as output from their CEHRT.

- Option 2: Submit the selected 24 CQMs in a manner similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using CEHRT.

We proposed that, as an alternative to the aggregate-level reporting schema described previously under Option 1, Medicare eligible hospitals and CAHs that successfully report CQMs through an electronic reporting method similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using CEHRT would satisfy their CQMs reporting requirement under the Medicare EHR Incentive Program. Please refer to the CY 2012 OPPS final rule (76 FR 74489 through 74492) for details on the pilot.

We noted that the Hospital IQR program does not currently have an electronic reporting mechanism. We solicited comments on whether an electronic reporting option is appropriate for the Hospital IQR Program and whether it would provide further alignment with the EHR Incentive Program.

Comment: One commenter preferred Option 1 because it seems less burdensome. This commenter believed that a third party data warehouse to store patient-level data and aggregate the results would be necessary prior to implementing Option 1. The commenter also believed that the hospital should be able to calculate its own results.

Response: Hospitals have access to patient-level data. A hospital could use a CEHRT that can calculate CQM results and also directly report patient-level data to CMS, so these functions are not mutually exclusive. No data warehouse is necessary.

Comment: One commenter supported both the aggregate XML-based reporting option and the option similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot as well as the longer-term goal of attaining full automatic electronic reporting. Another commenter urged us to make the strategy for automating the reporting of CQM data clear, so that hospitals can avoid reporting the same quality data through multiple reporting mechanisms. One commenter urged us to make the necessary investment to establish the infrastructure for the flow of EHR data, with careful consideration given to how we will ensure reliable, valid, and complete CQM data.

Response: We are working to align the EHR Incentive Program with various other quality reporting programs in order to reduce duplicative reporting to the extent feasible and practical, beginning with the Hospital IQR Program. Under the Hospital IQR Program, hospitals report some

measures by submitting chart-abstracted patient-level data, reflective of all patients without regard to payer. More information on the Hospital IQR Program, including the chart-abstracted measure data submission process, can be found in the ''Guide to CMS Hospital IQR Program'' on the QualityNet Web site (*http://www.qualitynet.org/*, select ''Hospital Inpatient Quality Reporting Program'' from the ''Hospitals—Inpatient'' dropdown menu and click on the link to the guide from the ''Handbooks'' menu on the right side of the page). We expect to establish a similar mechanism for electronic submission of CQM data for the EHR Incentive Program.

The Hospital IQR Program does not currently have an EHR reporting option or requirement, but eligible hospitals and CAHs have been able to meet the CQM requirement for the EHR Incentive Program via the electronic reporting pilot. However, we expect that the Hospital IQR Program will transition to EHR-based reporting in a manner similar to the electronic reporting pilot, using an electronic transmission format such as the QRDA–I (for patient-level data). If the Hospital IQR Program establishes an EHR reporting option or requirement, we would consider whether we should allow hospitals to report CQMs through that mechanism using CEHRT for purposes of satisfying the CQM reporting component of the EHR Incentive Program.

We proposed to consider an ''interim submission'' option for Medicare eligible hospitals and CAHs that are in their first year of Stage 1 beginning in FY 2014 through an electronic reporting method similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs. Under this option, eligible hospitals and CAHs would electronically submit CQM data for a continuous 90-day EHR reporting period, and the data would have to be received no later than July 1 to meet the requirements of the EHR Incentive Program for purposes of avoiding a payment adjustment in the following year. We solicited public comment on this potential option.

Comment: One commenter supported an ''interim submission'' option for those in their first year, which the commenter stated could also serve as a transitional step for those catching up.

Response: Since we are allowing eligible hospitals and CAHs to submit their CQM data through attestation if they are in their first year of Stage 1, we are not finalizing the proposed interim submission option.

After consideration of the public comments received, we are finalizing the following policy for CQM reporting methods for eligible hospitals and CAHs beginning in FY 2014.

Eligible hospitals and CAHs that are in their first year of Stage 1 must report the selected 16 CQMs through attestation (please refer to the Stage 1 final rule for an explanation of reporting CQMs through attestation (75 FR 44430 through 44434)). For purposes of avoiding a payment adjustment, eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must submit their CQM data no later than July 1 of such preceding year. We note that this deadline does not apply to CAHs. For more details on submission deadlines specific to CAHs, please refer to section II.D.4. of this final rule.

Eligible hospitals and CAHs that are beyond their first year of meaningful use will be required to electronically submit the selected 16 CQMs using CEHRT using one of the options listed in this section of this final rule. Consistent with section 1886(n)(3)(B)(ii) of the Act, in the unlikely event that the Secretary does not have the capacity to receive CQM data electronically, eligible hospitals and CAHs may continue to report aggregate CQM results through attestation.

- Option 1: Submit the selected 16 CQMs on an aggregate basis through a CMS-designated transmission method using CEHRT.

The CQM data will be submitted in the QRDA–III format reflective of all patients without regard to payer. This method will require transmitting the data via a CMS-designated transmission method.

- Option 2: Submit the selected 16 CQMs on a patient-level basis in a manner similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using CEHRT. As long as the CQM data originates from CEHRT, it may be submitted directly from the hospital's CEHRT to CMS or through a data intermediary to CMS.

The electronically reported patient-level CQM data must use the QRDA category I (release 2) based on the Quality Data Model (QDM), which will include only patients that meet the denominator criteria of each reported CQM without regard to payer. For example, if a hospital selects NQF #0438 to report, the denominator criteria include ischemic stroke patients, so the QRDA–I for this CQM would include only ischemic stroke patients. This method will require submitting the data via a transmission method similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs (76 FR 74122). The requirement that eligible hospitals and CAHs submit patient-level data under the EHR Incentive Program is consistent with the requirement that hospitals submit patient-level data under other quality reporting programs such as the Hospital IQR Program.

We proposed to consider the following 4 options of patient population—payer data submission characteristics:

- All patients—Medicare only.
- All patients—all payer.
- Sampling—Medicare only, or
- Sampling—all payer.

Currently, the Hospital IQR program uses the ''sampling—all payer'' data submission characteristic. We solicited public comment on each of these 4 sets of characteristics and the impact they may have to vendors and hospitals, including but not limited to potential issues with the respective size of data files for each characteristic. We proposed to select 1 of the 4 sets as the data submission characteristic for the electronic reporting method for eligible hospitals and CAHs beginning in FY 2014.

Comment: Many commenters favored the all patient-all payer submission option. Nearly all of these commenters supported this option because of challenges identifying whether a patient is covered by Medicare or not. One commenter also noted that sampling Medicare patients alone would severely decrease the population of patients reported in the denominator for many CQMs, and that it is difficult to validate that the sampling is being done correctly. The commenter also argued that since data is captured at the time of care, there should be no difficulty submitting the data and therefore no need for sampling. Another commenter advised against permitting sampling for CQM reporting beginning in 2014 as it adds an additional level of complexity. One commenter stated that the ideal solution would be having both—all patient-all payer, and all patient-Medicare only, which would allow for Medicare vs. non-Medicare comparisons.

Some commenters who favored the all patient-all payer data submission option suggested that sampling-all payer be made available as an alternative option, with one noting that a no-sampling method may be burdensome for hospital staff who must manually enter clinical data that is not captured electronically.

If sampling is adopted, the commenter asks that it align with existing Hospital IQR Program sampling methodologies. One commenter preferred the sampling-all payer submission option, noting that it aligns with the reporting method for the Hospital IQR Program.

Response: We acknowledge hospitals' concerns about accurately distinguishing Medicare patients from other patients in their populations, and recognize that reporting data on Medicare patients only would reduce the population of patients for whom data are reported in most cases. Since payer will be collected as a supplemental data element for all CQMs beginning in 2014, we will be able to stratify measure results by payer. In the 2014 Edition certification criteria, ONC has increased the focus on CEHRT's capability to capture the structured data elements required for reporting the CQMs finalized in this rule. Therefore, the burden on hospital staff to manually enter data from a source other than the CEHRT should be greatly reduced. We also expect to propose electronic sampling algorithms in future rulemaking.

After consideration of the public comments received, we are finalizing the ''sampling-all payer'' option for patient-level data. This submission characteristic will only include patients that meet the denominator criteria of the CQMs that the eligible hospital or CAH selects to report to CMS and only the data elements listed in the CQM and transmission specifications for those patients would be sent to CMS.

(c) Electronic Reporting of Clinical Quality Measures for Medicaid Eligible Hospitals

States that have launched their Medicaid EHR Incentive Programs plan to collect CQMs electronically from CEHRT used by eligible hospitals. Each state is responsible for sharing the details on the process for electronic reporting with its provider community. We anticipate that whatever means states have deployed for capturing CQMs included in the Stage 1 final rule electronically will be similar for CQMs beginning in 2014. However, we note that subject to our prior approval, the process, requirements, and the timeline is within the states' purview.

Comment: Commenters suggested unified Medicaid CQM reporting to reduce the burden on eligible hospitals operating in multiple states.

Response: For the purposes of the Medicaid EHR Incentive Program, eligible hospitals only have to report CQMs to the state making the EHR incentive payment. However, data from all practice locations that are equipped with CEHRT will be used for reporting CQMs, even if the practice locations are in different states.

After consideration of the public comments received, we are finalizing the policies for electronic reporting of CQMs for Medicaid eligible hospitals as proposed. We are clarifying that dually-eligible hospitals may submit their CQMs via the methods outlined in section II.B.8.b. of this final rule. As part of certification for EHR technology, ONC is including testing for data capture, CQM calculation, and electronic submission. For CQMs, this includes certification criteria for the QRDA–I and QRDA–III transmission format. We expect the states that have electronic reporting options for CQMs might choose to adopt QRDA–I for patient-level data and/or QRDA–III for aggregate data as the form in which eligible hospitals would report CQM data. By adopting the same QRDA–I and/or QRDA–III formats that CMS is requiring for CQM reporting, the states would be able to leverage the development of the specifications by CMS and the industry as well as the testing done by ONC for certification of EHR technology. This would reduce the burden on EHR vendors to implement and test different specifications.

C. Demonstration of Meaningful Use and Other Issues

1. Demonstration of Meaningful Use

a. Common Methods of Demonstration in Medicare and Medicaid

We proposed to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs. The demonstration methods we adopt for Medicare will automatically be available to the states for use in their Medicaid programs. The Medicare methods are segmented into CQMs and meaningful use objectives, both of which meaningful users must meet. (We note that the discussion in this part of the preamble discuss the methods for meaningful use objectives. For the discussion on CQM reporting, please refer to II.B. of this final rule). We did not receive any comments on this general policy and for this final rule will continue the policy that was proposed (that is, common methods of demonstration with some flexibility for states as described in II.A.3.c of this final rule).

b. Methods for Demonstration of the Stage 2 Criteria of Meaningful Use

Except for the batch reporting option discussed in section II.C.1.c. of this final rule, we proposed no other changes to the attestation process for Stage 2 meaningful use objectives. We proposed several changes to reporting for CQMs beginning 2014, regardless of Stage, as discussed in section II.B. of this final rule. An EP, eligible hospital or CAH must successfully attest to the Stage 2 meaningful use objectives and successfully submit clinical quality measures to be a meaningful EHR user. We have revised § 495.8 to accommodate the Stage 2 objectives and measures, as well as changes to Stage 1.

As discussed in our proposed rule (77 FR 13764), as HIT matures we expect to base demonstration more on automated reporting by CEHRT, such as the direct electronic reporting of measures, both clinical and nonclinical, and documented participation in HIE. As this occurs, fewer objectives will be demonstrated through attestation. As explained in the proposed rule, however, we do not believe that the current advances in HIT and the certification of EHR technologies allow an alternative to attestation for the Stage 2 final rule. We will continue to evaluate possible alternatives to attestation and the accompanying changes to certification and meaningful use.

In addition, in lieu of EP-by-EP attestation, we proposed a batch file process for attestation. This batch file process would continue to require that meaningful use measures be assessed at the individual EP, eligible hospital or CAH level. It would be available no later than January 1, 2014. Batch reporting would allow large group practices to submit a large number of attestations at once, while still maintaining individual assessments of meaningful use. We proposed that a batch file process as discussed later would occur through the CMS attestation Web site. Each EP would still meet the required meaningful use thresholds independently; our proposal did not allow the use of group averages or any other method of group demonstration.

We explained that CMS and the states could continue to test options, such as registries or the direct electronic reporting of some measures; however, any such testing would be voluntary.

c. Group Reporting Option of Meaningful Use Core and Menu Objectives and Associated Measures for Medicare and Medicaid EPs Beginning With CY 2014

As explained previously, we proposed a batch reporting process that would allow groups of EPs to report each individual EP's core and menu objective data through a batch process, but would

maintain individual assessments of meaningful use. (We note that the discussion in this part of the preamble does not discuss CQM reporting, which is discussed in II.B. of this final rule).

Specifically, we proposed to establish a file format in which groups could submit core and menu objective information for individual Medicare EPs (including the stage of meaningful use the individual EP is in, numerator, denominator, exclusion, and yes/no information for each core and menu objective) as well as a process for uploading such batch files.

We proposed that states would have the option, but not be required to, offer batch reporting of meaningful use data for Medicaid EP, and that states would outline their approaches in their state Medicaid HIT Plans (under current regulatory requirements in § 495.332(c)(2) and (c)(3)).

We proposed the following policies would apply to batch reporting:

- Define a Medicare EHR Incentive Group as 2 or more EPs, each identified with a unique NPI associated with a group practice identified under one tax identification number (TIN) through the Provider Enrollment, Chain, and Ownership System (PECOS).
- States choosing to exercise this option will have to clearly define a Medicaid EHR Incentive Group via their state Medicaid HIT Plan.
- None of the EPs in either a Medicare or Medicaid EHR Incentive Group could be hospital-based according to the definition for these programs (see 42 CFR 495.4).
- Any EP that successfully attests as part of one Medicare EHR Incentive Group will not be permitted to also attest individually or attest as part of a batch report for another Medicare EHR Incentive Group.
- Because EPs can only participate in either the Medicare or Medicaid incentive programs in the same payment year, an EP that is part of a Medicare EHR Incentive Group will not be able to receive a Medicaid EHR incentive payment or be included as part of a batch report for a Medicaid EHR Incentive Group or vice versa.
- The group reporting option discussed in this section is limited to data for the core and menu objectives and does not include the reporting of clinical quality measures, which is also required to demonstrate meaningful use and receive an EHR incentive payment. Clinical quality measures must be reported separately through other electronic submission options. (These options are described in section II.B. of this final rule.).
- Because we proposed multiple group reporting methods for clinical quality measures, EPs will *not* have to report core and menu objective data in the same EHR Incentive Group as they report clinical quality measures. An EP will be able to submit the core and menu objectives as part of a group and the clinical quality measures as an individual or submit the core and menu objectives as an individual and the clinical quality measures as part of a group.
- Batch reporting would not be required by CMS and t EPs will be permitted to attest individually through the CMS attestation Web site (as long as they did not also report as part of a group).
- As in Stage 1, EPs will be required to individually meet all of the thresholds of the core and menu objectives and could not use group averages or any other method of group demonstration.
- Batch reporting would not change the policy that payment adjustments will be applied to individual EPs and not to Medicare EHR Incentive Groups. This policy is described in section II.D. of this final rule.
- Batch reporting would not change incentive payment assignment. That is, as with Stage 1, an EP's incentive payment will not be automatically assigned to the Medicare EHR Incentive Group with which they batch report under this option. The EP will still have to select the payee TIN during the registration process.
- An EP who chooses the group reporting option will be required to include in such reporting core and menu objective information on all outpatient encounters (that is, all encounters except those in the inpatient and emergency departments) where CEHRT is available, even if some encounters occurred at locations not associated with the EP's Medicare EHR Incentive Group. We explained that this policy is required because EPs who practice in multiple practices or locations are responsible for submitting complete information for all actions taken at practices/locations equipped with CEHRT. Under § 495.4, to be considered a meaningful EHR user, an EP must have 50 percent or more of their outpatient encounters in practice(s) or location(s) where CEHRT is available. In the July 28, 2010 final rule (75 FR 44329), we also made clear that an EP must include outpatient encounters for all locations equipped with CEHRT.
- There would not be a minimum participation threshold for reporting as part of an EHR Incentive Group; in other words, an EP who is able to meet the 50 percent threshold of patient encounters in locations equipped with CEHRT could report all of their core and menu objective data as part of an EHR Incentive Group in which they had only 5 percent of their patient encounters with that group, provided they report all of the data from the other locations through the same batch reporting process with the EHR Incentive Group.

Many commenters supported our proposal to institute a batch reporting process.

Some commenters offered comments or requested clarification. The summary of the comments and our responses follow:

Comment: A few commenters questioned the statement that a group for purposes of batch reporting is two or more EPs, each identified with a unique NPI associated with a group practice identified under one tax identification number (TIN) through the Provider Enrollment, Chain, and Ownership System (PECOS). These commenters suggested that the difference between this definition of a group and the one under the Physician Quality Reporting System (PQRS) is confusing and should be harmonized or aligned.

Response: Generally we agree with the principle of aligning definitions when possible. However, this rulemaking does not address PQRS definitions. Alignment with the current PQRS definition would entail changing our policy from 2 or more EPs to 25 or more EPs. We do not believe the benefits of alignment are greater than the administrative relief to group practices made up of 2 to 24 EPs. However, we note that in the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 proposed rule (77 FR 44722) we proposed to revise the PQRS definitions to 2 or more EPs. If finalized, the PQRS definition would align with our policy. Therefore, we are finalizing our policy that would allow batch reporting for groups with 2 (or more) EPs that meet the rules for such reporting. After consideration of the comments, we will establish a file format in which groups could submit core and menu objective information for individual Medicare EPs (including the stage of meaningful use the individual EP is in, numerator, denominator, exclusion, and yes/no information for each core and menu objective) and also establish a process through which groups would submit this batch file for

upload as proposed. As noted previously, this batch file reporting process does not apply to CQM reporting, which is discussed in section II.B of this final rule.

After consideration of the public comments received, we are finalizing this option as proposed. There is no accompanying regulation text for this policy, as it governs the procedures for attestation, but not the meaningful use requirements.

We also sought public comment on a group reporting option that measures performance at a group, rather than at an individual, level (referred to as the ''group performance'' option.) Rather than proposing a set of rules for such group performance, we requested comment on a host of topics. Many commenters supported a group performance option; however, we received very few detailed comments on many of the specific issues we put forth for discussion. Therefore, we continue to believe that additional policy development is necessary to address specifically how group performance would operate. We are not finalizing the group performance policy at this time, as we wish to consider it further. EPs will continue to be required to individually meet all of the thresholds of the core and menu objectives. The following comments were received on issues relating to group performance.

We requested comments on the definition of ''group,'' noting that the PQRS Group Reporting Option requires a physician group practice to have a single tax payer identification number (TIN), with 25 or more individual eligible professionals who have reassigned their billing rights to the TIN. Commenters responded that 25 is too large a number, with some suggesting 4 to 6, or even 2 or more, as an appropriate range. Commenters recommended that each EP within the TIN, be given the choice of participation in the group or individually. Some commenters also questioned whether a consistent TIN indicates a coherent group practice with care coordination.

We requested comments on whether there should be a self-nomination process for groups, as in PQRS, or an alternative process for identifying groups. Commenters generally supported self-nomination, if it is a simple process.

We also asked whether groups should be required to use the same CEHRT. Some commenters believed such a requirement would be onerous, explaining that in some cases imaging providers, such as radiologists have their own CEHRT. Other commenters supported using the same CEHRT to ensure consistent reporting.

We questioned whether a group could be eligible for group reporting if CEHRT (same or different) were not available to all associated EPs at all locations. Some commenters responded yes, that in large systems clinics may be added or upgraded at different points in time and there may be transition times during which some clinics may not have CEHRT. Commenters stated that a threshold could be used to ensure that the EHR is available for most of the services provided by the group. Others stated that, no, groups should be held to the same standard; if the group as a whole is not eligible, individuals could still demonstrate meaningful use on an individual basis.

We requested comment on the appropriate policy when a group uses multiple certified EHR technologies that cannot share data easily. Some commenters stated that because the group as a whole should still have to meet the meaningful use objectives, interoperability should not be a barrier to group performance. These commenters stated that while interoperability is the ultimate goal of EHR technology, it should not become a requirement prematurely and providers and vendors are best positioned to remedy interoperability problems. Commenters also urged us to ensure that clearinghouses and software vendors are within the scope of the covered entities that must comply with the rule, although no authority was cited for requiring such compliance.

We questioned how meaningful use activities should be calculated, particularly when an EP practices individually and with a group, or in multiple group practices. Some commenters stated that meaningful use would always be at the group level. Others stated that if there are EPs practicing across two or more groups, then neither group should use the group reporting option, as this could result in different menu measure selections and other complications. Other commenters recommended that the EP's covered services be calculated as a whole to generate the incentive payment amount and separate payments be made to each TIN based on the percentage of the EP's covered services that were assigned to each TIN.

We noted that the HITECH Act provides EPs who are meaningful users an incentive payment equal to 75 percent of Medicare allowable charges for covered professional services furnished by the EP in a payment year. Thus, we questioned how covered professional services performed by EPs in some other practice could be assigned to another group's TIN. Commenters suggested that groups could submit lists of EPs covered under its group submission and that have reassigned payment to the TIN. The covered services should include all covered services for the EP, regardless of TIN under which the services were billed. Commenters asserted that this process is not different from the current method in which individual EPs that work for multiple TINs can still reassign their incentive payments to a single TIN. Others recommended that for purposes of determining the 75 percent, CMS should simply limit its analysis to those services furnished at that practice.

We solicited public comment on how meaningful use activities performed at other groups should be included. Some commenters stated that groups should attest only for the services within the group practice, not services outside of the group. These commenters expressed concern about not being able to validate outside data.

If meaningful use activities outside the group were not included in group performance, we asked what the CMS policy should be for these activities performed outside the group. Commenters recommended that only the group activities should be considered, and that those activities performed outside the group should essentially be ignored.

We solicited input on what our policy should be if an EP reports as part of a group, but he or she actually fails to meet a measure individually. Commenters generally stated that individual performance should be subsumed in the group performance. They assert that groups will have their own internal incentives to ensure that EPs are properly using the EHR system.

Along the same lines, we requested information on what should happen if an EP rejects a particular objective completely. Should such an EP be considered a meaningful EHR user as long as the EP's non-participation still allows group compliance with a percentage threshold? Again, commenters recommended measurement solely at the group level. Again, they stated that the group practice would have its own incentives to ensure EPs within the group properly use CEHRT.

We questioned how yes/no objectives should be handled in group reporting. Commenters again recommended measurement at the group level: A yes would mean that the group has ''enabled'' and is using that functionality of its CEHRT.

We questioned how group performance would operate in cases when some EPs in the group participate in Medicaid while others participate in Medicare. Commenters stated that groups could provide lists of EPs and indicate which EPs are covered under Medicare versus Medicaid. However, in any case we, could also encourage states to accept the group's submission as applying to Medicaid, as well as Medicare. While another commenter suggested that Medicare should be the default choice for a group, unless they all participate in Medicaid.

As to our question of whether any incentive payment would be reassigned to the group automatically, or whether the EP would assign it to the group at registration, commenters gave conflicting recommendations. Some stated that individual EPs could reassign incentive payments to a TIN, and that the group could, at the end of the period, present a list of EPs who are within the TIN and reassigned payment to such TIN. Others favored automatic reassignment to the group demonstrating group performance, particularly when an EP is employed or contracts with only one group, or when a state does not permit assignment to an entity promoting the adoption of EHR technology. A commenter requested clarification on how an EP joining midyear would be handled.

We requested comments on the policies that would apply if an EP participates in one group's performance and the incentive payment were reassigned to the group automatically, but the EP also has covered services billed to other TINs. Commenters stated that if an EP leaves a group, there should be a mechanism for reporting this and allowing the EP to report individually or become part of another group; regardless, the automatic reassignment should stand.

We solicited information on how to address situations when an EP leaves a group during an active EHR reporting period. Commenters recommended that incentives could be pro-rated on this basis, perhaps with ''beginning and ending dates'' included in the group performance file to streamline the proration.

We requested information regarding payment adjustments, and whether they should also be applied at the group level. Some stated that group performance should be consistent at the incentive and payment adjustment phases of the EHR Incentive Program. Thus, if groups can receive incentives based on group performance, then group performance should also dictate payment adjustments at a group level. Others favored maintaining payment adjustments at the individual EP level.

Finally, we solicited alternative options for reporting meaningful use, while capturing necessary data. One commenter recommended a ''sub-TIN'' group reporting option where a specific department, specialty or clinic could report performance on a group basis.

2. Data Collection for Online Posting, Program Coordination, and Accurate Payments

In addition to the data already being collected under our regulations at § 495.10, we proposed to collect the business email address of EPs, eligible hospitals and CAHs to facilitate communication with providers. We proposed to begin collecting the information as soon as the registration system can be updated following the publication of this final rule for both the Medicare and Medicaid EHR Incentive Programs. We did not propose to post this information online. In our preamble, we proposed to amend § 495.10 accordingly. However, no regulation text appeared. We did not receive any comments on our proposal. We are finalizing regulation text at § 495.10(a)(3) to collect business email address.

We note that we did not propose any changes to the registration for the Medicare and Medicaid EHR Incentive Programs, to the rules on EPs switching between programs, or to the record retention requirements in § 495.10.

We did not propose any changes to the registration for the Medicare and Medicaid EHR Incentive Programs, to the rules on EPs switching between programs, or to the record retention requirements in § 495.10.

We did not receive any comments and we are finalizing these provisions as proposed.

3. Hospital-Based Eligible Professionals

Our only proposed changes to the definition of hospital-based eligible professional were to allow the determination of hospital-based to continue once the payment adjustments go into effect, and to propose that the hospital-based analysis at the payment adjustment phase would, for Medicare, be based on federal FY 2 years prior to the payment adjustment year. (See proposed § 495.4 and section II.D.2. of this final rule.)

We also requested comments on whether the definition of hospital-based should be refined to exclude from the definition those EPs who are not furnishing professional services ''through the use of the facilities and equipment, including qualified electronic health records, of the hospital'' (section 1903(t)(3)(D) and 1848(o)(1)(C)(ii) of the Act). We noted that during implementation of Stage 1, we were asked about situations where clinicians may work in specialized hospital units, the clinicians have independently procured and utilize EHR technology that is completely distinct from that of the hospital, and the clinicians are capable, without the facilities and equipment of the hospital, of meeting the eligible professional (for example ambulatory, not inpatient) definition of meaningful use. We stated our belief that such situations would be uncommon and might not be generalized under the uniform definition used by place of service codes.

We specifically requested comments on the following subjects: (1) How to determine whether specialized hospital units are using stand-alone certified EHR technology separate from that of the hospital; and (2) how to determine whether EPs using stand-alone certified EHR technology separate from that of the hospital are truly not accessing the facilities and equipment of the hospital. We proposed that hospital facilities and equipment would include the physical environment needed to support the necessary hardware; internet connections and firewalls; the hardware itself, including servers; and system interfaces necessary for demonstrating meaningful use, for example, to health information exchanges, laboratory information systems, or pharmacies. We proposed possibly using attestation for such elements, and noted our belief that any such attestations would be subject to audit and the False Claims Act.

We also requested comments on whether the criteria for ambulatory EHRs and the meaningful use criteria that apply to EPs could be met in cases where EPs are primarily providing inpatient or Emergency Department services. By definition, the EPs affected by this issue are those who provide 90 percent or more of their services in the inpatient or emergency department, and who provide less than 10 percent of their services, and possibly none, in outpatient settings. However, since the beginning of the program, we have been clear that for EPs, meaningful use measures will not include patient encounters that occur within the inpatient or emergency departments (POS 21 or 23). See for example, FAQ 10068, 10466, and FAQ 10462 at *http://questions.cms.gov* or in section II.A.3.d.(2). of this final rule.

Some of our meaningful use criteria for EPs are measured based on office visits (clinical summaries) and others

assume an outpatient type of setting (patient reminders). The certification rules at 45 CFR part 170 differentiate between ambulatory and inpatient EHRs, and we requested comments on whether the EPs in this case would have inpatient or ambulatory technology.

Comment: We received detailed comments addressing the majority of the questions we asked about how EPs would demonstrate they are not hospital-based were we to revise our definition of hospital-based to exclude EPs using stand-alone CEHRT separate from that of the hospital. These comments explained in a comprehensive manner how EPs use stand-alone CEHRT separate from that of the hospital, and also provide the facilities and equipment that make the use of CEHRT possible, including internet connections and firewalls. Commenters supported using the ambulatory certification criteria and the EP meaningful use objectives and measures with the inclusion of inpatient and emergency department encounters in meeting such measures.

Response: Given such comprehensive comments, we believe that it is possible for EPs to provide CEHRT in the hospital environment, that is, sufficiently independent of the facilities and equipment, including qualified electronic health records, of the hospital. In the Stage 1 final rule, we explained why we were not interpreting the statute to provide for individualized determinations of whether EPs were hospital-based. We focused on language in the statute stating that ''The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service.'' (See 75 FR 44440 through 44441). We continue to believe that this interpretation was reasonable based on the Congressional directive regarding site of service. However, we are now persuaded that the statute is also capable of the interpretation advanced by the commenters. Thus, while we continue to believe our prior interpretation was proper, we are convinced that other permissible interpretations may also be put forward through rulemaking. Therefore, we have added a new § 495.5 to allow us to exclude EPs who can demonstrate to us that the EP funds the acquisition, implementation, and maintenance of Certified EHR Technology, including supporting hardware and any interfaces necessary to meet meaningful use without reimbursement from an eligible hospital or CAH; and uses such Certified EHR Technology in the inpatient or emergency department of a hospital (instead of the hospital's CEHRT).

Once an EP registers for a given year they will know whether they are hospital based or not. An EP who is designated as hospital based, but wishes to be determined non hospital-based due to their funding of the acquisition, implementation and maintenance of CEHRT, including supporting hardware; and use of such CEHRT at a hospital, in lieu of using the CEHRT of such hospital will utilize an administrative process throughout the incentive payment year (and extending 2 months after the end of the incentive payment year) to provide documentation and seek a non-hospital based determination. Following a successful non-hospital based determination, the EP must attest each subsequent year that they continue to be in the same situation of funding of the acquisition, implementation and maintenance of CEHRT, including supporting hardware; and use of such CEHRT at a hospital without reimbursement from an eligible hospital or CAH, in lieu of using the Certified EHR Technology of such hospital, but would not have to provide the supporting documentation again. If and when a nonhospital-based determination has been made, the EP would then have to meet the same requirements of the EHR incentive program as any other EP including being subject to payment adjustments if applicable with a sole exception: The EP would include in their attestation to meaningful use all encounters at all locations, including those in the inpatient and emergency departments of the hospital, rather than just outpatient locations (other than the emergency department) as is the case for all other EPs.

4. Interaction With Other Programs

There were no proposed changes to the ability of providers to participate in the Medicare and Medicaid EHR Incentive Programs and other CMS programs, and we are not finalizing any new policies in this area. 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 section II.B. of this final rule for the proposed alignment initiatives for clinical quality measures.

Comment: Several commenters suggested changes to other CMS programs.

Response: Our proposed rule included policies for the EHR incentive program, and not other programs. Therefore, we are not addressing comments on rules other than the EHR incentive program, as these programs are outside the scope of this rulemaking.

D. Medicare Fee-for-Service

1. General Background and Statutory Basis

As we discussed in the Stage 1 final rule, sections 4101(b) and 4102(b) of the HITECH Act provide for reductions in payments to EPs, hospitals, and CAHs that are not meaningful users of CEHRT; beginning in CY 2015 for EPs, FY 2015 for hospitals, and in cost reporting periods beginning in FY 2015 for CAHs. We discuss the specific statutory requirements for each of these payment reductions in the following three sections. In these sections, we also present our specific policies for implementing these mandatory payment reductions.

2. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs Who Are Not Meaningful Users of CEHRT for an Applicable Reporting Period

Section 1848(a)(7) of the Act, as amended by section 4101(b) of the HITECH Act, provides for payment adjustments effective for CY 2015 and subsequent years for EPs, as defined in § 495.100 of the regulations, who are not meaningful EHR users during the relevant EHR reporting period for the year. In general, 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'' (defined later) of the fee schedule amount that will otherwise apply. As we also discuss later, the HITECH Act includes an exception, which, if applicable, could exempt certain EPs from this payment adjustment. The payment adjustments do not apply to hospital-based EPs.

The term ''applicable percent'' is defined in the statute to mean: ''(I) for 2015, 99 percent (or, in the case of an eligible professional who was subject to the application of the payment adjustment [if the EP is 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 each subsequent year, 97 percent.''

In addition, section 1848(a)(7)(iii) of the Act provides that if, for CY 2018 and subsequent years, the Secretary finds that 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, but that in no case shall the applicable percent be less than 95 percent.

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 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.

a. Applicable Payment Adjustments in CY 2015 and Subsequent Calendar Years for EPs Who Are Not Meaningful Users of CEHRT

Consistent with these provisions, in the Stage 1 final rule (75 FR 44572), we provided in § 495.102(d)(1) and (2) that, beginning in CY 2015, if an EP is not a meaningful EHR user for an EHR reporting period for the year, then the Medicare PFS amount that will otherwise apply for covered professional services furnished by the EP during the year will be adjusted by the following percentages: for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment for e-prescribing under section 1848(a)(5) of the Act for 2014, 98 percent); (2) for 2016, 98 percent; and (3) for 2017 and each subsequent year, 97 percent.

However, while we discussed the application of the additional adjustment for CY 2018 and subsequent years if the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent in the preamble to the final rule (75 FR 44447), we did not include a specific provision for this adjustment in the regulations text. Therefore, we proposed to revise the current regulations, to provide specifically that, beginning with CY 2018 and subsequent years, if the Secretary has found that the proportion of EPs who are meaningful EHR users under § 495.8 is less than 75 percent, the applicable percent is decreased by 1 percentage point for EPs who are not meaningful EHR users from the applicable percent in the preceding year, but that in no case is the applicable percent less than 95 percent. In the proposed rule, we stated our expectation that we would base the determination of the proportion of EPs each year on the most recent CY for which we have sufficient data (that is, most likely, the data available as of October 1, 2017, as this is the last date for EPs to register and attest to meaningful use to avoid a payment adjustment in CY 2018). We proposed that the computation will be based on the ratio of EPs who have qualified as meaningful users in the numerator, to Medicare-enrolled EPs in the denominator. In the proposed rule we also explained that because hospital-based EPs and EPs are granted an exception meet the definition of ''EP,'' we would not include such EPs in the denominator, because such EPs would not be subject to a determination of meaningful use status ''under subsection (o)(2).'' We also stated that we would provide more specific detail on this computation in future guidance after the final regulation is published.

In general terms, the two aforementioned provisions for payment adjustments to EPs who are not meaningful users of EHR technology have the following effects for CY 2015 and subsequent years. The adjustment to the Medicare PFS amount that will otherwise apply for covered professional services furnished by the EP will be 99 percent in CY 2015. However, for CY 2015 the adjustment for an EP who, in CY 2014, was subject to the application of the payment adjustment for e-prescribing under section 1848(a)(5) of the Act will be 98 percent of the Medicare PFS amount. In CY 2016, the adjustment to the Medicare PFS amount that will otherwise apply will be 98 percent. Similarly, the adjustment to the Medicare PFS amount that will otherwise apply will be 97 percent in CY 2017. Depending on whether the proportion of EPs who are meaningful EHR users is less than 75 percent, the adjustment to the Medicare PFS amount can be as low as 96 percent in CY 2018, and 95 percent in CY 2019 and subsequent years.

We did not receive any comments on our proposed methodology for making the determination of the applicable payment adjustment for Medicare EPs, including our proposed methodology for making the ''75 percent determination'' beginning for CY2018. Therefore, we are finalizing these provisions as proposed.

We noted in our proposed rule that some eligible professionals may be eligible for both the Medicare and Medicaid EHR incentives, and have opted for the Medicaid EHR incentive. Under that program, in the first year of their participation, EPs may be eligible for an incentive payment for having adopted, implemented, or upgraded (AIU) to CEHRT. However, AIU does not constitute meaningful use of CEHRT. Therefore, those EPs who receive an incentive payment for AIU will not be considered meaningful EHR users for purposes of determining whether EPs are subject to the Medicare payment adjustment. Medicaid EPs who meet the first year requirements through AIU in either 2013 or 2014 will still be subject to the Medicare payment adjustment in 2015 if they are not meaningful EHR users for the applicable reporting period. However, Medicaid EPs can, avoid this consequence by making sure that they meet meaningful use in 2013 (or 2014 if this is the first year of demonstrating meaningful use). Since the Medicaid EHR Incentive Program allows EPs to initiate as late as 2016, AIU can still be an important initial step for providers who missed the window to avoid the Medicare penalties, assuming they then demonstrate meaningful use in the subsequent year.

Comment: Commenters stated universal support for our proposal that EPs who are meaningful EHR users under the Medicaid EHR Incentive Program for an applicable reporting period will also be considered meaningful EHR users for that period for purposes of avoiding the Medicare payment adjustments.

Response: We agree with commenters and are finalizing this provision as proposed for the reasons outlined in the proposed rule.

Comment: A few commenters suggested that we allow Medicaid AIU to be used to avoid the payment adjustment.

Response: The statute (section 1848(a)(7) of the Act) specifically requires that the Medicare payment adjustment be applied to an EP ''who is not a meaningful EHR user * * * for an EHR reporting period for the payment year.'' As we have discussed previously, AIU does not involve the demonstration of meaningful use. Therefore, we cannot accept the commenters' recommendation that demonstration of AIU be accepted to allow an EP to avoid the Medicare payment adjustment.

After consideration of the public comments received, we are finalizing these provisions as proposed.

TABLE 11—PERCENT ADJUSTMENT FOR CY 2015 AND SUBSEQUENT YEARS, ASSUMING THAT, FOR CY 2018 AND SUBSEQUENT YEARS, THE SECRETARY FINDS THAT LESS THAN 75 PERCENT OF EPS ARE MEANINGFUL EHR USERS

EPs who are non-meaningful users	2015	2016	2017	2018	2019	2020+
EP is not subject to the payment adjustment for e-prescribing in 2014	99%	98%	97%	96%	95%	95%
EP is subject to the payment adjustment for e-prescribing in 2014	98	98	97	96	95	95

TABLE 12—PERCENT ADJUSTMENT FOR CY 2015 AND SUBSEQUENT YEARS, ASSUMING THAT THE SECRETARY ALWAYS FINDS THAT, FOR CY 2018 AND SUBSEQUENT YEARS, AT LEAST 75 PERCENT OF EPS ARE MEANINGFUL EHR USERS

EPs who are non-meaningful users	2015	2016	2017	2018	2019	2020+
EP is not subject to the payment adjustment for e-prescribing in 2014	99%	98%	97%	97%	97%	97%
EP is subject to the payment adjustment for e-prescribing in 2014	98	98	97	97	97	97

Comment: A commenter noted use of the word, ''during,'' in section 1848(a)(7) of the Act, which states: ''* * * if the eligible professional is not a meaningful EHR user (as determined under subsection (o)(2) for an EHR reporting period for the year, the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).'' The commenter asserted that the phrase ''during the year'' allows the Secretary to apply the payment adjustment for any amount of time during the year and does not require that the payment adjustment be applied for the entire year.

Response: We disagree with this interpretation. Other parts of the statute clearly show the payment adjustment applies for a year at a time, and the Congress' intent was to have the physician fee schedule adjusted for an entire calendar year (that is, 99 percent (or 98 percent) in 2015, 98 percent in 2016, 97 percent in 2017, and so on.) The interpretation presented by the commenters would lead to absurd results, because it would allow the payment adjustment to be minimized to the point where it has no impact on the EP.

Therefore, we are finalizing the payment adjustment percentages and time periods as proposed.

b. EHR Reporting Period for Determining Whether an EP Is Subject to the Payment Adjustment for CY 2015 and Subsequent Calendar Years

In the Stage 1 final rule, we did not specifically discuss the EHR reporting periods that will apply for purposes of determining whether an EP is subject to the payment adjustments for CY 2015 and subsequent years. Section 1848(a)(7)(E)(ii) of the Act provides broad authority for the Secretary to choose the EHR reporting period for this purpose. Specifically, this section provides that ''term 'EHR reporting period' means, with respect to a year, a period (or periods) specified by the Secretary.'' Thus, the statute neither requires that such reporting period fall within the year of the payment adjustment, nor precludes the reporting period from falling within the year of the payment adjustment.

In developing our proposals in the case of EPs, we sought to establish appropriate reporting periods for purposes of the payment adjustments in CY 2015 and subsequent years to avoid creating a situation in which it might be necessary either to recoup overpayments or make additional payments after a determination is made about whether the payment adjustment should apply. We noted that this consideration is especially important in the case of EPs because, unlike the case with eligible hospitals and CAHs, there is not an existing mechanism for reconciliation or settlement of final payments subsequent to a payment year, based on the final data for the payment year. (Although, as we discussed in relation to our proposals on the payment adjustments for eligible hospitals in CY 2015 and subsequent years, this consideration also carries significant weight even where such a reconciliation or settlement mechanism is available.) Similarly, we did not want to create any scenarios under which providers would be required either to refund money, or to seek additional payment from beneficiaries, due to the need to recalculate beneficiary coinsurance after a determination of whether the payment adjustment should apply. If we were to establish EHR reporting periods that run concurrently with the payment adjustment year, we would not be able to safeguard against such retroactive adjustments (potentially including adjustments to beneficiary copayments, which are determined as a percentage of the Medicare PFS amount).

Therefore, we proposed that EHR reporting periods for payment adjustments will begin and end prior to the year of the payment adjustment. Furthermore, we proposed that the EHR reporting periods for purposes of such determinations will be far enough in advance of the payment adjustment year to give us sufficient time to implement the system edits necessary to apply any required adjustments correctly, and that EPs will know in advance of the payment adjustment year whether or not they are subject to the adjustments that we have discussed. Specifically, we proposed that the following rules would apply for establishing the appropriate reporting periods for purposes of determining whether EPs are subject to the payment adjustments in CY 2015 and subsequent years:

- Except as provided in the following bulleted paragraph for EPs who become meaningful users for the first time in 2014, we proposed that the EHR reporting period for the 2015 payment adjustment would be the same EHR reporting period that applies in order to receive the incentive for payment year

2013. We stated that this proposal would align reporting periods for multiple physician reporting programs. For EPs we proposed that the period would generally be a full calendar year of 2013 (unless 2013 is the first year of demonstrating meaningful use, in which case a 90-day EHR reporting period would apply). Under our proposed policy, an EP who receives an incentive for payment year 2013 would be exempt from the payment adjustment in 2015. An EP who received an incentive for payment years in 2011 or 2012 (or both), but who failed to demonstrate meaningful use in 2013 would be subject to a payment adjustment in 2015. (As all of these years will be for Stage 1 of meaningful use, we stated our belief that it is unnecessary to create a special process to accommodate providers that miss the 2013 year for meaningful use). For each year subsequent to CY 2015, we proposed an EHR reporting period for the payment adjustment that is the calendar year 2 years prior to the payment adjustment period, subject again to the special exception for new meaningful users of the CEHRT as follows:

• We proposed an exception for those EPs who never successfully attested to meaningful use prior to CY 2014. For these EPs, as it would be their first year of demonstrating meaningful use, for the 2015 payment adjustment, we proposed to allow a continuous 90-day reporting period that begins in 2014 and that ends at least 3 months before the end of CY 2014. In addition, the EP would have to successfully register for and attest to meaningful use no later than the date that occurs 3 months before the end of CY 2014. For EPs, we stated that under our proposal, the latest day the EP must successfully register for the incentive program and attest to meaningful use, and thereby avoid application of the adjustment in CY 2015, would be October 1, 2014. Thus, the EP's EHR reporting period would need to begin no later than July 3, 2014 (allowing the EP a 90-day EHR reporting period, followed by 1 extra day to successfully submit the attestation and any other information necessary to earn an incentive payment). We proposed that this policy would continue to apply in subsequent years for EPs who are in their first year of demonstrating meaningful use in the year immediately preceding the payment adjustment year.

Comment: Many commenters disagreed with our interpretation of the statute. These commenters asserted that both the Congressional intent and the language of the statute required an EHR reporting period aligned with the payment adjustment year. Thus, these commenters maintained that an EP should be subject to a payment adjustment during a payment year only if he or she fails to demonstrate meaningful use during that payment year. These commenters proposed several alternative methods for employing an EHR reporting period that is concurrent to the payment adjustment year for EPs. These recommended methods involved either making a determination of meaningful use early in a payment year, and then applying the payment adjustment (where applicable) for only a later part of the year, or developing a reconciliation process at the end of the year in which the payment adjustment is either collected from or refunded to the EP as appropriate.

Response: We disagree with the commenters' interpretation of the statutory language. As the commenters note, section 1848(a)(7) of the SSA specifically requires that the Medicare payment adjustment be applied to an EP ''who is not a meaningful EHR user * * * for an EHR reporting period for the payment year.'' However, as we discussed in the proposed rule, section 1848(a)(7)(E)(ii) of the Act specifically provides that ''term 'EHR reporting period' means, with respect to a year, a period (or periods) specified by the Secretary.'' Thus, the statute neither requires that such reporting period fall within the year of the payment adjustment, nor precludes the reporting period from falling within the year of the payment adjustment. Rather, the statute allows the Secretary the discretion to set the EHR reporting period and link to a year of payment adjustments. Indeed, given that Congress directed that the payment reduction that is applied to the physician fee schedule also apply for purposes of determining coinsurance, we believe there was an underlying intent to ensure that the physician fee schedule amount (and whether a percentage reduction applies) would be known at the time coinsurance is calculated. This would explain why Congress provided flexibility to the Secretary in determining which reporting period dictates whether the EP is subject to a payment adjustment. Finally, we note that other payment adjustment programs, such as the e-prescribing program, and the physician quality reporting system, also use a prior reporting period. Thus, it is consistent for us to adopt a prior reporting period for the EHR program as well.

Comment: Commenters also raised two more practical objections to our proposal to use a prior EHR reporting period. One objection is that there is insufficient vendor capacity for all providers to purchase CEHRT and achieve meaningful use prior to 2015, in order to avoid the payment adjustment in 2015. Some of these commenters asserted that the practical deadline for beginning the process of adopting and implementing CEHRT has already passed for some popular vendors; thus, vendor choice is limited by the proposed timeline. Commenters also assert that this issue is compounded because EHR vendors must upgrade current clients to 2014 CEHRT at roughly the same time.

Response: We understand the commenters' concerns. However, EPs have known for several years that they would face a payment adjustment beginning in 2015, and we believe that they have thus had adequate time to make appropriate preparations. During the last 2 years there has been a significant adoption of CEHRT with over 100,000 EPs receiving an incentive for adoption/implementation/upgrade or meaningful use. We also acknowledge the concerns expressed by many commenters about vendor capacity, and especially about whether every vendor will be available to every EP seeking to establish meaningful use. We note that to avoid the payment adjustment in 2015, all providers will be required to establish only Stage 1 of meaningful use in the applicable reporting period. For the payment adjustment in 2016, only those who first demonstrated meaningful use in 2011 or 2012 will have to demonstrate Stage 2 in the applicable reporting period and we are finalizing a shorter EHR reporting period for these EPs to account for the time limitations. We also believe other factors outweigh the concerns noted by commenters. As discussed previously, we do not believe the statute should be read to allow payment adjustments for only part of the year. Each of the other alternative suggestions presented by commenters would require reprocessing of claims for EPs, as well as addressing the difficult issue of how to adjust co-insurance in the context of this reprocessing (that is, to refund some coinsurance or to collect additional coinsurance, depending upon the results of the reprocessing on each claim). The administrative and financial cost of the reprocessing that would be required would be quite significant for both CMS and the affected EPs. Especially for smaller dollar claims, it is possible that in 2015 the cost of reprocessing for CMS and EPs could exceed that payment adjustment. For example, a claim of $100 will be

reduced $1 or $2 in CY 2015. If that claim was reprocessed, CMS Medicare Administrative Contractors (MACs) would have to reprocess the claim, utilize the banking system to send the payment; the EP's accounting process would have to accept the new payment and update the old claim and possibly incur the costs of collecting or refunding coinsurance. As the payment adjustments increase, the balance between the cost of the payment adjustments weighed against the cost of claim reprocessing may shift. In addition, as time passes we also anticipate that the supply of CEHRT and supporting services will increase to better match demand, lessening the concerns presented by the commenters. Therefore, we are finalizing the EHR reporting period for determining whether an EP is subject to the payment adjustment for CY 2015 and subsequent calendar years as proposed. The issue requiring all providers regardless of stage of meaningful use to upgrade to 2014 CEHRT is addressed by ONC in their final rule published elsewhere in this issue of the **Federal Register**. We note that all providers, regardless of stage, will use a 3-month EHR reporting period in 2014.

c. Exception to the Application of the Payment Adjustment to EPs in CY 2015 and Subsequent Calendar Years

As previously discussed, section 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustments in CY 2015 and subsequent CYs if the Secretary determines that compliance with the requirements for being a meaningful EHR user will result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient Internet access. As provided in the statute, the exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years. We note that the HITECH Act does not obligate the Secretary to grant exceptions. Nonetheless, in the proposed rule, we expressed our belief that there are hardships for which an exception should be granted. We therefore proposed three types of exceptions in the proposed rule and discussed a potential fourth. The three proposed exceptions were, by definition, time limited and we stated that the circumstances justifying such exceptions should not be present for more than 5 years. The fourth exception related to certain EPs and did not, by definition, involve time limited circumstances. Nevertheless, we noted that the 5 year limitation is statutory and cannot be altered by regulations, and that barriers to achieving meaningful use should be minimized over time.

Comment: Some commenters suggested that the exception be granted for an all 5 years rather than an annual determination to reduce the burden on EPs seeking the exception and the burden on CMS to process the exceptions.

Response: Section 1848(a)(7)(B) of the Act makes the hardship exception subject to annual renewal. Therefore, we would not grant an exception for more than 1 year unless we are certain that the circumstances that qualify an EP for an exception will not change for 5 years. The only such definitive case is for new EPs, and we grant a 2-year exception for such new EPs, because the date when an individual becomes an EP is a fixed point in time and not subject to change. However, all other exceptions discussed in the proposed rule depend on variable circumstances and could change from year to year. For example, although the exception we are finalizing for certain EPs (see § 495.102(d)(4)(iv)) could depend on scope of practice, which may be relatively fixed, it also depends on the ability to control the availability of CEHRT, which could easily change from year to year. Therefore, for these cases, we are not adopting this recommendation, and are finalizing a requirement for annual renewal.

As mentioned previously, we proposed three specific exceptions and a potential fourth in the proposed rule. First, we proposed that the Secretary may grant an exception to EPs who practice in areas without sufficient Internet access. We noted that section 1848(a)(7)(B) of the Act specifically allows the Secretary to establish a significant hardship ''in the case of an eligible professional who practices in a rural area without sufficient Internet access.'' However, our proposal recognized that a nonrural area may also lack sufficient Internet access to make complying with the requirements for being a meaningful EHR user a significant hardship for an EP.

We noted that exceptions on the basis of insufficient Internet connectivity must intrinsically be considered on a case-by-case basis. Therefore, we proposed to require that EPs must demonstrate insufficient Internet connectivity to qualify for the exception through an application process. As we discussed in the proposed rule, the rationale for this exception is that lack of sufficient Internet connectivity renders compliance with the meaningful EHR use requirements a hardship, particularly for meeting those meaningful use objectives requiring Internet connectivity, such as, summary of care documents, electronic prescribing, making health information available online, and submission of public health information. Therefore, we proposed that the application must demonstrate insufficient Internet connectivity to comply with the meaningful use objectives and that there are insurmountable barriers to obtaining such infrastructure, such as a high cost of extending the Internet infrastructure to their facility. We also proposed that an EP must establish the existence of the hardship was for the year that is 2 years prior to the payment adjustment year. Therefore, we proposed to require that applications be submitted no later than July 1 of the calendar year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the EP to be notified about whether an exception has been granted prior to the payment adjustment year. This proposed timeline for submission and consideration of hardship applications was intended to allow sufficient time to adjust our payment systems so that payment adjustments are not applied to EPs who have received an exception for a specific payment adjustment year.

In our proposed rule, we also encouraged EPs to apply for the exception as soon as possible, which is after the first 90 days (the earliest EHR reporting period) of CY 2013. If applications are submitted close to or on the latest date possible (that is, July 1, 2014 for the 2015 payment adjustment year), then the applications could not be processed in sufficient time to conduct an EHR reporting period in CY 2014 in the event that the application is denied.

Comment: Commenters stated universal support for this exception. However, commenters expressed the concern about the situation of an EP who might have sufficient internet access in the 2 years prior, but lose it in 2014.

Response: We are finalizing our proposed significant hardship exception for insufficient Internet connectivity with one modification. We believe that it is extremely unlikely that an EP would lose sufficient internet access at one location. However, an EP may relocate to a location without sufficient Internet access. Therefore, we are finalizing our proposal with the modification to allow for the demonstration of insufficient internet access for any 90-day continuous period between the start of the year 2 years prior to the payment adjustment year and through the application submission

date of July 1 of the year prior to the payment adjustment year. The 90-day period should be within this timeframe (for example, for payment adjustment year 2015, the hardship would need to be shown for any continuous 90-day period that begins on or after January 1, 2013 and ends on or before July 1, 2014.

Second, we proposed to provide an exception for new EPs for a limited period of time after the EP has begun practicing. Newly practicing EPs will not be able to demonstrate that they are meaningful EHR users for a reporting period that occurs prior to the payment adjustment year. Therefore, we proposed that for 2 years after they begin practicing, EPs could receive an exception from the payment adjustments that will otherwise apply in CY 2015 and thereafter. We also proposed that, for purposes of this exception, an EP who switches specialties and begins practicing under a new specialty will not be considered newly practicing. For example, an EP who begins practicing in CY 2015 will receive an exception from the payment adjustments in CYs 2015 and 2016. However, as discussed previously, the new EP will still be required to demonstrate meaningful use in CY 2016 in order to avoid being subject to the payment adjustment in CY 2017. In the absence of demonstrating meaningful use in CY 2016, an EP who had begun practicing in CY 2015 will be subject to the payment adjustment in CY 2017. We proposed to employ an application process for granting this exception, and will provide additional information on the timeline and form of the application in guidance subsequent to the publication of the final rule.

Comment: Commenters stated universal support for this exception in public comments, and we are finalizing this exception as proposed for the reasons outlined in the proposed rule.

Third, we proposed an additional exception in this final rule for extreme circumstances that make it impossible for an EP to demonstrate meaningful use requirements through no fault of her own during the reporting period. Such circumstances might include: a practice being closed down; a hospital closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we proposed to require EPs to qualify for the exception through an application process.

Comment: Many commenters supported this exception. However a number of the supporters requested that various circumstances be added to the list of example circumstances that we provided. These examples dealt primarily with concerns related to vendors of CEHRT. Specifically, commenters were concerned about vendors of CEHRT not maintaining their certification status, ability to meet implementation schedules, and ability to find a vendor of CEHRT willing to work with them. In addition, commenters suggested that the provider facing severe financial distress, such as bankruptcy or restructuring of debt should be included as an example.

Response: In evaluating these circumstances, we considered whether first and foremost they met the criteria of making it impossible for the EP to demonstrate meaningful use requirements through no fault of his or her own during the EHR reporting period. Second, we considered whether they establish a definitive circumstance that would always rise to the level of the exception or whether they would be dependent on the individual scenario. We are including two examples submitted by commenters in the preamble of the final rule that match the former criteria. First, we would consider the case an EP whose CEHRT loses its certification either through revocation or because the vendor did not upgrade their CEHRT to the latest requirements as an extreme circumstance that might qualify for this exception. Second, we would consider the case of an EP suffering severe financial distress resulting in a bankruptcy or restructuring of debt as an extreme circumstance that might qualify for this exception.

We require applications to be submitted no later than July 1 of the calendar year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the EP to be notified about whether an exception has been granted prior to the payment adjustment year. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to EPs who have received an exception for a specific payment adjustment year.

The purpose of this exception is to accommodate EPs who would have otherwise been able to become a meaningful EHR user and avoid the payment adjustment for a given year in the absence of the extreme circumstances they face. Therefore, it is necessary to establish whether the relevant circumstances exist during the EHR reporting period for a given payment adjustment year rather than the payment adjustment year itself. In the proposed rule, we explained the inherently case-by-case nature of this exception request. While we discussed circumstances that arise in ''either of the 2 calendar years before the payment adjustment year,'' our intent was to ensure that the regulations recognized the two different EHR reporting periods for new meaningful users (that is, those demonstrating meaningful use for the first time in the year immediately prior to the payment adjustment year), versus current meaningful users (that is, those demonstrating meaningful use in the calendar year that is two years before the payment adjustment year). Obviously, a ''current'' meaningful user, who is required under our regulations to demonstrate meaningful use in the calendar year two years before the payment adjustment year, may not receive an exception for circumstances that occur after that reporting period. While a new meaningful user might be able to demonstrate that extreme circumstances that occurred prior to the reporting period continue to warrant an exception, we believe the case-by-case nature of the exception requests would allow such ''new'' meaningful users this opportunity to demonstrate that a significant hardship continues to exist during the reporting period. Therefore, in this final rule, we are clarifying our regulation to distinguish between new and current meaningful users, to be clear that the extreme circumstances must exist during the period in which the provider would otherwise be required to demonstrate meaningful use. EPs should apply for this exception on the basis of circumstances arising in the CY 2 years prior to the payment adjustment year, or, in the case of EPs who have never attested to meaningful use, the year immediately prior to the payment adjustment year.

Finally, we solicited comment on the appropriateness of granting a fourth exception for EPs meeting certain specific general criteria that might render demonstration of meaningful use very difficult. The criteria that we discussed were—

- Lack of face-to-face or telemedicine interaction with patients, thereby making compliance with meaningful use criteria more difficult. Meaningful use requires that a provider collect a considerable amount of information about the patient and is able transport information online (to a PHR, to another provider, or to a patient) and is significantly easier if the provider has direct contact with the patient and a need for follow up care or contact. Certain physicians often do not have a consultative interaction with the

patient. For example, pathologist and radiologists seldom have direct consultations with patients. Rather, they typically submit reports to other physicians who review the results with their patients;

• Lack of follow up with patients. Again, the meaningful use requirements for collecting information about the patient and transporting information online are significantly easier to meet if a provider has direct contact with a patient and a need to follow-up with the patient; and

• Lack of control over the availability of CEHRT at their practice locations.

In our proposed rule, we stated that we did not believe any one of these barriers taken independently would constitute an insurmountable hardship; however, our experience with Stage 1 of meaningful use suggests that, taken together, they may pose a substantial obstacle to achieving meaningful use. Therefore, we discussed several options in the proposed rule. One option was to provide a time-limited, 2-year payment adjustment exception for all EPs who meet the previous criteria. This approach would allow us to reconsider this issue in future rulemaking. Another option was to provide such an exception with no specific time limit. However, we noted that even under this less restrictive option, by statute no individual EP can receive an exception for more than 5 years. As discussed earlier, we believe the proliferation of both CEHRT and health information exchange will reduce the barriers faced by specialties with less CEHRT adoption over time as other providers may be providing the necessary data for these specialties to meet meaningful use. We particularly requested comment on how soon EPs who meet the previous criteria will reasonably be able to achieve meaningful use.

In the proposed rule, we encouraged comment on whether these criteria, or additional criteria not accounted for in the meaningful use exclusions, constitute a significant hardship to meeting meaningful use. We indicated that we that we would consider whether to adopt an exception based on these or similar criteria in the final rule, and, if so, whether such an exception should apply to individual EPs or across-the-board based on specialty or other groupings that generally meet the appropriate criteria.

Comment: Numerous commenters expressed support for including this exception. Some commenters agreed with CMS' assertion that all three barriers must be in place for this to be considered a significant hardship, while others maintained that any one of these barriers constitutes a significant hardship. Commenters from specific groups also presented arguments that they face one or more (up to all three) of the barriers presented in a sufficiently uniform way to have the exception apply across the board to their group.

Response: After reviewing the comments on this issue, we believe that the hardships presented are significant. Some EPs in the specialties that face all three barriers have already successfully attested to meaningful use. Thus, even when all three barriers are present, meaningful use may be difficult, but not impossible to achieve. In establishing the criteria for meaningful use itself, we have adopted exclusions and constructed the measures to lower the first two barriers as much as possible. For example, EPs with no office visits (that is, without direct patient contact) do not have to provide visit summaries, nor do they have to provider patient reminders. Due to both the allowances built into the meaningful use criteria and the fact at least a few EPs in nearly all specialties have attested to meaningful use, we do not believe that each barrier stands alone as a significant hardship. However, in considering the hardships and how they would be overcome there are significant differences between the first two and the latter (lack of control of CEHRT). Lack of face-to-face and need for follow up are both overcome through robust health information exchange. However, we do not believe that the existing availability health information exchange is sufficient to overcome these hardships. Therefore, we are finalizing an exception for those EPs who lack both face-to-face interactions with patients and those who lack the need to follow up with patients. An EP may apply for this exception only on the grounds that they meet both of these criteria (lack of face-to-face interactions and lack the to follow up with patients). We consider lack of face-to-face and need for follow-up care to be situations where the EP has no or nearly no face-to-face patient interactions or need for follow-up care. The EP would need to demonstrate either a complete lack of face-to-face interactions and follow-up or that cases of face-to-face interaction and follow-up are extremely rare and not part of normal scope of practice for that EP.

In reviewing the arguments presented for a group determination as well as considering common knowledge about the scope of practice of various specialties, we agree with commenters that the specialties of anesthesiology, radiology, and pathology lack face-to-face interactions and need to follow up with patients with sufficient frequency to warrant granting an exception to each EP with one of these primary specialties. We note that anesthesiologists do interact with patients, but not in a manner that is conducive to collecting the information needed for many aspects of meaningful use. As discussed previously, this exemption is subject to annual renewal. In future rulemaking we will consider whether the proliferation of health information exchange or any other developments are sufficient to remove lack of face-to-face interaction as a barrier, and whether the proliferation of CEHRT is sufficient to remove lack of control over the availability of CEHRT as a barrier. We will consider these issues in relation both to the exception itself and its application to the specialties of anesthesiology, radiology, and pathology. As such, physicians in these three specialties should not expect that this exception will continue indefinitely, nor should they expect that we will grant the exception for the full 5-year period permitted by statute. We will consider the extent to which these specialties continue to face these barriers in the Stage 3 rule and in other future rulemaking. We will also work to develop strategies to assist physicians who lack face-to-face interactions and the need to follow up with patients in demonstrating meaningful use. We may develop such strategies in the context of future rulemaking (for example, the Stage 3 rule) or in the form of additional guidance to physicians in these specialties. We also encourage all anesthesiologists, radiologists, and pathologists to continue to build out their ability to participate in health information exchange, adopt CEHRT and apply for the Medicare or Medicaid EHR incentives. Those seeking the Medicare EHR incentives can start through 2014, while those seeking the Medicaid EHR incentives can start through 2016.

As hospital-based anesthesiologists, radiologists, and pathologists are not eligible for the incentive and are thus exempted from the payment adjustment, the exception discussed in this section relates to these specialists in nonhospital settings.

With regard to the third barrier (lack of control over the availability of CEHRT at practice locations), we believe that in cases where an EP practices at multiple locations just this one barrier could be sufficient to constitute a significant hardship. In such cases, the EP would have to truly have no control over the availability of CEHRT. Control does not imply final decision-making authority. For example, we would

generally view EPs practicing in a large, corporate, group as having control over the availability of CEHRT, because they can influence the group's purchase of CEHRT, they may reassign their claims to the group, they may have a partnership/ownership stake in the group, or any payment adjustment would affect the group's earnings, and the entire impact would not be borne by the individual EP. These EPs can influence the availability of CEHRT and the group's earnings are directly affected by the payment adjustment. Thus, such EPs would not, as a general rule, be viewed as lacking control over the availability of CEHRT and would not be eligible for the hardship exception based solely on their membership in a group practice that has not adopted CEHRT.

On the other hand, there are EPs who practice at multiple locations who truly have little to no control over whether CEHRT is available at their locations. These might include, surgeons using ambulatory surgery centers or physicians treating patients in a nursing home. In these cases, the surgeon or physician likely would bear the entire impact of any payment adjustment—and such adjustment would not affect the earnings of the ambulatory surgery center or nursing home. In addition, because the surgeon or physician merely sees patients at the center or home, and does not have any other interest in the facility, we believe they would exert little to no influence over whether the nursing home, center, or other similar outpatient site adopts and implements CEHRT.

We note that we already have in place an eligibility requirement that allows for an EP to still qualify as a meaningful EHR user even if up to 49.9 percent of the EP's outpatient encounters are in locations that lack CEHRT. Thus, our exception would apply only in the case of EPs practicing in multiple locations where the lack of control (as discussed previously) exists for a majority (50 percent or more) of their outpatient encounters at such locations, causing such EPs to not be eligible to become meaningful EHR users. (In addition, we wish to make clear that we will not grant the exception to EPs that lack control in their practice locations but where those locations have adopted CEHRT would mean that the EP could become a meaningful EHR user.)

For the reasons discussed earlier, we have adopted a final regulation that allows an EP practicing at multiple locations to demonstrate that the EP was truly unable to control the availability of CEHRT at either one or a combination of locations that constitute more than 50 percent of their outpatient encounters. Inpatient hospital and emergency department encounters would not be included in either the numerator or the denominator for purposes determining whether the 50 percent threshold is met. This approach is consistent with the categories of encounters that are considered to be outpatient for purposes of determining hospital based status. (As noted previously, the locations cited by the EP for purposes of qualifying for this exception could not have CEHRT available—otherwise, we would view the EP as being potentially able to demonstrate meaningful use.)

After considering the public comments, we are finalizing an exception by adding a new § 495.102(d)(4)(iv) to the regulations. EPs whose primary specialty is listed in PECOS as anesthesiology, radiology or pathology 6 months prior to the first day of the year in which payment adjustments that would otherwise apply will be deemed to qualify for this exception, subject to the 5-year limit that applies to all exceptions under this paragraph.

Comment: Many commenters requested that these and other commenter proposed exceptions apply to other programs besides the Medicare EHR incentive program.

Response: This final rulemaking focuses on the EHR Incentive program, and we did not propose to make changes to other programs. We encourage interested parties to submit comments on proposed rules (if any) for those other programs.

Comment: Commenters suggested the following additional exceptions:

- All EPs over 60 or eligible for Social Security and for all practices with 5 or fewer physicians.
- EPs who make a good faith effort, but fail to reach the thresholds thereby making a distinction between those who make an effort and those who do not attempt to become meaningful EHR user.
- EP is not practicing for a significant period of time during the reporting period.
- EP working in a practice without CEHRT changes to a new practice that has CEHRT during the reporting period.

Response: We address each of these in turn. We agree that there is evidence that older EPs and those in smaller practices have been slower to adopt CEHRT.[6] [7] The HITECH Act even acknowledged the problems for smaller practices by creating assistance programs for EPs in individual or small practices in Title XIII, section 3012(c)(4) of the Act. However, based on attestation information submitted to us, EPs in both groups are successfully meeting meaningful use in significant numbers. Therefore, we do not believe that either an EP's age or practice size constitutes a significant hardship. In addition, we believe it would be problematic to exempt a category of EPs based on age or size of practice given that the intent of the payment adjustments and incentives is to ensure widespread modernization to electronic health records. We do not believe that these elements, in themselves, demonstrate that the EP experiences a ''significant hardship'' in becoming a meaningful EHR user.

The next exception suggested by commenters is for EPs who attempt to become a meaningful EHR user, but fail to do so. Because we have already adopted an exception for EPs who face circumstances beyond their control, the application of this suggested exception would necessarily be limited to EPs who face normal difficulties, rather than significant hardship, in becoming meaningful EHR users. Again, the statute requires demonstration of a significant hardship as the basis for an exception, and we do not believe that a good faith attempt, in and of itself, demonstrates the existence of a significant hardship exists sufficient to prevent the EP from becoming a meaningful EHR user. Furthermore, Congress set the benchmark for receiving full payment, without being subject to payment adjustment, on the achievement of meaningful use rather than on the attempt to achieve meaningful use. Therefore, we do not believe that EPs who attempt, but fail, to meet meaningful use and do not qualify for one of our other exceptions should be granted a significant hardship exception.

We also do not believe that it is appropriate to establish an exception for EPs not practicing for significant time periods during the EHR reporting period. First, we already proposed (and are finalizing) an exception for newly practicing EPs. Second, EPs who are not newly practicing, but only practice for part of the EHR reporting period should be able to report in the numerator and denominators simply the numbers that pertain to the time during which they

[6] Chun-Ju Hsiao, Sandra L. Decker, Esther Hing and Jane E. Sisk. Most Physicians Were Eligible For Federal Incentives In 2011, But Few Had EHR Systems That Met Meaningful Use Criteria, Health Affairs, 31, No. 5 (2012).

[7] Sandra L. Decker, Eric W. Jamoom and Jane E. Sisk. Physicians In Nonprimary Care And Small Practices And Those Age 55 And Older Lag In Adopting Electronic Health Records Systems, Health Affairs, 31, No. 5 (2012).

are practicing. For example, a measure based on number of patients seen or actions taken would include only those patients/actions during the time the EP is practicing during the applicable reporting period. We recognize that some meaningful use measures, such as drug-drug and drug-allergy interaction checks, require a functionality to be enabled for the entire EHR reporting period. In this case, the EP would have the functionality enabled for the period s/he is practicing.

The final exception suggested by commenters is for an EP working in a practice without CEHRT who changes to a new practice with CEHRT. Again, the commenters did not explain why such a circumstance, by itself, supports a significant hardship that prevents the EP from becoming a meaningful EHR user. Moreover, if the EP has never demonstrated meaningful use he or she should have an initial 90-day reporting period that allows the EP to demonstrate meaningful use in a shorter period. In addition, under current guidance, if the EP has more than 50 percent of their outpatient encounters at the new practice equipped with CEHRT then they would be able to exclude the old practice from their meaningful use measures.

After considering the public comments, we are not finalizing these exceptions recommended by the commenters. The following table summarizes the timeline for EPs to avoid the applicable payment adjustment by demonstrating meaningful use or qualifying for an exception from the application of the payment adjustment:

TABLE 13—TIMELINE FOR ELIGIBLE PROFESSIONALS (OTHER THAN HOSPITAL-BASED) TO AVOID PAYMENT ADJUSTMENT

EP payment adjustment year (calendar year)	Demonstrate MU during EHR reporting period 2 years prior to year of payment adjustment	or	For an EP demonstrating meaningful use for the first time in the year prior to the payment adjustment year, EHR reporting period is a continuous 90-day reporting period beginning no later than	or	Apply or otherwise qualify for an exception no later than
2015	CY 2013 (with submission no later than February 28, 2014).		July 3, 2014 (with submission no later than October 1, 2014).		July 1, 2014.
2016	CY 2014 (with submission no later than February 28, 2015).		July 3, 2015 (with submission no later than October 1, 2015).		July 1, 2015.
2017	CY 2015 (with submission no later than February 29, 2016).		July 3, 2016 (with submission no later than October 1, 2016).		July 1, 2016.
2018	CY 2016 (with submission no later than February 28, 2017).		July 3, 2017 (with submission no later than October 1, 2017).		July 1, 2017.
2019	CY 2017 with submission no later than February 28, 2018).		July 3, 2018 (with submission no later than October 1, 2018).		July 1, 2018.

Notes: (CY refers to the calendar year, January 1 through December 31 each year.)
The timelines for CY 2020 and subsequent calendar years will follow the same pattern.

TABLE 14—PERIOD HARDSHIP MUST BE SHOWN WITH APPLICATION DATE

Exception	Period of consideration for exception	Application for CY 2015 submitted no later than
Insufficient internet access	Demonstrate insufficient internet access for any continuous 90-day period from the start of the CY 2 years prior to the payment adjustment year to July 1 of the year prior to the payment adjustment year (For CY 2015—January 1, 2013–July 1, 2014).	July 1, 2014.
New EP	New EP granted an exception for the year they become an EP and the following year (For CY 2015, the EP would have to be new in either CY 2014 or CY 2015).	Guidance to be issued following publication of the final rule.
Extreme Circumstances outside of the EP's Control.	For an EP who has previously demonstrated meaningful use, the EP must demonstrate extreme circumstances that affect either of the CYs in the 2 years prior to the payment adjustment year. (For CY 2015–CY 2013). For EPs who have never demonstrated meaningful use, the EP must demonstrate extreme circumstances that affect the CY prior to the payment adjustment year. (For CY 2015–CY 2014).	July 1, 2014.
Lack of Face-Face/Telemedicine Patient Interactions and Lack of Need for Follow Up Care,.	The CY 2 years prior to the payment adjustment year (For CY 2015–CY 2013) through the application deadline..	For applications only: July 1, 2014.
Lack of Control Over Availability of CEHRT for EPs practicing in multiple locations.	For all EPs, if they are registered in PECOS with a primary specialty of anesthesiology, pathology or radiology 6 months prior to first day of the payment adjustment year they meet the exception. (For CY 2015—July 1, 2014)	

d. HPSA Bonus Technical Change

In this final rule we are also making a technical change to our regulations to correctly reflect our policy on EPs who predominantly furnish services in a geographic HPSA. This change is necessary to reflect the current policy that the 50 percent determination is based on the covered professional services provided during the payment year, in accordance with the preamble discussion in the Stage 1 final rule (75 FR 44444 through 44445). The current regulation erroneously uses the phrase ''the year prior to the payment year,'' which conflicts with our preamble discussion in both the proposed (75 FR 1908 through 1909) and final Stage 1 rules. We note that we are not changing the policy (already adopted) that the HPSA must be so designated by December 31 of the year prior to the payment year.

e. Payment Adjustment Not Applicable to Hospital-Based EPs

Section 1848(a)(7)(D) of the Act provides that no EHR payment adjustments otherwise applicable for CY 2015 and subsequent years ''may be made * * * in the case of a hospital-based eligible professional (as defined in subsection (o)(1)(C)(ii)) of the Act.'' We proposed that the same definition of hospital-based should apply during the incentive and payment adjustment phases of the Medicare EHR incentive program (that is, those eligible to receive incentives will also be subject to adjustments). Therefore, we proposed that our regulations at § 495.100 and § 495.102(d) would retain, during the payment adjustment phase of the EHR Incentive Program, the definition of hospital-based eligible professional at § 495.4. For purposes of the Medicare EHR incentive payment program, the determination of whether an EP is hospital-based is made on the basis of data from ''the Federal FY prior to the payment year.'' In the preamble to the Stage 1 final rule (75 FR 44442), we also stated that ''in order to provide information regarding the hospital-based status of each EP at the beginning of each payment year, we will need to use claims data from an earlier period. Therefore, we will use claims data from the prior fiscal year (October through September). Under this approach, the hospital-based status of each EP will be reassessed each year, using claims data from the fiscal year preceding the payment year. The hospital-based status will be available for viewing beginning in January of each payment year.''

We proposed to retain the concept established in the Stage 1 final rule (75 FR 44442) of making hospital-based determinations based upon a prior fiscal year of data. However, in the proposed rule we expressed concern about ensuring that EPs are aware of their hospital-based status in time to purchase EHR technology and meaningfully use it during the EHR reporting period that applies to a payment adjustment year. EPs who believe that they are not hospital based will have already either worked towards becoming meaningful EHR users or planned for the payment adjustment. EPs who believe that they will be determined hospital based may not have done so. EPs in these circumstances will need to know they are not hospital based in time to become a meaningful EHR user for a 90-day EHR reporting period in the year prior to the payment adjustment year. To use the example of the CY 2015 payment adjustment year, a determination based on FY 2013 data will allow an EP to know whether he or she is hospital-based by January 1, 2014. This timeline would give the EP approximately 6 months to begin the EHR reporting period, which could last from July through September of 2014. We stated in the proposed rule that we did not believe this to be sufficient time for the EP to implement CEHRT. Therefore, we proposed to base the hospital based determination for a payment adjustment year on determinations made 2 years prior. Again using CY 2015 payment adjustment year as an example, the determination would be available on January 1, 2013 based on FY 2012 data. This proposed determination date will give the EP up to 18 months to implement CEHRT and begin the EHR reporting period to avoid the CY 2015 payment adjustment. In the proposed rule, we asserted that this a reasonable time frame to accommodate a difficult situation for some EPs. However, we also are aware that there may be EPs who are determined nonhospital-based under this ''2-years prior'' policy when they will be determined hospital-based if we made the determination just 1-year prior. Again, using the example of the CY 2015 payment adjustment year, an EP determined nonhospital-based as of January 1, 2013 (using FY 2012 data) may be found to be hospital-based as of January 1, 2014 (using FY 2013 data). In this situation, we stated in the proposed rule that we did not believe the EP should be penalized for having been nonhospital-based as of January 1, 2013, especially if the EP has never demonstrated meaningful use, and the EP's first EHR reporting period will have fallen within CY 2014. Therefore, in the proposed rule we requested comments on expanding the hospital-based determination to encompass determinations made either 1 or 2 years prior. Under this alternative, if the EP were determined hospital based as of either one of those dates, then the EP would be exempt from the payment adjustments in the corresponding payment adjustment year. This would mean that for the CY 2015 payment adjustment year, an EP determined hospital based as of either January 1, 2013 (using FY 2012 data) or January 1, 2014 (using FY 2013 data) would not be subject to the payment adjustment. In all cases, we would need to know that the EP is considered hospital based in sufficient time for the payment adjustment year.

Comment: Commenters provided only general supportive comments on this proposal.

Response: We thank the commenters for the support. For the reasons stated in the proposed rule, we are finalizing a rule that will determine hospital based using either of the following fiscal year's data: (1) The fiscal year before the year that is 1 year prior to the payment adjustment year (for example, FY 2013 data for payment adjustment year 2015); or (2) the fiscal year before the year that is 2 years prior to the payment adjustment year (for example, FY 2012 data for payment adjustment year 2015). If the data from either year result in a hospital-based determination, then the EP would not be subject to the payment adjustments for the relevant year.

We discuss one aspect of determining hospital-based status, specifically the circumstances of EPs who fund the acquisition, implementation, and maintenance of their own CEHRT in a hospital-based setting, in section II.C.3. of the preamble to this final rule.

3. Incentive Market Basket Adjustment Effective in FY 2015 and Subsequent Years for Eligible Hospitals That Are Not Meaningful EHR Users for an Applicable Reporting Period

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 year, beginning in FY 2015. Specifically, section 1886(b)(3)(B)(ix)(I) of the Act provides that, ''for FY 2015 and each subsequent FY,'' 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 will apply to ''three-quarters of the percentage increase otherwise applicable.'' The reduction to three-quarters of the applicable update for an eligible hospital that is not a meaningful EHR user will be ''33⅓ percent for FY 2015, 66⅔ 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 is required to reduce the percentage increases otherwise applicable by 25 percent (33⅓ percent of 75 percent) in 2015, 50 percent (66⅔ 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 such ''reduction shall apply only with respect to the FY involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase * * * for a subsequent FY.''

TABLE 15—PERCENTAGE DECREASE IN APPLICABLE HOSPITAL PERCENTAGE INCREASE FOR HOSPITALS THAT ARE NOT MEANINGFUL EHR USERS

	2015	2016	2017+
Hospital payment update is subject to EHR payment reduction	25%	50%	75%

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 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 provides that such determinations are subject to annual renewal, and that in no case may a hospital be granted such an exemption for more than 5 years.

Finally section 1886(b)(3)(B)(ix)(III) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides that, for FY 2015 and each subsequent FY, a state in which hospitals are paid for services under section 1814(b)(3) of the Act shall adjust the payments to each eligible hospital in the state that is not a meaningful EHR user in a manner that is designed to result in an aggregate reduction in payments to hospitals in the state that is equivalent to the aggregate reduction that will have occurred if payments had been reduced to each eligible hospital in the state in a manner comparable to the reduction in section 1886(b)(3)(B)(ix)(I) of the Act. This section also requires that the state shall report to the Secretary the method it will use to make the required payment adjustment. (At present, section 1814(b)(3) of the Act applies to the State of Maryland.) As we discussed in the Stage 1 final rule establishing the EHR incentive program (75 FR 44448), for purposes of determining whether hospitals are eligible for receiving EHR incentive payments, we employ the CMS Certification Number (CCN). We also proposed to use CCNs to identify hospitals for purposes of determining whether the reduction to the percentage increase otherwise applicable for FY 2015 and subsequent years applies. (In other words, whether a hospital was a meaningful EHR user for the applicable EHR reporting period will be dependent on the CCN for the hospital.) We noted the results of this policy for certain cases in which hospitals change ownership, merge, or otherwise reorganize and the applicable CCN changes. In cases where a single hospital changes ownership, we determine whether to retain the previous CCN or to assign a new CCN depending upon whether the new owner accepts assignment of the provider's prior participation agreement. Where a change of ownership has occurred, and a new CCN is assigned due to the new owner's decision not to accept assignment of the prior provider agreement, we proposed not to recognize a meaningful use determination that was established under the prior CCN for purposes of determining whether the payment adjustment applies. Where the new owner accepts the prior provider agreement and is assigned the same CCN, we proposed to continue to recognize the demonstration of meaningful use under that CCN. The same policy was proposed for merging hospitals that use a single CCN. For example, if hospital A is not a meaningful EHR user (for the applicable reporting period), and it absorbs hospital B, which was a meaningful EHR user, then the entire hospital will be subject to a payment adjustment if hospital A's CCN is the surviving identifier. The converse is true as well—if it were hospital B's CCN that survived, the entire merged hospital will not be subject to a payment adjustment. (The guidelines for determining CCN assignment in the case of merged hospitals are described in the State Operations Manual, sections 2779Aff. *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html*) We advised hospitals that are changing ownership, merging, or otherwise reorganizing to take this policy into account.

Comments received on the treatment of CCNs and new hospitals are addressed in the context of discussing our exception for new hospitals later in this section.

a. Applicable Market Basket Adjustment for Eligible Hospitals Who Are Not Meaningful EHR Users for FY 2015 and Subsequent FYs

In the stage 1 final rule on the Medicare and Medicaid Electronic Health Record Incentive Payment Programs, we revised § 412.64 of the regulations to provide for an adjustment to the applicable percentage increase update to the IPPS payment rate for those eligible hospitals that are not meaningful EHR users for the EHR reporting period for a payment year, beginning in FY 2015. Specifically, § 412.64(d)(3) now provides that—

• Beginning in fiscal year 2015, in the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR) user as defined in part 495, three-fourths of the applicable percentage change specified in paragraph (d)(1) is reduced—

++ For fiscal year 2015, by 33⅓ percent;

++ For fiscal year 2016, by 66⅔ percent; and

++ For fiscal year 2017 and subsequent fiscal years, by 100 percent.

In order to conform with this new update reduction, as required in section 4102(b)(1)(A) of the HITECH Act, we also revised § 412.64(d)(2)(C) of our regulations to provide that, beginning with FY 2015, the reduction to the IPPS applicable percentage increase for failure to submit data on quality measures to the Secretary shall be one-quarter of the applicable percentage increase, rather than the 2 percentage point reduction that applies for FYs 2007 through 2014 in § 412.64(d)(2)(B). The effect of this revision is that the combined reductions to the applicable percentage increase for meaningful EHR use and quality data reporting will not produce an update of less than zero for a hospital in a given FY as long as the hospital applicable percentage increase remains a positive number.

We did not propose any changes to the establishment of the payment adjustment amounts. We did propose the applicable EHR reporting period, for purposes of determining whether a hospital is subject to the applicable percentage increase adjustment for FY 2015 and subsequent FYs, as a prior EHR reporting period (as defined in § 495.4 of the regulations). We also proposed an amendment to § 412.64(d) to provide for the hardship and other exceptions we discuss later, as well as the application of the applicable percentage increase adjustment in FY 2015 and subsequent FYs to a state operating under a payment waiver provided by section 1814(b)(3) of the Act. We discuss these proposals and the

comments relating to them in the following sections of this preamble.

b. EHR Reporting Period for Determining Whether a Hospital Is Subject to the Market Basket Adjustment for FY 2015 and Subsequent FYs

Section 1886(b)(3)(B)(ix)(IV) of the Act makes clear that the Secretary has discretion to ''specify'' as the EHR reporting period ''any period (or periods)'' that will apply ''with respect to a fiscal year.'' Thus, as in the case of designating the EHR reporting period for purposes of the EP payment adjustment, the statute governing the applicable percentage increase adjustment for hospitals that are not meaningful users of EHR technology neither requires that such reporting period fall within the year of the payment adjustment, nor precludes the reporting period from falling within the year of the payment adjustment.

As in the case of EPs, we sought to avoid creating a situation in which it might be necessary to make large payment adjustments, either to lower or to increase payments to a hospital, after a determination is made about whether the applicable percentage increase adjustment should apply. We stated in the proposed rule that we believe that this consideration remains compelling in the case of hospitals, despite the fact that the IPPS for acute care hospitals provides, unlike the case of EPs, a mechanism to make appropriate changes to hospital payments for a payment year through the cost reporting process. Despite the availability of the cost reporting process as a mechanism for correcting over- and underpayments made during a payment year, we seek to avoid wherever possible circumstances under which it may be necessary to make large adjustments to the rate-based payments that hospitals receive under the IPPS. Since the EHR payment adjustment in FYs 2015 and subsequent years is an adjustment to the applicable percentage increase used in determining prospective payments, we believe that it is far preferable to determine whether the adjustment applies on the basis of an EHR reporting period before the payment period, rather than to make the adjustment (where necessary) in a settlement process after the payment period on the basis of a determination concerning whether the hospital was a meaningful user during the payment period.

Therefore, we proposed, for purposes of determining whether the relevant applicable percentage increase adjustment applies to hospitals who are not meaningful users of EHR technology in FY 2015 and subsequent years, that we would establish EHR reporting periods that begin and end prior to the year of the payment adjustment. Furthermore, we proposed that the EHR reporting periods for purposes of such determinations would be far enough in advance of the payment year that we have sufficient time to implement the system edits necessary to apply any required applicable percentage increase adjustment correctly, and that hospitals will know in advance of the payment year whether or not they are subject to the applicable percentage increase adjustment. Specifically, we proposed the following rules establishing the appropriate reporting periods for purposes of determining whether hospitals are subject to the applicable percentage increase adjustment in FY 2015 and subsequent years (parallel to the rules that we proposed previously for determining whether EPs are subject to the payment adjustments in CY 2015 and subsequent years):

- Except as provided in second bulleted paragraph for eligible hospitals that become meaningful users for the first time in 2014, we proposed that the EHR reporting period for the FY 2015 applicable percentage increase adjustment will be the same EHR reporting period that applies in order to receive the incentive for FY 2013. For hospitals this will generally be the full fiscal year of 2013 (unless FY 2013 is the first year of demonstrating meaningful use, in which case a 90-day EHR reporting period will apply). Under our proposed policy, a hospital that receives an incentive for FY 2013 would be exempt from the payment adjustment in FY 2015. A hospital that received an incentive for FYs 2011 or 2012 (or both), but that failed to demonstrate meaningful use for FY 2013 will be subject to a payment adjustment in FY 2015. (As all of these years will be for Stage 1 of meaningful use, we do not believe that it is necessary to create a special process to accommodate providers that miss the 2013 year for meaningful use). For each year subsequent to FY 2015, the EHR reporting period payment adjustment will continue to be the FY 2 years before the payment adjustment period, subject again to the special provision for new meaningful users of CEHRT.
- We proposed an exception for those hospitals that have never successfully attested to meaningful use prior to FY 2014. For these hospitals, as it is their first year of demonstrating meaningful use, we proposed to allow a continuous 90-day reporting period that begins in 2014 and that ends at least 3 months prior to the end of FY 2014. In addition, the hospital would have to actually successfully register for and attest to meaningful use no later than the date that occurs 3 months before the end of the year. For hospitals, this means specifically that the latest day the hospital must successfully register for the incentive program and attest to meaningful use, and thereby avoid application of the adjustment in FY 2015, is July 1, 2014. Thus, the hospital's EHR reporting period must begin no later than April 2, 2014 (allowing the hospital a 90-day EHR reporting period, followed by 1 extra day to successfully submit the attestation and any other information necessary to earn an incentive payment). In the proposed rule we used the date April 3, 2014 which would only allow an 89-day period through June 30, 2014. The correct date is April 2, 2014 to allow September 30, 2014 to be the last day of the 90-day EHR reporting period with the extra day (Oct 1, 2014) to attest. This policy would continue to apply in subsequent years. If a hospital is demonstrating meaningful use for the first time for the fiscal year immediately before the applicable percentage increase adjustment year, then the reporting period will be a continuous 90-day period that begins in such prior fiscal year and ends at least 3 months before the end of such year. In addition, all attestation, registration, and any other details necessary to determine whether the hospital is subject to a applicable percentage increase adjustment for the upcoming year will need to be completed by July 1. (As we discuss later, exception requests will be due by the April 1 before the beginning of the payment adjustment fiscal year.)

In conjunction with adopting these rules for establishing the EHR Reporting Period for determining whether a hospital is subject to the applicable percentage increase adjustment for FY 2015 and subsequent FYs, we proposed to revise § 412.64(d)(3) of our regulations to insert the phrase ''for the applicable EHR reporting period,'' so that it is clear that the EHR reporting period will not fall within the year of the market basket adjustment.

We stated our belief that these proposed EHR reporting periods provide adequate time both for the systems changes that will be required for CMS to apply any applicable percentage increase adjustments in FY 2015 and subsequent years, and for hospitals to be informed in advance of the payment year whether any adjustment(s) will apply. They also provide appropriate flexibility by allowing more recent adopters of EHR technology a

reasonable opportunity to establish their meaningful use of the technology and to avoid application of the payment adjustments.

Comment: As with the comments on the EHR reporting period for EPs, many commenters made the same assertion that an EHR reporting period aligned with the payment adjustment year would be more consistent with the Congressional intent and the language of the statute. Some commenters contended that the statutory language requires the reporting period and payment adjustment year to coincide.

Response: We believe our response to this comment in the context of the EP payment adjustments applies equally to his eligible hospital comment. The language in section 1886(b)(3)(B)(ix)(I) of the Act is substantially similar to the language in section 1848(a)(7) of the Act. As in the case of EPs, Congress provided the Secretary with flexibility to determine the EHR reporting period applicable to the payment adjustment year. Section 1886(b)(3)(B)(ix)(IV) of the Act specifically provides that ''term 'EHR reporting period' means, with respect to a fiscal year, any period (or periods) specified by the Secretary.'' In addition, because the payment adjustment will be used to reduce the applicable percent increase that is used in the prospective ratesetting for hospitals, it is reasonable to conclude that this Secretarial flexibility was granted precisely because Congress understood that the Department needed to have final determinations on meaningful use prior to the fiscal year that is the payment adjustment year. As we have previously noted, other payment adjustment programs, such as the e-prescribing program, and the physician quality reporting system, also use a prior reporting period. Thus, it is consistent for us to adopt a prior reporting period for the EHR program as well.

Comment: Commenters made the same comments as they did for EPs (relating to insufficient vendor capacity; the practical deadline having passed for adopting and implementing CEHRT, especially for popular vendors; and the issues surrounding upgrading current clients to 2014 CEHRT). As with EPs, the options presented by commenters all involved a reconciliation process, in this case, using the cost reporting process.

Response: The issue of upgrading to 2014 CEHRT is addressed by ONC in their final rule published elsewhere in this issue of the **Federal Register**. We appreciate the concerns of vendor capacity raised by the commenters. We discuss this situation and the reasons we are not revising our timetables in our previous discussion of the parallel policy for EPs. In the hospital context, the commenters correctly point out the existence of a payment reconciliation method, the hospital cost report, that it unavailable within the payment systems for EPs. We have carefully considered whether it is feasible to adopt a later reporting period (perhaps even the payment year itself) as the basis for determining whether eligible hospitals are subject to the EHR payment adjustment, and then to employ the cost reporting process to correct over and under payments in regards to the payment adjustments, as a number of commenters recommended. As a matter of course in the rate setting system, the basic rates and applicable percentage increase updates are fixed in advance and are not matters that are taken into account in the settlement of final payment amounts under the cost report reconciliation process. As the payment adjustment directly affects this rate we believe that it would not be possible to employ a cost report settlement process, but that claims would have to be reprocessed.

It is true, as several commenters pointed out, that several components of the IPPS, including DSH and IME payments, are settled in the cost reporting process on the basis of final data (for example, bed days, resident FTEs) from the payment year. However, changes in other aspects of the payment system, such as outlier payments, cannot reconciled within the cost reporting process, but require reprocessing of claims. Application of the EHR payment adjustment changes the standardized amount upon which IPPS payments are based. Any change in the standardized amount applicable to a hospital changes the number of outlier payments the hospital would receive, and the amount of those payments. If we were to base final determination of whether the EHR payment adjustment should apply on meaningful use status during the payment year, it would be necessary to increase the standardized amount for some hospitals, that is, those that were assumed not to meet meaningful use requirements for purposes of making interim payments, but that subsequently established meaningful use during the payment year. Conversely, it would be necessary to decrease the standardized amount for those hospitals that had been assumed to meet meaningful use requirements for purposes of making interim payments, but that subsequently failed to meet those requirements during the payment year. In both cases, mass reprocessing of payments would be necessary in order to adjust outlier payments. Generally, hospitals whose standardized amounts are decreased at the time of final payment determination (due to application of a payment adjustment that was not applied to interim payments) would generally receive greater outlier payments. Conversely, hospitals whose standardized amounts are increased at the time of final payment determination (due to application of the full update that was not applied to interim payments) would generally receive lower outlier payments. (Reprocessing would also be necessary for new technology add-on payments, although the claims volume and dollar amounts involved in such reprocessing would be significantly lower.) Such reprocessing imposes significant costs on both the eligible hospital and CMS. As in the case of EPs, then, we continue to believe that the timeline we proposed is the most realistic approach to making payment adjustment determinations in an effective manner.

Therefore, we are finalizing the proposed EHR reporting period for determining whether an eligible hospital is subject to the payment adjustment for CY 2015 and subsequent calendar years as proposed.

c. Exception to the Application of the Market Basket Adjustment to Hospitals in FY 2015 and Subsequent FYs

As mentioned previously, 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 provides that such determinations are subject to annual renewal, and that in no case may a hospital be granted such an exception for more than 5 years.

We proposed to add a new § 412.64(d)(4), specifying the circumstances under which we will exempt a hospital from the application of the applicable percentage increase adjustment for a fiscal year. To be considered for an exception, a hospital must submit an application demonstrating that it meets one more of the exception criteria.

As noted previously, the statute does not mandate the circumstances under which an exception must be granted,

but (as in the case of a similar exception provided under the statute for EPs) it does state that the exception may be granted when ''requiring such hospital to be a meaningful EHR user during such fiscal year will result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access.'' Therefore, we proposed to provide in new § 412.64(d)(4) that the Secretary may grant an exception to a hospital that is located in an area without sufficient Internet access. Furthermore, while the statute specifically states that such an exception may be granted to hospitals in ''a rural area without sufficient Internet access,'' it does not require that such an exception be restricted only to rural areas without such access. While we believe that a lack of sufficient Internet access will rarely be an issue in an urban or suburban area, we do not believe that it is necessary to preclude the possibility that, in very rare and exceptional cases, a nonrural area may also lack sufficient Internet access to make complying with meaningful use requirements a significant hardship for a hospital. Therefore, we proposed that the Secretary may grant such an exception to a hospital in any area without sufficient Internet access.

Because exceptions on the basis of insufficient Internet connectivity must intrinsically be considered on a case-by-case basis, we proposed to require hospitals to demonstrate insufficient Internet connectivity to qualify for the exception through an application process. The rationale for this exception is that lack of sufficient Internet connectivity renders compliance with the meaningful EHR use requirements a hardship particularly those objectives requiring Internet connectivity, summary of care documents, electronic prescribing, making health information available online, and submission of public health information. Therefore, we proposed that such an application must demonstrate insufficient Internet connectivity to comply with the meaningful use objectives listed previously and insurmountable barriers to obtaining such Internet connectivity such as high cost to build out Internet to their facility. As with EPs, the hardship would be demonstrated for period that is 2-years prior to the payment adjustment year (for example, FY 2013 for the payment adjustment in FY 2015). As with EPs, we will require applications to be submitted 6 months before the beginning of the payment adjustment year (that is, by April 1 before the FY to which the adjustment will apply) in order to provide sufficient time for a determination to be made and for the hospital to be notified about whether an exception has been granted. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to hospitals who have received an exception for a specific FY. (Please also see our previous discussion of the parallel exception for EPs, with respect to encouraging providers to file these applications as early as possible, and the likelihood that there will not be an opportunity to subsequently demonstrate meaningful use if hospitals file close to or at the application deadline of April 1.)

Comment: Commenters provided universal support for this proposed exception. However, some commenters raised concern about the situation of hospitals that might have Internet access in the 2-years prior, but lose it in the next year.

Response: We are finalizing this exception as proposed with one modification. We appreciate the commenters' concern about hospitals that might have sufficient Internet access in the 2 years prior to the adjustment period, but lose it in next year. We believe this is even less likely for hospitals than EPs, but as there is no downside to extending the time, we are finalizing a modification of our proposal to allow for the demonstration of insufficient Internet access for any 90-day period between the start of the year 2 years prior to the payment adjustment year through the application submission date of April 1 of the year prior to the payment adjustment year.

For the same reasons we proposed an exception for new EPs, we proposed an exception for a new hospital for a limited period of time after it has begun services. We proposed to allow new hospitals an exception for at least 1 full year cost reporting period after they accept their first patient. For example, a hospital that accepted its first patient in March of 2015, but with a cost reporting period from July 1 through June 30, would receive an exception from payment adjustment for FY 2015, as well as for FY 2016. However, the new hospital would be required to demonstrate meaningful use within the 9 months of FY 2016 (register and attest by July 1, 2016) to avoid being subject to the payment adjustment in FY 2017.

In proposing such an exception for new hospitals, however, we wanted to ensure that the exception would not be available to hospitals that have already been in operation in one form or another, perhaps under a different owner or merely in a different location, and thus have in fact had an opportunity to demonstrate meaningful use of EHR technology. Therefore, for purposes of qualifying for this exception, we proposed that the following hospitals would not be considered new hospitals under the exception:

- A hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.
- A hospital that closes and subsequently reopens.
- A hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years.
- A hospital that changes its status from a CAH to a hospital that is subject to the Medicare hospital in patient prospective payment systems.

It is important to note that we proposed to consider a hospital that changes its status from a hospital (other than a CAH) that is excluded from the Medicare hospital inpatient prospective payment system (IPPS) to a hospital that is subject to the IPPS to be a new hospital for purposes of qualifying for the proposed exception. These IPPS-exempt hospitals, such as long-term care hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, children's hospitals, and cancer hospitals, are excluded from the definition of ''eligible hospital'' for purposes of the Medicare EHR Incentive Program and have not necessarily had an opportunity to demonstrate meaningful use. On the other hand, CAHs are eligible for incentive payments and subject to payment adjustments. Under the guidelines for assigning CCNs to Medicare providers, a CAH that changes status to an IPPS hospital will necessarily receive a new CCN. This is because several digits of the CCN encode the provider's status (for example, IPPS, CAH) under the Medicare program, However, we proposed to allow the CAH to register its meaningful use designation obtained under its previous CCN in order to avoid being subject to the hospital payment adjustment. It is worth noting that we adapted the proposed definition of ''new hospital'' for these purposes from similar rules that have been employed in the capital prospective payment system in § 412.300(b) of our regulations. We invited comment concerning the appropriateness of adapting these rules to the exception under the EHR program, and about whether modifications or other

revisions to these rules will be appropriate in the EHR context.

Comment: Several commenters recommended that the new hospitals exception for at least 1 full year cost reporting period be triggered not when the hospital accepts its first patient, but rather when it accepts its first Medicare covered patient. These commenters point out that there can be significant lapse between the time when a hospital accepts its first patient and the time when it accepts its first Medicare covered patient. Because the EHR payment adjustment applies to the Medicare payments, the commenters argued it is more appropriate to base the beginning of the new hospital exception on the admission of its first Medicare covered patient.

Response: We agree with the commenters and are revising the new hospital exception in this final rule to run for at least one full year cost reporting period after the hospital accepts its first Medicare-covered patient. This change renders our third criterion (a hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years) for not considering a hospital new moot as the exception is now based on the admission of the first Medicare-covered patient, which we believe is sufficiently analogous to starting participation in the Medicare program to allow us to remove this criterion.

Comment: Some commenters argued that a hospital that undergoes a change of ownership and has a new CCN assigned due to the new owner's decision not to accept the assignment of the prior provider agreement should be allowed to register its meaningful use designation for the old CCN in the same manner a CAH that becomes an inpatient PPS hospital would.

Response: When a hospital has a new CCN assigned due to the new owner's decision not to accept the assignment of the prior provider agreement it is not considered a change of ownership. Rather the hospital is terminated from the Medicare program and then reapplies for a new CCN. We disagree with the commenters that the history of the old CCN should carry forward in this case. In cases where a new owner decides not to accept the previous provider agreement and a new CCN is assigned by CMS, the new owner is in effect, making a conscious decision to create a rupture with significant, and relevant, aspects of the hospital's history. Specifically, when a new owner acquires a Medicare participating hospital, CMS automatically assigns the provider agreement to the new owner. The new owner must then decide whether to accept or reject assignment of the existing agreement. If the new owner accepts assignment, the provider agreement remains intact and the owner retains all the benefits and liabilities of that agreement (as provided under 42 CFR 489.18 of the regulations). If the new owner rejects assignment, the owner has voluntarily terminated the previous provider agreement, the CCN of the hospital is terminated, and the owner is not responsible for Medicare liabilities (known or unknown), as well as eligibility for Medicare payment. Under these circumstances, where the new owner has made a conscious decision to terminate the previous provider agreement, we believe it is appropriate not to recognize the meaningful use designation obtained under that provider agreement and CCN. We have consistently reminded new owners of hospitals that they cannot obtain the benefits of a decision not to accept assignment of the provider agreement without accepting the burdens of the decision as well. Unlike the case of a CAH that becomes an inpatient PPS hospital, the assignment of a new CCN follows from a voluntary decision of the new owner not to retain the previous provider agreement and CCN.

We believe a similar result should apply in other cases where acquisitions and/or combinations of hospitals lead to the discontinuation of a CCN under which meaningful use had been demonstrated. For example, in some cases there is a combination of two or more certified hospitals under one agreement and one CCN. If the combined hospital has multiple locations, one location becomes the ''main location,'' and all other locations become remote and/or provider based. The hospital is considered ''one hospital'' by Medicare and must be truly integrated at all levels, including its system for maintaining medical records. Where the new owner rejects the assignment of the provider agreement for one or more of the facilities that are being combined into the integrated hospital, known and unknown Medicare liabilities of those facilities do not transfer to the new owner. Under these circumstances, for the same reasons discussed in the previous case, it is appropriate not to recognize the meaningful use designation that was obtained under the provider agreement(s) and CCN(s) that have not been retained under the integrated hospital.

Even where the new owners retain the acquired hospital's Medicare provider agreement, the acquired hospital's agreement is subsumed (although not terminated) into the single provider agreement of the combined hospital, and the acquired hospital's CCN is retired (again, not terminated). The new owners are responsible for all known and unknown Medicare liabilities of previous owners of the hospital, and there is no break in Medicare payments, as is the case where assignment of the prior provider agreement is rejected. However, as noted previously, in these cases, if the combined hospital has multiple locations, one location becomes the ''main location,'' and all other locations become remote and/or provider based. The hospital is considered ''one hospital'' by Medicare and must be truly integrated at all levels. In these cases it is most appropriate to recognize the prior meaningful use status of the surviving CCN of the main location for purposes of determining whether the payment penalty applies to the newly integrated hospital. In that way, the meaningful use determination will be based on the prior status of the major portion of the newly integrated hospital. Otherwise, the meaningful use designation of a relatively minor remote and/or provider-based hospital may become the basis for the designation of a much larger combined and integrated hospital. Therefore, we are finalizing our proposed policy, in cases of various ownership changes, acquisitions, and combinations of hospitals, to employ the meaningful use status of the surviving CCN to determine whether the payment adjustment applies.

Finally, we proposed an additional exception in this final rule for extreme circumstances that make it impossible for a hospital to demonstrate meaningful use requirements through no fault of its own during the reporting period. Such circumstances might include: A hospital closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we believe that it is appropriate to require hospitals to qualify for the exception through an application process.

Comment: Commenters stated universal support for this exception. However many commenters requested various circumstances be added to the list of example circumstances. This list is very similar, but not entirely identical to that for EPs. These examples dealt primarily with concerns related to vendors of CEHRT. Specifically, commenters were concerned about vendors of CEHRT not maintaining their

certification status, ability to meet implementation schedules, and ability to find a vendor of CEHRT willing to work with them. In addition, commenters suggested that the provider facing severe financial distress, such as bankruptcy or restructuring of debt should be included as an example.

Response: We used the same evaluation criteria we used for EPs and came to the same conclusion to add two examples to the list that was proposed: (1) A hospital whose CEHRT (complete or modular) loses its certification either through revocation or because the vendor did not upgrade their CEHRT to the latest requirements; and (2) a hospital suffering severe financial distress resulting in a bankruptcy or restructuring of debt.

We will require applications to be submitted no later than April 1 of the year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the hospital to be notified about whether an exception has been granted prior to the payment adjustment year. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to hospitals who have received an exception for a specific payment adjustment year. As discussed earlier, in relation to EPs, in order for a hospital to apply for this exception, extreme circumstances would need to exist for the period in which the hospital would otherwise demonstrate meaningful use (that is, the EHR reporting period). We have modified our regulation to be clear that the circumstances must exist during the EHR reporting period (that is, 2 years prior to the payment adjustment year or, for hospitals that have never attested to meaningful use before, in the year immediately prior to the payment adjustment year).

Comment: Commenters suggested the following additional exceptions:

- Hospitals who make a good faith effort to purchase CEHRT, but could not find a vendor willing to work with them.
- Hospitals that determine they must switch EHR vendors to achieve meaningful use.
- Hospitals unable to meet meaningful use requirements because of failures on the part of EHR vendors.

Response: For the first suggested exception, we do not believe that hospitals that attempt to purchase CEHRT but cannot find a vendor would warrant an exception. The mere failure of an attempt to purchase CEHRT does not demonstrate that the hospital faces hardship significant enough to prevent it from becoming a meaningful EHR user. We also believe it would be problematic to define the parameters for determining that no vendor was willing to work with a hospital. Moreover, we already have provided for an exception for hospitals that face extreme circumstances beyond their control. Under this exception, eligible hospitals could attempt to show that their situation is extreme and out of the ordinary and that failure to obtain CEHRT was truly beyond their control. We are skeptical that such showings could be made when all the hospital has done is to make an attempt to purchase CEHRT. However, this exception provides hospitals with the opportunity to demonstrate that their failure of attempts to obtain CEHRT was due to circumstances beyond their control.

The next two exceptions may fall under the exception for extreme circumstances beyond the hospital's control, but the hospital would need to demonstrate that it meets this extreme exception. Any determination would be highly dependent on individual circumstances and evaluation of whether it is truly necessary to switch vendors, whether the switching vendors would prevent the hospital from reaching meaningful use, and whether the ''failures'' of the EHR vendor are both outside the norm of EHR implementation and beyond the control of the hospital.

Table 16 summarizes the timeline for hospitals to avoid the applicable payment adjustment by demonstrating meaningful use or qualifying for an exception from the application of the adjustment.

TABLE 16—TIMELINE FOR ELIGIBLE HOSPITALS TO AVOID PAYMENT ADJUSTMENT

Hospital payment adjustment year (fiscal year)	Demonstrate MU during EHR reporting period 2 years prior to year of payment adjustment	Or	For an eligible hospital demonstrating meaningful use for the first time in the year prior to the payment adjustment year use a continuous 90-day reporting period beginning no later than:	Or	Apply for an exception no later than:
2015	FY 2013 (with submission no later than November 30, 2013).		April 2, 2014 (with submission no later than July 1, 2014).		April 1, 2014.
2016	FY 2014 (with submission no later than November 30, 2014).		April 2, 2015 (with submission no later than July 1, 2015).		April 1, 2015.
2017	FY 2015 (with submission no later than November 30, 2015).		April 2, 2016 (with submission no later than July 1, 2016).		April 1, 2016.
2018	FY 2016 (with submission no later than November 30, 2016).		April 2, 2017 (with submission no later than July 1, 2017).		April 1, 2017.
2019	FY 2017 (with submission no later than November 30, 2017).		April 2, 2018 (with submission no later than July 1, 2014).		April 1, 2018.

Notes: (FY refers to the Federal fiscal year: October 1 to September 30. For example, FY 2015 is October 1, 2014 through September 30, 2015.)

The timelines for FY 2020 and subsequent fiscal years follow the same pattern.

TABLE 17—PERIOD HARDSHIP MUST BE SHOWN WITH APPLICATION DATE

Exception	Period of consideration for exception	Submit application for FY 2015 no later than
Insufficient Internet access	Demonstrate insufficient Internet access for any 90 days from the start of the FY 2 years prior to the payment adjustment year to April 1 of the year prior to the payment adjustment year (For FY 2015–October 1, 2012–April 1, 2014).	April 1, 2014.

TABLE 17—PERIOD HARDSHIP MUST BE SHOWN WITH APPLICATION DATE—Continued

Exception	Period of consideration for exception	Submit application for FY 2015 no later than
New hospital	New hospital granted an exception for one full cost reporting period after they admit their first Medicare patient.	Guidance to be issued following publication of the final rule.
Extreme Circumstances outside of the hospital's Control.	For a hospital that has previously demonstrated meaningful use, the hospital must demonstrate extreme circumstances that affect the FY 2 years prior to the payment adjustment year. (For FY 2015–FY 2013). For a hospital that has never demonstrated meaningful use, the hospital must demonstrate extreme circumstances that affect the FY prior to the payment adjustment year. (For FY 2015–FY 2014).	April 1, 2014.

d. Application of Market Basket Adjustment in FY 2015 and Subsequent FYs to a State Operating Under a Payment Waiver Provided by Section 1814(b)(3) of the Act

As discussed previously, the statute requires payment adjustments for eligible hospitals in states where hospitals are paid under section 1814(b)(3) of the Act. The statute also requires such adjustments to be designed to result in an aggregate reduction in payments equivalent to the aggregate reduction that would have occurred if payments had been reduced under section 1886(b)(3)(B)(ix)(I) of the Act. We proposed that an aggregate reduction in payments would mean the same dollar amount in reduced Medicare payments that that would have occurred if payments had been reduced to each eligible hospital in the state in a manner comparable to the reduction under § 412.64(d)(3).

To implement this provision, we proposed a new § 412.64(d)(5) that includes this statutory requirement and that required states operating under a payment waiver under section 1814(b)(3) of the Act to provide to the Secretary, no later than January 1, 2013, a report on the method that it proposes to employ in order to make the requisite payment adjustment.

We did not receive any comments on this proposal; and therefore, we are finalizing these provisions as proposed.

4. Reduction of Reasonable Cost Reimbursement in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users

Section 4102(b)(2) of the HITECH Act amends section 1814(l) of the Act to include an adjustment to a CAH's Medicare reimbursement for inpatient services if the CAH has not met the meaningful EHR user definition for an EHR reporting period. The adjustment will be made for a cost reporting period that begins in FY 2015, FY 2016, FY 2017, and each subsequent FY thereafter. Specifically, sections 1814(l)(4)(A) and (B) of the Act now provide that, if a CAH has not demonstrated meaningful use of CEHRT for an applicable reporting period, then for a cost reporting period that begins in FY 2015, its reimbursement will be reduced from 101 percent of its reasonable costs to 100.66 percent. For a cost reporting period beginning in FY 2016, its reimbursement will be reduced to 100.33 percent of its reasonable costs. For a cost reporting period beginning in FY 2017 and each subsequent FY, its reimbursement will be reduced to 100 percent of reasonable costs.

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 an exception under this provision for more than 5 years.

a. Applicable Reduction of Reasonable Cost Payment Reduction in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users

In the Stage 1 final rule (75 FR 44564), we finalized the regulations regarding the CAH adjustment at § 495.106(e) and § 413.70(a)(6).

b. EHR Reporting Period for Determining Whether a CAH Is Subject to the Applicable Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years

For CAHs we proposed an EHR reporting period that is aligned with the payment adjustment year. For example, if a CAH is not a meaningful EHR user in FY 2015, then its Medicare reimbursement will be reduced to 100.66 percent for its cost reporting period that begins in FY 2015. This differs from what was proposed for eligible hospitals: an EHR reporting period prior to the payment adjustment year. We stated in the proposed rule that we believed the Medicare cost report process would allow us to make the CAH reduction for the cost reporting period that begins in the payment adjustment year, with minimal disruptions to the CAH's cash flow and minimal administrative burden on the Medicare contractors as discussed later.

CAHs are required to file an annual Medicare cost report that is typically for a consecutive 12-month period. The cost report reflects the inpatient statistical and financial data that forms the basis of the CAH's Medicare reimbursement. Interim Medicare payments may be made to the CAH during the cost reporting period based on the previous year's data. Cost reports are filed with the CAH's Medicare contractor after the close of the cost reporting period and the data on the cost report are subject to reconciliation and a settlement process prior to a final Medicare payment being made.

We proposed to amend the definition of the EHR reporting period that will apply for purposes of payment adjustments under § 495.4. For CAHs this will be the full Federal fiscal year that is the same as the payment adjustment year (unless a CAH is in its first year of demonstrating meaningful use, in which case a continuous 90-day reporting period within the payment adjustment year will apply). The adjustment would then apply based upon the cost reporting period that begins in the payment adjustment year (that is, FY 2015 and thereafter). Thus, if a CAH is not a meaningful user for FY 2015, and thereafter, then the adjustment would be applied to the CAH's reasonable costs incurred in a cost reporting period that begins in that affected FY as described in § 413.70(a)(6)(i).

We proposed to require CAHs to submit their attestations on meaningful use by November 30th of the following FY. For example, if a CAH is attesting that it was a meaningful EHR user for FY 2015, the attestation must be submitted no later than November 30, 2015. Such an attestation (or lack

thereof) will then affect interim payments to the CAH made after December 1st of the applicable FY. If the cost reporting period ends prior to December 1st of the applicable FY then any applicable payment adjustment will be made through the cost report settlement process.

All comments received on this provision were in support. We thank commenters for their support and finalize as proposed for the reasons outlined in the proposed rule.

c. Exception to the Application of Reasonable Cost Payment Reductions to CAHs in FY 2015 and Subsequent FYs

As discussed previously, CAHs may receive exceptions from the payment adjustments for significant hardship. While our current regulations, in § 413.70(a)(6)(ii) and (iii) contain this hardship provision we proposed revising these regulations to align them with the exceptions being proposed for EPs and subsection (d) hospitals. As with EPs and subsection (d) hospitals we proposed that CAHs could apply for an exception on the basis of lack of sufficient Internet connectivity. Applications will be required to demonstrate insufficient Internet connectivity to comply with the meaningful use objectives requiring internet connectivity (that is, summary of care documents, electronic prescribing, making health information available online, and submission of public health information) and insurmountable barriers to obtaining such internet connectivity. As CAHs will have an EHR reporting period aligned with the payment adjustment year, we proposed that the insufficient Internet connectivity will need to be demonstrated for each applicable payment adjustment year. For example, as proposed, to avoid a payment adjustment for cost reporting periods that begin during FY 2015, the hardship would need to be demonstrated for FY 2015. For each year subsequent to FY 2015, the basis for an exception would continue to be for the hardship in the FY in which the affected cost reporting period begins. As stated in § 413.70(a)(6)(iii), any exception granted may not exceed 5 years. After 5 years, the exception will expire and the appropriate adjustment will apply if the CAH has not become a meaningful EHR user for the appropriate EHR reporting period.

Comment: Commenters have suggested that it is inappropriate to base the Internet connectivity exception on the same year that a CAH is expected to demonstrate meaningful use. They assert that it is impractical for a CAH to achieve sufficient internet connectivity and meet meaningful use all in 1 year. A few commenters recommended a 2-year prospective exception for Internet connectivity as used for the EPs and inpatient PPS hospitals.

Response: We agree with commenters that established sufficient Internet connectivity and meaningful use in the same year is not feasible. However, since the payment adjustment year is aligned with the CAH's EHR period, we believe that using a 2-year lookback period similar to EPs and eligible hospitals is inappropriate for CAHs. Therefore, we will base the insufficient internet access exception on the cost reporting period that begins prior to or during the payment adjustment year. For FY 2015, the CAH must submit the application by November 30, 2015, but eligibility for this exception would be based on the information for any 90-day period within the cost reporting period that begins prior to or during the payment adjustment year.

After consideration of the comments, we are revising this exception to base it on any 90-day period within the cost reporting period that begins prior to or during the payment adjustment year.

As with new EPs and new eligible hospitals, we proposed an exception for a new CAH for a limited period of time after it has begun services. We proposed to allow an exception for 1 year after they accept their first patient. For example, a CAH that is established in FY 2015 would be exempt from the penalty through its cost reporting period ending at least 1 year after the CAH accepts its first patient. If the CAH is established March 15, 2015 and its first cost reporting period is less than 12 months (for example, from March 15 through June 30, 2015), the exception would exist for both the short cost reporting period and the following 12-month cost reporting period lasting from July 1, 2015 through June 30, 2016. However, the new CAH would be required to submit its attestation that it was a meaningful EHR user for FY 2016 no later than November 30, 2016, in order to avoid being subject to the payment adjustment for the cost reporting period that begins in FY 2016 (in the previous example from July 1, 2016 through June 30, 2017).

We stated in the proposed rule that in proposing such an exception for newly established CAHs, it is important to ensure that the exception is not available to CAHs that have already been in operation in one form or another, perhaps under a different ownership or merely in a different location, and thus have in fact had an opportunity to demonstrate meaningful use of EHR technology. Therefore, we proposed that for the purposes of qualifying for this exception, a new CAH means a CAH that has operated (under previous or present ownership) for less than 1 year.

We stated in the proposed rule that in some cases an eligible hospital may convert to a CAH. An eligible hospital is a subsection (d) hospital that is a meaningful user and is paid under the inpatient hospital prospective payment systems as described in subpart A of Part 412 of the regulations. In these cases, eligible hospitals were able to qualify for purposes of the EHR hospital incentive payments by establishing meaningful use, and (as discussed previously) are also subject to a payment adjustment provision in FY 2015 and subsequent years if they fail to demonstrate meaningful use of EHR technology during an applicable reporting period. Therefore, we proposed not to treat a CAH that has converted from an eligible hospital as a newly established CAH for the purposes of this exception.

On the other hand, we stated in the proposed rule that other types of hospitals such as long-term care hospitals, psychiatric hospitals, and inpatient rehabilitation facilities are not subsection (d) hospitals. These other types of hospitals do not meet the definition of an ''eligible hospital'' for purposes of the Medicare EHR hospital incentive payments and the application of the proposed hospital market basket adjustment in FY 2015 and subsequent years under section 1886(n)(6)(B) of the Act. In some instances, a CAH may be converted from one of these types of hospitals. In that case, the CAH would not have had an opportunity to demonstrate meaningful use, and it is therefore appropriate to treat them as newly established CAHs if they convert from one of these other types of hospitals to a CAH for purposes of determining whether they should qualify for an exception from the application of the adjustment in FY 2015 and subsequent years. Thus, we proposed to consider a CAH that converts from one of these other types of hospitals to be a newly established CAH for the purposes of qualifying for this proposed exception from the application of the adjustment in FY 2015 and subsequent years.

In summary, we proposed for purposes of qualifying for the exception to revise § 413.70(a)(6)(ii) to state that a newly established CAH means a CAH that has operated (under previous or present ownership) for less than 1 year. We also proposed to revise § 413.70(a)(6)(ii) to state that the

following CAHs are not newly established CAHs for purposes of this exception:

- A CAH that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.
- A CAH that closes and subsequently reopens.
- A CAH that has been in operation for more than 1 year but has participated in the Medicare program for less than 1 year.
- A CAH that has been converted from an eligible subsection (d) hospital.

Comment: Identical to the concerns raised for subsection (d) hospitals, several comments stated that the new CAH exception for at least 1 full year cost reporting period be triggered not by when the hospital accepts its first patient, but rather when it accepts its first Medicare-covered patient.

Response: We agree with the commenters and revise the exception for new CAHs to be for at least 1 full year cost reporting period after they accept their first Medicare-covered patient. This change renders our third criteria (a CAH that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years) for not considering a CAH new moot as the exception is now based on the admission of the first Medicare-covered patient, which we believe is sufficiently analogous to starting participation in the Medicare program to allow us to remove this criteria.

After consideration of comments, we are revising this exception to base it on the point when the CAH accepts their first Medicare patient.

Finally, we proposed an additional exception in this final rule for extreme circumstances that make it impossible for a CAH to demonstrate meaningful use requirements through no fault of its own during the reporting period. Such circumstances might include: A CAH is closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we believe that it is appropriate to require CAHs to qualify for the exception through an application process.

Comment: Commenters supported this exception in principle. However, many commenters requested various circumstances be added to the list of example circumstances. This list is nearly entirely identical to that for EPs and subsection (d) hospitals as described earlier.

Response: We used the same evaluation criteria we used for EPs and came to the same conclusion to add two examples. First, a CAH whose CEHRT (complete or modular) loses its certification either through revocation or because the vendor did not upgrade their CEHRT to the latest requirements; and second, a CAH suffering severe financial distress resulting in a bankruptcy or restructuring of debt

As described previously, we are finalizing the policy to align a CAH's payment adjustment year with the applicable EHR reporting period. A CAH must submit their meaningful use attestation for a specific EHR reporting period no later than 60 days after the close of the EHR reporting period (no later than November 30th of the year) otherwise the payment penalty could be applied to the CAH's cost reporting period that begins in that payment adjustment year. We proposed to require a CAH to submit an application for an exception, as described previously, to its Medicare contractor by the same November 30th date that the meaningful use attestation is due. Therefore, we proposed that a CAH will be subject to the payment adjustment if it has not submitted its meaningful use attestation (or its attestation has been denied) and has not submitted an application for an exception by November 30th of the subsequent EHR reporting period. If a CAH's request for an exception is not granted by the Medicare contractor then we proposed that the payment adjustment will be applied. We stated in the proposed rule that if a CAH anticipates submitting an exception application we recommend that the CAH communicate with its Medicare contractor to determine the necessary supporting documentation to submit by the November 30th due date.

After consideration of public comments, we are finalizing these application deadlines exception as proposed.

Table 18, summarizes the timeline for CAHs to avoid the applicable payment adjustment by demonstrating meaningful use or qualifying for an exception from the application of the adjustment.

Comment: Commenters provided the same suggestions for additional exceptions for CAHs that they did for eligible hospitals.

Response: As we stated in our response to similar comments submitted for eligible hospitals these additional exceptions could have been suggested as examples for the exception for extreme circumstances. We encourage hospitals in these situations to utilize the extreme circumstances exception. We believe these exceptions are too subjective to be finalized as new exceptions as suggested by commenters.

TABLE 18—TIMELINE FOR CAHS TO AVOID PAYMENT ADJUSTMENT

CAH with cost reporting period beginning during payment adjustment year	Demonstrate MU for EHR reporting period	Or	For a CAH demonstrating MU for the first time, a continuous 90-day reporting period ending no later than	Or	Apply for an exception no later than
FY 2015	FY 2015 (with submission no later than November 30, 2015).		September 30, 2015 (with submission no later than November 30, 2015).		November 30, 2015.
FY 2016	FY 2016 (with submission no later than November 30, 2016).		September 30, 2016 (with submission no later than November 30, 2016).		November 30, 2016.
FY 2017	FY 2017 (with submission no later than November 30, 2017).		September 30, 2017 (with submission no later than November 30, 2017).		November 30, 2017.
FY 2018	FY 2018 (with submission no later than November 30, 2018).		September 30, 2018 (with submission no later than November 30, 2018).		November 30, 2018.
FY 2019	FY 2019 (with submission no later than November 30, 2019).		September 30, 2019 (with submission no later than November 30, 2019).		November 30, 2019.

Notes: (FY refers to the Federal fiscal year October 1 to September 30. For example, FY 2015 is October 1, 2014 to September 30, 2015.) The timelines for FY 2020 and subsequent fiscal years follow the same pattern.

TABLE 19—PERIOD HARDSHIP MUST BE SHOWN WITH APPLICATION DATE FOR CAHS

Exception	Period of consideration for exception	Submit application for FY 2015 no later than
Insufficient Internet access—CAHs	Demonstrate insufficient internet access for any 90 day period within the cost reporting period that begins prior to or during the payment adjustment year.	Nov 30, 2015.
New CAHI	New CAH granted an exception for one full cost reporting period after they admit their first Medicare patient.	Guidance to be issued following publication of the final rule.
Extreme Circumstances outside of the CAH's Control.	Oct 1 through Sept 30 of the payment adjustment year	Nov 30, 2015.

5. Administrative Review Process of Certain Electronic Health Record Incentive Program Determinations

In the Stage 2 proposed rule we proposed an administrative appeals process would apply to both Stage 1 and Stage 2 of meaningful use. We also posted guidance on the CMS Web site, *http://www.cms.gov/qualitymeasures/05_ehrincentiveprogramappeals.asp*, in the interim between the publication of this proposed rule and the publication of the final rule. We sought public comments both on the guidance and the proposed rule.

We proposed to limit permissible appeals to the following three types of appeals:

- Eligibility Appeals
- Meaningful Use Appeals
- Incentive Payment Appeals

We also proposed certain filing and other deadlines for such administrative appeals. We refer readers to our proposed rule at (77 FR 13779 through 13780) for a full explanation of these proposals.

We received several comments on our appeals proposals, which are discussed in this section of the preamble. However, after review of the public comments and the appeals filed as of the writing of this final rule, we believe the administrative review process is primarily procedural and does not need to be specified in regulation. The appeals process we proposed essentially constituted an agency reconsideration of certain types of determinations regarding eligibility for the program, meaningful use, or incentive payment amounts. We believe such an informal reconsideration process may be included in procedural guidance, rather than in our regulations. Therefore, our administrative appeals process will be included on our Web site at *www.cms.gov/EHRIncentivePrograms*.

We recognize that there is a procedural appeals process currently in effect, and in all cases, we will require that requests for appeals, all filings, and all supporting documentation and data be submitted through a mechanism and in a manner specified by us. We expect all providers to exhaust this administrative review process prior to seeking review in Federal Court.

As we stated in the proposed rule, we also note that the HITECH Act prohibits both administrative and judicial review of the standards and method used to determine eligibility and payment (including those governing meaningful use) (see 42 CFR 413.70(a)(7), 495.106(f), 495.110, 495.212). Our limited appeal process would not provide administrative review of these areas; but rather would involve cases of individual applicability; that is, where a provider is challenging not the standards and methods themselves, but whether the provider met the regulatory standards and methods promulgated by CMS in its rules.

While we are not finalizing regulations on appeals, we respond to comments we received on our proposals.

Comment: Several commenters requested CMS make more explicit information available to providers on the documentation that should be available in the event of an audit.

Response: In the event of an audit, at a minimum, providers should have available electronic or paper documentation that supports providers' completion of the Attestation Module responses, including the specific information that supports each measure. In addition, providers should have documentation to support the submission of CQMs, including the specific information that supports each measure. Providers should also maintain documentation to support their incentive payment calculations, for example data to support amounts included on their cost report, which are used in the calculation. As indicated in the Stage 1 final rule, providers should keep documentation for at least 6 years following the date of attestation.

Comment: A commenter noted that states may need to change their audit procedures or State Medicaid Health Information Technology (HIT) Plans (SMHPs) regarding audit and appeals by CMS for demonstrating meaningful use.

Response: We proposed that states would have an option to have CMS audit and conduct appeals of eligible hospitals' meaningful use. We finalize that proposal in our Medicaid regulations at § 495.332. We agree that SMHPs regarding audit and appeals may need revising. We are working closely with states to align principles regarding both audit and appeals process for both the Medicare and Medicaid EHR Incentive Programs. We intend to give states both technical support and program information to ensure consistency in the application of those audit and appeals principles.

Comment: A number of commenters asked for the addition of appeal categories beyond those we proposed. Several commenters requested CMS implement an appeals process for penalties and hardship exemptions. One commenter requested more comprehensive language to better define the requirements and circumstances under which appeals may be heard and acted upon. Another commenter requested CMS institute an appeals process relating to MACs' decisions regarding reasonable costs and determining incentive payments for CAHs.

Response: We appreciate the number of commenters that requested additional appeal categories. Since the writing and publication of the Stage 1 final rule, we have had the opportunity to review a number of appeals, and we note that many of these appeals do not necessarily fit easily into the categories we proposed. Based on the comments we received and the information we have regarding appeals that have already been filed, we are concerned that finalizing the categories we proposed for appeals could negatively impact providers and potentially add unnecessary burden and complexity. We are also concerned that specifying these categories could limit the flexibility we might otherwise have in addressing new or unanticipated appeal categories in the future, or in adding greater detail regarding the scope and requirements of particular types of

appeals. For example, a number of the appeals we have received are related neither to eligibility, meaningful use, or incentive payments directly, but instead address registration or attestation system changes that we are currently in the process of implementing for providers' benefit. Because of these concerns, we decline to finalize the categories of appeals as proposed and intend to issue guidance regarding types or categories of appeals and accompanying requirements on our Web site at *www.cms.gov/EHRIncentivePrograms*.

As stated earlier, the HITECH Act prohibits both administrative and judicial review of the standards and methods used to determine eligibility and payment (including those governing meaningful use) (see 42 CFR 413.70(a)(7), 495.106(f), 495.110, 495.212). Any procedures would not allow administrative appeals of these issues. As for reasonable costs reported by CAHs, we already stated in the Stage 1 final rule that a CAH ''may appeal the statistical and financial amounts from the Medicare cost report used to determine the CAH incentive payment,'' but that the CAH ''would utilize the current provider appeal process pursuant to section 1878 of the Act.'' (75 FR 44464)

Finally, we note that there will not be appeal reconsiderations of hardship exception or payment adjustment determinations. As specified in section II.D.2.c. of this final rule, the granting of a hardship exception will be through an application process, and we expect providers to make a full declaration of all relevant information at the time of filing of that application. We are concerned that there would not be adequate time to process hardship exception applications, render determinations, and also process appeals of those redeterminations. Therefore, we decline to allow appeal reconsiderations of hardship exception determinations. We note that the HITECH Act prohibits both administrative and judicial review of the standards and methods used to determine payment adjustments, including hardship exceptions to those payment adjustments.

Comment: A number of commenters noted concerns regarding the timelines proposed for filing appeals and forwarding documentation.

Response: We appreciate the many comments regarding the proposed timelines for appeals. However, we are not finalizing our appeal regulations in this final rule. We intend to issue guidance regarding timelines for types or categories of appeals on our Web site at *www.cms.gov/EHRIncentivePrograms*.

E. Medicare Advantage Organization Incentive Payments

1. Definitions (§ 495.200)

We proposed to add definitions of the terms ''Adverse eligibility determination,'' ''Adverse payment determination'' and ''MA payment adjustment year.'' We also proposed to add a definition for the term ''Potentially qualifying MA–EPs and potentially qualifying MA-affiliated eligible hospitals,'' to cross reference the existing definition at § 495.202(a)(4).

We proposed to clarify the application of ''hospital-based EP'' as that term is used in paragraph 5 of the definition of ''qualifying MA–EP'' in § 495.200, to make clear that the calculation is not based on FFS-covered professional services, but rather on MA plan enrollees. Otherwise, qualifying MA–EPs who provide at least 80 percent of their covered professional services to MA plan enrollees of a qualifying MA organization might be considered ''hospital based'' solely on the basis of 90 percent of their FFS-covered professional services being provided in a hospital setting. We provided an example of a qualifying MA–EP that might bill FFS 10 times over a year for emergency room services provided to various Medicare patients. Although the vast majority of the MA–EP's covered services were reimbursed under his or her arrangement with a qualifying MA organization, 100 percent (or 10) of the MA–EP's FFS-covered services would have been for hospital-based services, which would prohibit the MA organization from receiving reimbursement under the MA EHR incentive program for the MA–EP. We do not believe that we should exclude MA–EPs from the MA EHR Incentive Program due to only a few FFS claims. Therefore, we are clarifying the definition of ''qualifying MA–EP'' to state that for purposes of the MA EHR Incentive Program, a hospital-based MA–EP provides 90 percent or more of his or her covered professional services in a hospital setting to MA plan enrollees of the qualifying MA organization.

We did not receive any comments on these provisions and we are finalizing them as proposed with the exception of the definitions of the terms ''Adverse eligibility determination,'' and ''Adverse payment determination.'' As we explain later in this preamble discussion, we do not believe formal regulations for an informal reconsideration procedural rule are necessary and therefore, we are not finalizing these two definitions in our regulations.

2. Identification of Qualifying MA Organizations, MA–EPs, and MA-Affiliated Eligible Hospitals (§ 495.202)

We proposed a technical change to § 495.202(b)(1) to require that the qualifying MA organization identify those MA–EPs and MA-affiliated eligible hospitals that the qualifying MA organization believes would be meaningful users of CEHRT during the reporting period, when a qualifying MA organization intends to claim an incentive payment for a given qualifying MA–EP or MA-affiliated eligible hospital.

We also proposed an amendment to § 495.202(b)(2) to reflect current policy that qualifying MA organizations must report the CMS Certification Number (CCN) for qualifying MA-affiliated eligible hospitals. We explained that as the program matures, it is necessary to report this detail to effectively administer the program. We are adopting this change in this final rule (§ 495.202(b)(2)).

We proposed a new § 495.202(b)(3) to establish a reporting requirement to identify qualifying MA–EPs who have furnished more than 50 percent of their covered Medicare professional services to MA enrollees of the qualifying MA organization in a designated geographic Health Professional Shortage Area (HPSA) during the reporting period. We also proposed to redesignate the current § 495.202(b)(3) as (b)(4), and revised the introductory language in (b)(2) to reflect this redesignation.

We also proposed to require MA organizations to identify qualifying MA–EPs or MA-affiliated eligible hospitals within 2 months of the close of the payment year (rather than within 60 days) (previously § 495.202(b)(3), now newly redesignated § 495.202(b)(4)). We explained that this change would be consistent with the Medicare FFS EHR Incentive Program, but in nonleap years this would reduce the time for reporting revenue amounts to CMS for qualifying MA–EPs from 60 days to 59 days. We proposed conforming amendments to § 495.204(b)(2) and § 495.210(b) and (c).

We also explained that because the redesignated § 495.202(b)(4) relates to both the payment phase and the payment adjustment phase of the program, we are adding the word ''qualifying'' to the text of the regulation. Therefore, we explained, this regulation applies to both qualifying MA–EPs and MA-affiliated eligible hospitals (both payment and payment adjustment phases of the program) and

potentially qualifying MA–EPs and MA-affiliated eligible hospitals (only the payment adjustment phase of the program).

We proposed to redesignate the current § 495.202(b)(4) as § 495.202(b)(5), and to require a qualifying MA organization to identify the MA–EPs and MA-affiliated eligible hospitals that it believes would be both ''qualifying'' and ''potentially qualifying.'' To calculate the payment adjustment, we explained that we will need to know how many qualifying MA–EPs and MA-affiliated eligible hospitals are, and are not, meaningful users. We also proposed to correct a cross-reference.

We did not receive any comments on these provisions and we are finalizing them as proposed.

3. Incentive Payments to Qualifying MA Organizations for Qualifying MA–EPs and Qualifying MA-Affiliated Eligible Hospitals (§ 495.204)

a. Amount Payable to a Qualifying MA Organization for Its Qualifying MA–EPs

In § 495.204(b), we proposed to clarify that methods relating to overhead costs may be submitted for MA–EPs regardless of whether the MA–EPs are salaried or paid in another fashion, such as on a capitated basis.

As stated previously, we also proposed to require MA organizations, to submit revenue amounts relating to their qualifying MA–EPs within 2 months of the close of the payment year, (rather than within 60 days).

b. Increase in Incentive Payment for MA–EPs Who Predominantly Furnish Services in a Geographic Health Professional Shortage Area (HPSA)

In a new § 495.204(e) (we proposed to redesignate the current paragraph (e) as paragraph (f)), we proposed to add a provision clarifying the currently existing policy governing whether a qualifying MA organization is entitled to a HPSA increase for a given qualifying MA–EP. We explained that section 1848(o)(1)(B)(iv) of the Act, which is currently in effect, and as applied to the MA program, provides a 10-percent increase in the maximum incentive payment available for MA–EPs that predominantly furnish covered professional services during the MA EHR payment year in a geographic HPSA. We explained that consistent with the Medicare FFS EHR Incentive Program, we interpreted the term ''predominantly'' to mean more than 50 percent. For the MA EHR Incentive Program, we proposed to determine eligibility for the geographic HPSA increase on whether the qualifying MA–EP predominantly provided services to MA plan enrollees of the qualifying MA organization in a HPSA during the applicable MA EHR payment year.

Further, we explained that it is worth noting that an MA organization does not automatically receive a HPSA bonus merely because its qualifying MA–EPs predominantly served a geographic HPSA. We stated that in order for the MA organization to receive the 10 percent increase, the MA–EP needs to provide at least 10 percent or more of Medicare Part B covered professional services to MA plan enrollees of the qualifying MA organization. In other words, to qualify for the HPSA bonus an MA–EP needs to provide more than $24,000 of Medicare Part B covered professional services to MA plan enrollees of the qualifying MA organization. The MA–EP needs to provide up to $26,400 in covered services to earn the maximum HPSA-enhanced bonus of $19,800 if the first payment year is 2011 or 2012. Thus, for MA–EPs who predominantly furnish services in a geographic HPSA, the ''incentive payment limit'' in § 495.102(b) would be $19,800, instead of $18,000, if the first MA EHR payment year for the MA organization with respect to the MA–EP is 2011 or 2012. If an MA organization could show that an MA–EP predominantly served beneficiaries in a HPSA during the payment year and that that MA–EP provided, for example, for the 2011 payment year, at least $26,400 in Part B professional services to MA plan enrollees of the MA organization during the payment year, we stated that the MA organization could receive the entire $19,800 incentive payment for that MA–EP. If the MA–EP provided less than $26,400 in Part B professional services, the potential incentive payment for that MA–EP for that MA organization would be less than $19,800 for the payment year. We proposed a conforming amendment in § 495.202(b)(2)(ii) to require MA organizations to notify CMS whether the qualifying MA–EP predominantly provided covered services to MA plan enrollees in a HPSA.

We added a new paragraph (5) to redesignated paragraph (f). This new paragraph (5) clarifies that we would recoup the EHR incentive payment if one of the following entities fails to comply with an audit request to produce documents or data needed to audit the validity of an EHR incentive payment:—(1) A qualifying MA–EP, (2) an entity that employs a qualifying MA–EP (or in which a qualifying MA–EP had a partnership interest), (3) an MA-affiliated eligible hospital, or (4) any other party contracting with the qualifying MA organization. We explained that we already have the authority to do this under the current § 495.204(e)(4), (to be redesignated as (f)(4)); however, we proposed to amend the regulations to specifically address what would happen in the case of a failure to produce documents or data related to an audit request.

We added a new paragraph (g) to § 495.204 to clarify the current policy that in the unlikely event we paid a qualifying MA organization for a qualifying MA–EP, and it was later determined that the MA–EP—(1) was entitled to a full incentive payment under the Medicare FFS EHR Incentive Program; or (2) had received payment under the Medicaid EHR Incentive Program, we would recover the funds paid to the qualifying MA organization for such an MA–EP from the MA organization. (We stated that the former case would be in the unlikely event an MA–EP appeared to have earned an EHR incentive of less than the full amount under FFS, and then later was determined to have earned the full amount under FFS. In accordance with duplicate payment avoidance provisions in section 1853(l)(3)(B) of the Act and implementing regulations at § 495.208, we would recover the MA EHR incentive payment since a full FFS EHR payment was due.) If the organization still had an MA contract, we would recoup the amount from the MA organization's monthly payment under section 1853(a)(1)(A) of the Act. If the organization no longer had an MA contract, we would recoup any amounts through other means, such as formal collection. We stated that since duplicate and overpayments are prohibited by statute (sections 1853(l)(3)(B), 1853(m)(3)(B), and 1903(t)(2) of the Act), we believe that this policy must apply to all years of the program, beginning with payment year 2011. Thus, we would recover overpaid MA EHR incentive payments for all MA EHR payment years, including payment year 2011.

We also clarified that, in accordance with statutory requirements, if it is determined that an MA organization received an incentive payment for an MA-affiliated eligible hospital that also received a payment under the Medicare FFS EHR Incentive program or that otherwise should not have received such payment, we would similarly recover the funds paid to the qualifying MA organization for such MA-affiliated eligible hospital from either the MA organization's monthly payment under section 1853(a)(1)(A) of the Act, from

the MA-affiliated eligible hospital's CMS payment through the typical process for recouping Medicare funds from a ''subsection (d)'' hospital, or through other means such as a collection process, as necessary. As with EPs, as the statute prohibits us from making duplicate and overpayments, we explained that this policy does not constitute a new rule and must apply to all years of the program, beginning with payment year 2011.

We did not receive any comments on these provisions and are finalizing them as proposed.

4. Avoiding Duplicate Payments

We stated that qualifying MA–EPs are eligible for the Medicare FFS EHR incentive payment if they meet certain requirements under that program. However, we also stated that an EHR incentive payment is only allowed from one program. We believe that the requirement that MA organizations notify MA–EPs that the MA organization intended to claim them for the MA EHR Incentive Program would minimize misunderstandings among MA–EPs (particularly if they expected to receive an incentive payment under the Medicare FFS Incentive Program). We stated that it was important for MA–EPs to understand certain aspects of the program such as when a qualifying MA organization claimed an MA–EP under the MA EHR Incentive Program and the MA–EP was not entitled to a full FFS EHR Incentive payment, the MA organization claim would prevent a partial payment under the Medicare FFS EHR Incentive Program from being paid directly to the MA–EP.

We proposed to require each qualifying MA organization to attest that it notified the MA–EPs it intends to claim. We proposed to require that this attestation be submitted along with the MA organization's meaningful use attestation for the MA EHR payment year for which the MA organization is seeking payment.

Therefore, we proposed to revise § 495.208 by adding—(1) a new paragraph (a) that requires a qualifying MA organization to notify MA–EPs when the MA organization intends to claim them for the MA EHR Incentive Program prior to making its attestation of meaningful use to CMS; (2) a new paragraph (b) that requires a qualifying MA organization to notify MA–EPs when it is claiming them, that the MA–EPs may still receive an incentive payment under the Medicare FFS or Medicaid EHR Incentive Program, if certain requirements are met; and (3) a new paragraph (c) that requires a qualifying MA organization to attest to CMS that these notification requirements have been satisfied by the MA organization. We also proposed to redesignate the current paragraphs (a) through (c) of § 495.208 as (d) through (f), respectively.

As discussed previously, in § 495.210, we proposed to change the requirement that MA organizations attest to meaningful use within 60 days after the close of the MA EHR payment year for both MA–EPs and MA-affiliated eligible hospitals, to a requirement to do so within 2 months in order to provide consistency between the Medicare FFS and MA EHR Incentive Programs.

Comment: A commenter requested that CMS confirm that MA organization reporting to CMS under HEDIS, HOS, and CAHPS will continue to apply for purposes of the MA EHR Incentive Payment Program during Stage 2. The commenter questioned if MA organizations, for both qualifying MA–EPs and MA-affiliated eligible hospitals, will be permitted to continue to submit HEDIS, HOS, and CAHPS data in lieu of CQMs during Stage 2.

Response: We are confirming that during Stage 2 and subsequent stages of MA EHR Program implementation, we will continue to require qualifying MA organizations to successfully report HEDIS, HOS, and CAHPS measures in lieu of CQMs for purposes of meaningful use reporting for qualifying MA–EPs and MA-affiliated eligible hospitals.

After review of the public comments received, we are finalizing these provisions as proposed.

5. Payment Adjustments Effective for 2015 and Subsequent MA Payment Adjustment Years (§ 495.211)

In the proposed rule we explained that beginning in 2015, the law provides for adjustments to monthly MA payments under sections 1853(l)(4) and 1853(m)(4) of the Act if a qualifying MA organization's potentially qualifying MA–EPs or MA-affiliated eligible hospitals (or both) are not meaningful users of certified EHR technology. We proposed to add a definition of ''MA Payment Adjustment Year'' to the definitions in § 495.200. The definition was needed in part because the payment adjustment phase of the MA EHR program continued indefinitely—beyond the last year for which MA EHR incentive payments could be made to qualifying MA organizations. Additionally, since we proposed to operationalize MA EHR payment adjustments in a different manner than under the FFS Medicare program, we believed a definition was warranted.

We proposed that an MA organization would have to had at least initiated participation in the incentive payment phase of the program from 2011 through 2014 for MA–EPs or through 2015 for MA-affiliated eligible hospitals, to have its Part C payment under section 1853(a)(1)(A) of the Act adjusted during the payment adjustment phase of the program, and would have to continue to qualify for participation in the program as a ''qualifying MA organization'' as defined for purposes of this program. The imposition of a payment adjustment is also conditioned on the qualifying MA organization having potentially qualifying MA–EPs and MA-affiliated eligible hospitals for the respective payment adjustment years. We took this approach because we believed that it would be impossible to verify that a given MA organization is, in fact, a qualifying MA organization with potentially qualifying MA–EPs and MA-affiliated eligible hospitals, unless the MA organization had first demonstrated that it met these requirements through receipt of MA EHR incentive payments for at least one of the MA EHR payment years as defined for purposes of this program. We noted that although MA EHR payment years for both MA–EPs and MA-affiliated eligible hospitals could theoretically continue through 2016, the last first MA EHR payment year for which an MA organization could receive an EHR incentive payment is 2014 for MA–EPs, and 2015 for MA-affiliated hospitals.

Furthermore, we believe that payment adjustments under section 1853 of the Act would have limited applicability in the MA EHR Incentive Program because the HITECH Act limited the type of organization that would qualify as a ''qualifying MA organization'' for purposes of the MA EHR Incentive Program in both phases of the program (the phase of the program during which we make incentive payments, and the phase of the program when we adjust payments under sections 1853(l)(4) and 1853(m)(4) of the Act). We stated that section 1853(l)(5) of the Act limits which MA organizations may participate by defining the term ''qualifying MA organization.'' We explained that a ''qualifying MA organization'' must be organized as a health maintenance organization (HMO), as defined in section 2791(b)(3) of the Public Health Service (PHS) Act (42 U.S.C. 1395w–23(l)(5)). The PHS Act further defines an HMO as a ''federally qualified HMO, an organization recognized under state law as an HMO, or a similar organization regulated under state law for solvency in the same

manner and to the same extent as such an HMO.'' (See 42 U.S.C. 300gg–91). We explained that an MA organization participating in Medicare Part C might not be a federally qualified HMO, nor an organization recognized under state law as an HMO, nor a similar organization regulated under state law for solvency in the same manner and to the same extent as such an HMO. We noted that organizations that do not meet the PHS definition of ''HMO'' may not receive an incentive payment, nor would they be eligible to have their Part C payment adjusted for having potentially qualifying MA–EPs or MA-affiliated eligible hospitals that do not successfully demonstrate meaningful use of certified EHR technology.

Secondly, section 1853(l)(2) of the Act requires that MA–EPs be as described in that paragraph. We stated that the vast majority of MA organizations do not employ their physicians; nor do they use physicians who work for, or who are partners of, an entity that contracts nearly exclusively with the MA organization (as set out in the definition of a ''Qualifying MA–EP'' in § 495.200).

Thirdly, section 1853(m)(2) of the Act requires that a qualifying MA organization have common corporate governance with a hospital in order for it to be considered an MA-affiliated eligible hospital, and we did not expect many qualifying MA organizations to meet this test.

We explained that the current § 495.202(b)(4) (which we proposed to redesignate as § 495.202(b)(5)) requires all qualifying MA organizations that have potentially qualifying MA–EPs or MA-affiliated eligible hospitals that are not meaningful users to initially report that fact to us beginning in June of MA plan year 2015. We proposed that this reporting requirement would include only qualifying MA organizations that participated in and received MA EHR incentive payments.

Further, we discussed that there may be MA organizations that participated in the incentive payment phase of the program, but then ceased being qualifying MA organizations, or that no longer have any qualifying MA–EPs or MA-affiliated eligible hospitals. We provided an example of a qualifying MA organization that contracts with a specific entity to deliver physicians' services during the payment phase of the EHR Incentive Program, but then the entity changes, or the MA organization loses its contract with the entity. We explained that such changes could cause the MA organization's MA EPs to no longer meet the 80/80/20 rule due to loss of the contract, or the entity might begin contracting with additional MA organizations. (See § 495.200, for the definition of ''Qualifying MA–EP.'') Therefore, we explained, the MA organization would not necessarily have its monthly payment adjusted because it might no longer meet the basic requirements under which MA EHR incentive payments were made to it.

Therefore, we proposed to adjust payments, beginning for payment adjustment year 2015, only for qualifying MA organizations that received MA EHR payments and that had potentially qualifying MA–EPs or MA-affiliated eligible hospitals that were not meaningful EHR users. We proposed to rely on the existing self-reporting requirement in redesignated § 495.202(b)(5) and subsequent audits to ensure compliance.

Comment: A commenter recommended that CMS apply MA payment adjustments to qualifying MA organizations only for the category of MA provider (that is, MA–EP versus MA-affiliated hospital) for which it claimed and received MA EHR incentive payments. For example, if a qualifying MA organization claimed incentive payments during the payment phase of the program only for MA–EPs and not for any MA-affiliated eligible hospitals, then the MA organization should only be required to report on qualifying and potentially qualifying MA–EPs during the adjustment phase of the program, and should not be subject to payment adjustments for MA-affiliated hospitals.

Response: We agree with the commenter that we will apply payment adjustments only to qualifying MA organizations for the category (or categories) of MA provider (either MA–EP, MA-affiliated eligible hospital, or both) for which it claimed and received MA EHR incentive payments. To the same extent that qualifying MA organizations have identified themselves and their qualifying MA–EPs and/or MA-affiliated eligible hospitals during the payment phase of the MA EHR Incentive Program, we expect them to continue to identify themselves and their MA–EPs and MA-affiliated hospitals during the adjustment phase of the program. We are taking this approach because we believe it would be impossible to verify that a given qualifying MA organization has potentially qualifying MA–EPs or MA-affiliated eligible hospitals, unless it had first identified those providers to us. We have modified § 495.211(c) to clarify that MA EHR payment adjustments with respect to MA-affiliated hospitals will only apply to qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program for MA-affiliated hospitals, and similarly, that MA EHR payment adjustments with respect to MA–EPs will only apply to qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program for MA–EPs.

We proposed to collect payment adjustments made under sections 1853(l)(4) and 1853(m)(4) of the Act after meaningful use attestations have been made. Final attestations of meaningful use occur after the end of an EHR reporting period, which for MA–EPs would run concurrent with the payment adjustment year. In the case of potentially qualifying MA-affiliated eligible hospitals, attestations of meaningful use would occur by the end of November after the EHR reporting period. As noted previously, we proposed to amend § 495.202(b) to indicate that in addition to initial identification of potentially qualifying MA–EPs and MA-affiliated eligible hospitals that are not meaningful users (as required by redesignated § 495.202(b)(5)), qualifying MA organizations would also need to finally identify such MA–EPs and MA-affiliated eligible hospitals within 2 months of the close of the applicable EHR reporting period. Final identification by qualifying MA organizations of potentially qualifying MA–EPs and/or MA-affiliated eligible hospitals that are not meaningful users would then result in application of a payment adjustment by CMS. On the other hand, final identification of all qualifying MA–EPs and/or MA-affiliated eligible hospitals as meaningful users would obviate an adjustment. We stated that, through audit, we would verify the accuracy of an applicable MA organization's assertions or nonreporting.

We proposed to adjust one or more of the qualifying MA organization's monthly MA payments made under section 1853(a)(1)(A) of the Act after the qualifying MA organization attested to the percent of hospitals and professionals that either were, or were not, meaningful users of certified EHR technology. We stated that, to the extent a formerly qualifying MA organization did not report under § 495.202(b)(4) or (5), we would verify, upon audit, the accuracy of the applicable MA organization's nondisclosure of such qualifying and potentially qualifying users.

Under our proposed approach, the adjustment would be calculated based on Part C payment data made under section 1853(a)(1)(A) of the Act for the payment adjustment year. We stated

that since an MA-affiliated eligible hospital must attest to meaningful use by November 30th, we could use the Part C payment information in effect at the time of the attestation to calculate the payment adjustment for a specific potentially qualifying MA-affiliated eligible hospital with respect to a specific MA organization. Although we expected (and preferred) to make an adjustment to a single MA monthly payment totaling the adjustment for the year, we requested comment on whether more than one monthly payment should be adjusted. We stated that one possible approach would be to make this decision on a case-by-case basis depending upon a given qualifying MA organization's situation (for example, payment adjustment amount versus MA organization monthly payment).

For payment adjustments based on potentially qualifying MA–EPs that are not meaningful users of certified EHR technology, we also proposed to calculate the adjustment based on the Part C payment made under section 1853(a)(1)(A) of the Act for the payment adjustment year. Because attestations of meaningful use for qualifying MA–EPs occur in February of the calendar year following the EHR reporting year, we noted that we could calculate the payment adjustment based on the prior MA payment year's payment, and that we could apply that adjustment to one or more of the prospective Part C payments. While we preferred to make an adjustment to one MA prospective payment for the full amount of the payment adjustment when possible, we solicited comment on whether we should make adjustments over several months or in a single month (for the entire adjustment amount), when possible. We received no comments on this proposal and therefore we are adopting the policy of collecting payment adjustments as quickly as possible in a single month, when possible.

Thus, adjustments for MA payment adjustment year 2015 would be based on MA payment data under section 1853(a)(1)(A) of the Act. However, while the payment adjustment for the 2015 payment adjustment year would be collected as soon as possible, we stated that this might not be until CY 2016 through an adjustment to the MA organization's MA capitation payment or payments under section 1853(a)(1)(A) of the Act.

We stated that proposed § 495.211(c) made clear that the potentially qualifying MA–EP and MA-affiliated eligible hospital payment adjustments would be calculated separately, and that each adjustment was applied to the qualifying MA organization's monthly payment under section 1853(a)(1)(A) of the Act. As discussed previously, we are modifying § 495.211(c) to clarify that MA EHR payment adjustments for MA-affiliated hospitals only apply to qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program for MA-affiliated hospitals, and that payment adjustments for MA–EPs only apply to qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program for MA–EPs.

Proposed paragraphs (a) through (c) would apply to adjustments based on both potentially qualifying and qualifying MA–EPs and MA-affiliated eligible hospitals that were not meaningful EHR users. Proposed paragraph (d) would apply only to adjustments based on potentially qualifying and qualifying MA–EPs that were not meaningful users of certified EHR technology. We also stated that paragraph (d) makes it clear that if a potentially qualifying MA–EP was not a meaningful user of CEHRT in payment adjustment year 2015 (and subsequent payment adjustment years), the qualifying MA organization's monthly Part C payment would be adjusted accordingly.

During the payment phase of the MA EHR Incentive Program qualifying MA organizations attest to meaningful use for each qualifying MA–EP and MA-affiliated eligible hospital they claimed. We also stated that during the payment adjustment phase of the program, we would need to know the percentage of both qualifying and potentially qualifying MA–EPs and MA-affiliated eligible hospitals that were not meaningful users of certified EHR technology. This percentage could be derived by taking the total number of the qualifying MA organization's qualifying and potentially qualifying MA–EPs, or MA-affiliated eligible hospitals, and identifying the portion of those MA–EPs or MA-affiliated hospitals that were not meaningful EHR users. We would use this percentage to make the adjustment proportional to the percent that were not meaningful users for a given adjustment year and qualifying MA organization.

Moreover, in determining the proportion of potentially qualifying MA–EPs and potentially qualifying MA-affiliated eligible hospitals (those that were not meaningful users), we would exclude EPs and hospitals that were neither qualifying nor potentially qualifying in accordance with the definition of ''qualifying'' and ''potentially qualifying MA–EPs'' and ''MA-affiliated eligible hospitals'' in § 495.200. Thus, an MA–EP that was a hospital-based EP would not be a qualifying or potentially qualifying MA–EP since such an EP did not meet item (5) of the definition of qualifying MA–EP in § 495.200 and thus would not be used in our computation of the proportion of MA–EPs for purposes of applying the payment adjustment. We proposed the following formula to apply the payment adjustments proposed in § 495.211(d)(2) to MA–EPs:

[the total number of potentially qualifying MA–EPs]/[(the total number of potentially qualifying MA–EPs) + (the total number of qualifying MA–EPs)].

Similarly, the formula we proposed for purposes of applying payment adjustments in § 495.211(e)(2)(iii) with respect to MA-affiliated hospitals was:

[the total number of potentially qualifying MA-affiliated eligible hospitals]/[(the total number of potentially qualifying MA-affiliated eligible hospitals) + (the total number of qualifying MA-affiliated eligible hospitals)].

Keeping in mind that redesignated § 495.202(b)(4) and (5) required qualifying MA organizations to identify potentially qualifying MA–EPs and potentially qualifying MA-affiliated eligible hospitals and to provide other information beginning for plan year 2015, we solicited comment on the question of whether, in the payment adjustment phase of this program, qualifying MA organizations with potentially qualifying MA–EPs and MA-affiliated eligible hospitals should—(1) still be required to attest to the meaningful use objectives and measures; or (2) instead be required only to report the percent of MA–EPs and MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology. We suggested that commenters take into account that MA-affiliated eligible hospitals would still be required to perform a reporting function on behalf of their MA-affiliated organization in the National Level Repository (NLR), and that they were generally bound to ''subsection (d)'' hospital reporting requirements of the NLR. Thus, we were primarily interested in comments related to MA–EPs.

We explained that while we wished to minimize burden, we were also concerned with our ability to audit the information reported to ensure compliance with MA program requirements. Having received no comments on this provision, we therefore adopt a final requirement to

use only percentage-based reporting and, require MA organizations to retain and produce data and records necessary to substantiate their submissions, including evidence of meaningful use by those MA–EPs and MA-affiliated eligible hospitals so reported.

We proposed that payment adjustments for MA–EPs would be calculated by multiplying: (1) The percent established under § 495.211(d)(4) (which, in accordance with the statute, increases the adjustment amount up until 2017 and potentially beyond); with (2) the Medicare Physician Expenditure Proportion; and (3) by the percent of the qualifying MA organization's qualifying and potentially qualifying MA–EPs that were not meaningful users. We explained that section 1853(l)(4)(B)(i) of the Act requires MA payments to be reduced using the ''percentage points'' reduction of section 1848(a)(7)(A)(ii) of the Act. As section 1848(a)(7)(A)(ii) of the Act is ''subject to clause (iii),'' and as clause (iii) of that same provision requires payment adjustments to increase when the proportion of EPs who are meaningful EHR users is less than 75 percent, we proposed to apply a similar policy for the MA program. Specifically, we proposed that if the proportion of MA–EPs of a qualifying MA organization did not meet the 75 percent threshold (as determined in proposed § 495.211(d)(2)) in 2018 and subsequent years, the percentage reduction could increase to 4 percent in 2018, and 5 percent in 2019 and subsequent years. We did not propose a possible 2 percent reduction for 2015 (consistent with the Medicare FFS EHR Incentive Program when an EP is subject to an adjustment in 2014 under the e-prescribing program), because MA organizations are not independently subject to e-prescribing payment adjustments.

We proposed that the Medicare Physician Expenditure Proportion for a year would be the Secretary's estimate of expenditures under Parts A and B not attributable to Part C that are attributable to expenditures for physician services. While we proposed a uniform portion for all MA organizations, we also proposed to adjust the proportion on a more individual basis to account for the fact that qualifying MA organizations may contract with a large number of EPs that are neither qualifying nor potentially qualifying. We explained that this individualized policy was based on the statutory language in section 1853(l)(1) of the Act, which states that the provisions of section 1848(a)(7) of the Act (that is, the payment adjustments) apply ''with respect to'' the EPs ''described in paragraph (2)'' of section 1853(l) of the Act. As section 1853(l)(2) of the Act creates several additional requirements for MA–EPs (that is, that they be employed by the qualifying MA organization, that they meet the 80/80/20 requirements, and so on), we proposed adjusting the Physician Expenditure Proportion to recognize that many EPs may not qualify as MA–EPs, regardless of meaningful use. Thus, we proposed to adjust each MA organization's Physician Expenditure Proportion to recognize that not all of the EPs would meet the technical (nonmeaningful use) requirements to be potentially qualifying or qualifying MA–EPs. Without our proposed adjustment, a small sample size of MA–EPs could magnify the reduction amount during the payment adjustment phase of the program, because the actions of a limited set of qualifying and potentially qualifying MA–EPs (and whether they meaningfully used certified EHR technology) would determine whether all of an MA organization's physician expenditure proportion was reduced.

We provided an example of our proposed MA payment adjustment for adjustment year 2015 as follows:

Assume the hypothetical Medicare Physician Expenditure Proportion, adjusted as described previously, is 10 percent for 2015;

The qualifying MA organization's percent of qualifying and potentially qualifying MA–EPs that are not meaningful users is 15 percent for 2015; and

The monthly payment in 2015 for the given qualifying MA organization is $10,000,000.

The proposed formula would read as follows:

0.01 (the payment adjustment for 2015) × 0.1 (the hypothetical Medicare Physician Expenditure Proportion) × 0.15 (the percentage of qualifying and potentially qualifying MA–EPs that are not meaningful EHR users) × $10,000,000 (monthly Part C payment) × 12 (number of months in the MA payment year) = $18,000 for the entire year, or $1,500 a month. We proposed that this adjustment would then be collected against one or more of the qualifying MA organization's payments under section 1853(a)(1)(A) of the Act.

In proposed § 495.211(e), we set out a formula for payment adjustments based on potentially qualifying MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology.

We proposed an adjustment equal to the product of the following:

- Monthly Part C payment for the payment adjustment year;
- The percentage point reduction that applies to FFS hospitals as a result of section 1886(b)(3)(B)(ix)(I) of the Act;
- The Medicare hospital expenditure proportion, adjusted in the same manner as the Physician Expenditure Proportion to recognize that not all hospitals are necessarily qualifying or potentially qualifying MA-affiliated eligible hospitals; and
- The percentage of qualifying and potentially qualifying MA-affiliated eligible hospitals of a given qualifying MA organization that are not meaningful users of certified EHR technology.

We proposed that the percentage point reduction of the first bullet (that is, the reduction that applies as a result of section 1886(b)(3)(B)(ix)(I) of the Act) would be based on the point reduction that results when three-fourths of the otherwise applicable percentage increase for the fiscal year was reduced by 33⅓ percent for FY 2015, 66⅔ percent for FY 2016, and 100 percent for FY 2017 and subsequent fiscal years. We stated this had the result of decreasing the otherwise applicable market basket update by one-fourth (for 2015), one-half (for 2016), and three-fourths (for 2017 and subsequent payment adjustment years).

We stated that the Medicare Hospital Expenditure Proportion for a year was the Secretary's estimate of expenditures under Medicare Parts A and B that were not attributable to Part C, that were attributable to expenditures for inpatient hospital services. As mentioned previously, we proposed that this proportion reflects only the MA-affiliated eligible hospitals that were either qualifying or potentially qualifying MA-affiliated eligible hospitals.

We also proposed to use the market basket percentage increase that would otherwise apply to ''subsection (d)'' hospitals for an MA payment adjustment year. We provided the following hypothetical example. The market basket percentage increase for FY 2015 was hypothetically 4 percent. Three-quarters of one-third of 4 percent would be 1 percent. The hypothetical Medicare Hospital Expenditure proportion for the year was 15 percent, and one of two of the relevant MA-affiliated eligible hospitals was not a meaningful EHR user for the applicable period (FY 2015). The monthly payment to the MA organization in 2015 was $10,000,000 a month.

The calculation would be as follows:

0.01 (the market basket percentage point reduction) × 0.15 (the Medicare Hospital Expenditure Proportion) × 0.5 (percent of the qualifying MA organization's qualifying and potentially qualifying MA-affiliated eligible hospitals that are not meaningful users) × $10,000,000 (monthly Part C payment) × 12 (number of months in the MA payment year) = $90,000 for the year, or $7,500 a month. The payment adjustment would be applied on either a monthly basis, or in one adjustment. As stated previously, we requested comment on this aspect of the final rule.

Comment: A commenter stated that the formula for computing the Medicare Physician Expenditure Proportion percent in § 495.211(d)(3)(ii) was not clear on whether physicians who saw no Medicare patient at all would be excluded from the expenditure proportion calculation (for example, most pediatricians), and whether a distinction would be made between services provided by MA–EPs and potential MA–EPs of the organization, and other physicians and the services they provide. The commenter explained that under the model of reimbursement for physician services it uses, the ability to track Part A and Part B costs to individual physicians was limited. The commenter proposed an alternate method for computing the Medicare Physician Expenditure Proportion based on what it called a ''uniform distribution model as a proxy for the adjustment to the MPEP percent.''

Response: We believe it is unnecessary to specifically exclude physicians, such as pediatricians, who see no Medicare patients from the Medicare Physician Expenditure Proportion calculation. Expenditures that are provided by EPs that are neither qualifying nor potentially qualifying MA–EPs are already adjusted out. This would be true in two ways for physicians, such as pediatricians, who see no Medicare patients. First, these physicians would not meet item (2) of the definition of a ''qualifying MA–EP'' in § 495.200, since these physicians do not provide ''at least 80 percent'' of their Medicare-covered professional services to enrollees of the qualifying MA organization. Since they provide no Medicare-covered professional services to enrollees of the qualifying MA organization, they do not meet the ''80 percent'' requirement. Second, the Physician Expenditure Proportion is based only on Medicare expenditures for physician services (that is, the proportion of expenditures under Parts A and B not attributable to Part C that are attributable to expenditures for physician's services). Physician expenditures for non-Medicare services (like most services of a pediatrician) do not count in the calculation. Finally, we do not believe an alternative method of computing the Medicare Physician Expenditure Proportion is necessary and therefore are not considering the alternate approach proposed by this commenter in this final rule. It should be noted that tracking Part B costs to individual MA–EPs (physicians) is a critical part of determining the incentive payment due a qualifying MA organization (see 42 CFR 495.204(ff)). To the extent methodologies for estimating the portion of MA–EP compensation that is attributable to Part B professional services are used during the payment phase of the MA EHR Incentive Program, we believe these methodologies can also be successfully used during the adjustment phase of the Program.

Comment: A commenter questioned if section 3401 of the Affordable Care Act market basket update adjustment due to changes in economy-wide productivity for FY 2012 and each subsequent fiscal year would be included, or if any other adjustment would be included in the market basket update rate used in the penalty adjustment formula.

Response: Section 1853(m)(4)(B)(i) of the Act directs us to use the ''number of the percentage point reduction effected under section 1886(b)(3)(B)(ix)(I) for the period.'' That reduction is based off of a starting point of the applicable percentage increase otherwise applicable under clause (i), while mandating that this be ''determined without regard to clause (viii), (xi), or (xii)'' of section 1886(b)(3)(B) of the Act. Thus, the starting point for determining the percentage points by which the update is reduced is the applicable percentage increase in clause (i) of section 1886(b)(3)(B) of Act, before it has been further reduced for productivity (under clause (xi) for other statutory reductions (in clause (xii)), or for failure to report on certain measures (under clause (viii)). Currently, the applicable percentage increase in clause (i), before the other reductions have been made, is the market basket percentage increase for hospitals in all areas. Thus, such a market basket increase will be our starting point, and the percentage points by which that increase is reduced solely due to the application of EHR Program adjustments will be the point reduction we use in the MA formula.

Comment: A commenter proposed an alternate method for computing the Medicare Hospital Expenditure Proportion based on what they believe is ''consistent with fee-for-service hospital penalties.''

Response: We believe our proposed method is consistent with the method the Medicare fee-for-service program will use to implement EHR adjustments for ''subsection (d)'' hospitals.

Comment: One commenter expressed concern that CMS had proposed that payment adjustments would be based on an earlier payment period.

Response: We believe the commenter is confused, as we did not propose a prior EHR reporting period for the MA program.

We received no other comments on this section of the proposed rule. After consideration of the public comments received, we are finalizing these provisions as proposed with the one modification noted to § 495.211(c).

6. Reconsideration Process for MA Organizations

We proposed a reconsideration process in new section, § 495.213. We did not receive any comments on the proposed process. However, for the reasons stated in section II.D.5 of this final rule, we do not believe formal regulations for an informal reconsideration procedural rule are necessary and therefore we are not including this new section in this final rule.

As noted in the proposed rule and as required by statute, our administrative reconsideration process would not permit administrative review of the standards and methods used to determine eligibility and payment (see sections 1853(l)(8) and (m)(6) of the Act, and § 495.212 of the regulations). However, it would allow a reconsideration of the application of such standards and methods, in certain circumstances.

F. Revisions and Clarifications to the Medicaid EHR Incentive Program

Unless otherwise specified, the changes discussed in this section of the rule will take effect upon publication of this final rule.

1. Net Average Allowable Costs

In this final rule, we are formalizing through rulemaking the guidance that was shared with state Medicaid Directors in a letter on April 8, 2011 (available at: *http://www.cms.gov/smdl/downloads/SMD11002.pdf*). These technical changes are required to implement section 205(e) of the Medicare and Medicaid Extenders Act of 2010 (Extenders Act, Pub. L. 111–309). The Extenders Act, enacted on

December 15, 2010, amended sections 1903(t)(3)(E) and 1903(t)(6)(B) of the Act. The amended sections change the requirements for an EP to demonstrate the ''net average allowable costs,'' the contributions from other sources, and the 15 percent provider contribution requirements to participate in the Medicaid EHR Incentive Payment Program. The Extenders Act provided that an EP has met this responsibility, as long as the incentive payment is not in excess of 85 percent of the net average allowable cost ($21,250 for first year payments).

Before the Extenders Act, Medicaid EPs who wanted to participate in the EHR Incentive Payment Program were required to provide documentation of certain costs related to acquiring and implementing certified EHR technology. The Extenders Act amended the relevant statute by allowing for providers to simply document and attest that they have adopted, implemented, upgraded, or meaningfully used certified EHR technology, while allowing us to set these average costs.

As a result, rather than requiring each EP to calculate the payments received from outside sources, each will use the average costs and contribution amount we established. After conducting a meta-analysis of existing data of an EP's costs to adopt, implement, or upgrade certified EHR technology, we determined that average contributions from outside sources should not exceed $29,000. The documentation originally required by an EP to demonstrate that he or she contributed 15 percent (for example, $3,750 for year 1) of the ''net average allowable costs'' is also no longer needed. The Act now provides that an EP has met this responsibility as long as the incentive payment is not in excess of 85 percent of the net average allowable cost ($21,250). Given that this change is already in effect, we proposed to remove from the required content in the state Medicaid HIT Plan, the requirement that states describe the process in place to ensure that Medicaid EHR incentive payments are not paid at amounts higher than 85 percent of the net average allowable cost of certified EHR technology, as described in § 495.332.

We received no comments on our proposal to codify this already-existing policy, and we are finalizing our proposals without modification.

TABLE E1—DETERMINATION OF NET AVERAGE ALLOWABLE COSTS FOR THE FIRST PAYMENT YEAR

First year variables [1]	Amounts	Prior to Extenders Act changes	Currently
Average Allowable Costs.	$54,000	Determined through a CMS meta-analysis, described in both the proposed rule (75 FR 1844) and the final rule (75 FR 44314).	No change.
Contributions from Other Sources.	Does not exceed $29,000.	Subtracted from Average Allowable Costs to reach ''Net'' Average Allowable Costs. An EP was required to show documentation of all contributions from certain other sources.	No documentation is needed. We have determined that average contributions do not exceed $29,000.
Capped Amount of ''Net'' Average Allowable Costs.	$25,000	Capped by statute and designated in CMS final rule.	No change.
Contribution from the EP.	$3,750	An EP was required to demonstrate that he or she had contributed at least 15 percent of the net average allowable costs towards a certified EHR.	No documentation needed. Determined to have been met by virtue of EP receiving no more than $21,250 in the first payment year.
Incentive payment [2]	$21,250	85 percent of the Net Average Allowable Costs; determined through statute. An EP could receive less than this amount if he or she had contributions from other sources exceeding $29,000.	All EPs will receive the maximum incentive payment of $21,250, as all EPs will be determined to have contributions from other sources under $29,000.

[1] These same concepts (but not figures) apply to the second through sixth years, integrating the figures from the Stage 1 final rule. Ultimately, the incentive paid in the second through sixth years is still the statutory maximum of $8,500.

[2] This figure is further reduced to two-thirds for pediatricians qualifying with reduced Medicaid patient volumes. This is described at 42 CFR 495.310.

2. Definition of Adopt, Implement Upgrade

We are adding clarifying language that maintains our policy that to qualify for an AIU payment, a provider must adopt, implement or upgrade to certified EHR technology that would allow that provider to qualify as a meaningful user. Our regulation has always defined certified EHR technology by reference to the ONC definition at 45 CFR 170.102, and ONC's definition of certified EHR technology has consistently required the technology to support meaningful use. While ONC is changing the definition of certified EHR technology, we do not believe this change would allow a provider to receive an incentive for technology that could not support meaningful use (that is for purchasing only ''Base EHR'' technology). Nevertheless, in order to be absolutely clear in our regulations, we are amending them to ensure that providers do not receive Medicaid incentives for adopting technology that would not allow them to demonstrate meaningful use.

3. Eligibility Requirements for Children's Hospitals

We proposed to revise the definition of a children's hospital in § 495.302 to also include any separately certified hospital, either freestanding or hospital within hospital that predominately treats individuals under 21 years of age; and does not have a CMS certification number (CCN) because they do not serve any Medicare beneficiaries but has been provided an alternative number by CMS for purposes of enrollment in the Medicaid EHR Incentive Program. We will provide future guidance on how to obtain these alternative numbers.

The only comments we received on this proposal were favorable. We are finalizing these policies as proposed. Guidance to these hospitals and the states on enumeration and determining eligibility is also forthcoming.

4. Medicaid Professionals Program Eligibility

Section 1903(t) of the Act authorizes Medicaid payments to encourage the adoption and use of certified EHR

technology, and places Medicaid patient volume requirements on EPs to qualify for such payments under the Medicaid program. Patient volume requirements ensure that Medicaid funding is used to encourage the adoption and use of technology specifically to benefit the care of Medicaid populations. Therefore, we proposed that at least one of the clinical locations used for the calculation of an EP's patient volume have CEHRT during the payment year for which the EP is attesting to adoption, implementation or upgrade or meaningful use. This will ensure that Medicaid funding goes to EPs using CEHRT to improve Medicaid patients' care.

The only comments that we received on this proposal were in support of the proposal. For the reasons explained in the proposed rule, we are finalizing this policy as proposed. We have amended § 495.304 and § 495.332 accordingly.

a. Calculating Patient Volume Requirements

We proposed to revise § 495.306(c) to allow states the option for their providers to calculate total Medicaid encounters or total needy individual patient encounters in any representative, continuous 90-day period in the 12 months preceding the EP or eligible hospital's attestation. This option will be in addition to the current regulatory language that bases patient volume on the prior calendar or fiscal year. We believe this adjustment will provide greater flexibility in eligible providers' patient volume calculations.

Likewise, we proposed to revise § 495.306(d)(1)(i)(A) to allow for the calculation of the total Medicaid patients assigned to the EP's panel in any representative, continuous 90-day period in either the preceding calendar year, as is currently permitted, or in the 12 months preceding the EPs' attestation, when at least one Medicaid encounter took place with the Medicaid patient in the 24 months prior to the beginning of the 90-day period. We also proposed to revise § 495.306(d)(1)(ii)(A) accordingly, so that the numerator and denominator are using equivalent periods. We proposed conforming changes to § 495.306(d)(2)(i) and (ii) for needy individual patient volume. We proposed changing the period during which the encounter must take place from 12 months to 24 months to account for new clinical guidelines from the U.S. Preventive Health Services Task Force that allow greater spacing between some wellness visits. Therefore, in order for a patient to be considered ''active'' on a provider's panel, we proposed 24 months is more appropriate. This change is also in order to be consistent with the proposed Stage 2 meaningful use measure for patient reminders sent to ''active patients.''

The only comments we received on this proposal were supportive. For the reasons explained in the proposed rule, we are finalizing this policy as proposed. We note that as explained in the proposed rule, this will be an option for states to implement at their discretion. States must seek prior approval from CMS via an amendment to their state Medicaid HIT Plan before implementing this change.

We also proposed to expand the definition of ''encounter'' to include any service rendered on any one day to an individual enrolled in a Medicaid program. We explained that such a definition will ensure that patients enrolled in a Medicaid program are counted, even if the Medicaid program did not pay for the service (because, for example, a third party payer paid for the item or service, or the service is not covered under Medicaid). We also explained that the definition would include encounters for patients who are Title XIX eligible and who meet the definition of ''optional targeted low income children'' under section 1905(u)(2) of the Act. Thus, individuals in Title XXI-funded Medicaid expansions (but not separate CHIPs) could be counted in providers' patient volume calculations. We stated that this approach is consistent with existing policies that provide Title XIX protections to children enrolled in Title XXI-funded Medicaid expansions.

In the proposed rule, we noted that as of 2010, 33 states have Title XXI Medicaid expansions via approved state plan amendments. Therefore, under our proposed policy, providers in those states would be able to include encounters with individuals in such expansions in their patient volume calculation for purposes of this program. In 2010, over 2.1 million children were covered in Medicaid expansion programs. We stated that our proposed change would likely increase the number of eligible providers who qualify for the Medicaid EHR Incentive Program, particularly those serving children because it allows states to create a larger base of Medicaid patients to be counted toward the patient volume requirements than existed under the Stage 1 rule.

Comment: Some commenters were concerned about verifying patient volume requirements for patients seen for a service where Medicaid did not pay for all or part of the service. Commenters asked CMS to clarify the prepayment audit expectations of states with this broader definition.

Response: This final rule does not change states' obligations to complete due diligence to verify all eligibility criteria, including patient volume. Existing subregulatory guidance is available to states to assist in developing audit processes. We encourage states to take advantage of those materials, guidance, and technical assistance resources that we have made available to support their auditing activities.

Comment: Commenters, while supportive of these changes, inquired whether these changes would be retroactive and affect payments already disbursed. They asked, for example, whether EPs who attested to Medicare for CY 2011 would be able to refund Medicare incentive payments and qualify for the Medicaid payment; or whether pediatricians who received the incentive for a patient volume of 20 percent would be able to receive a replacement payment associated with the 30 percent patient volume.

Response: These changes are not retroactive. Patient volume requirements for 2011 and 2012 are not affected by these changes. Eligibility for the program is determined at the time of attestation and prior to payment. States should implement this new definition of an encounter no later than 6 months after this rule is published and only for providers attesting for the 2013 program year and subsequent program years. In no event will this definition apply to attestations for the 2012 program year.

Comment: Commenters also inquired whether these new eligibility changes meant that an EP or eligible hospital denied an incentive payment because of failure to satisfy patient volume requirements could reapply in the same program year.

Response: As explained in our response to the previous comment, these changes would not be retroactive. Existing rules permit an EP or eligible hospital to reapply if they fail to meet the requirements for an incentive payment. If a provider fails to meet the requirements in 2013 before their state has implemented this change, they may then reapply after the change is made to their state's systems. Additionally, an EP or eligible hospital denied eligibility in a previous year is always permitted to reapply for a subsequent year (subject to rules for EPs switching programs as explained in § 495.10).

For the reasons explained in the proposed rule, and because this change will help more Medicaid providers qualify for the program, we are finalizing this policy as proposed. The expanded definition of encounter will

include individuals enrolled in Medicaid who had a billable service on any one day during the 90-day patient volume timeframe.

In our proposed rule, we also clarified that we understand that multiple providers may submit an encounter for the same individual. For example, it may be common for a PA or NP to provide care to a patient, then a physician to also see, or invoice for services to that patient. We explained that it is acceptable in these and similar circumstances to count the same encounter for multiple providers for purposes of calculating each provider's patient volume when the encounters take place within the scope of practice. We did not receive any comments on this clarification and retain it for the final rule.

b. Practices Predominantly

Similar to our proposed revisions for patient volume, we proposed to revise the definition of ''practices predominantly'' at § 495.302 in order to provide more flexibility for eligible professionals and states. A state could choose to allow EPs to use either: (1) The most recent calendar year; or (2) the most recent 12 months prior to attestation. Also, as with the previously noted patient volume changes, these ''practices predominantly'' changes are not retroactive. Patient volume requirements for 2011 and 2012 are not affected by these changes. States should implement this new definition of an encounter no later than 6 months after this rule is published and only for providers attesting to meeting program requirements for the 2013 program year and subsequent program years. In no event will this definition apply to attestations for the 2012 program year.

Comment: Some commenters—commenting on the patient volume changes in § 495.306, the ''practice predominantly'' changes in § 495.302, and the revised definition of encounter—expressed concerns about the system challenges associated with such changes. They requested that CMS consider the burden on state systems to implement these changes.

Response: We recognize that system changes must be considered when enacting or revising policies. However, we note that much of what we have proposed would be optional for states, while some would be required. We believe our final rule strikes a balance between optional and required policies for states, and providing 6 months to make systems changes balances implementation timelines with the overall goal to promote EHR adoption through the Medicaid EHR Incentive Program. We note that states receive 90 percent Federal matching funds for administrative costs associated with the EHR Incentive Program.

Comment: Although we did not make any proposals on the subject, some commenters requested a more prescriptive definition of pediatrician be provided to the states that includes pediatric ophthalmologists.

Response: We did not make any proposals on the definition of pediatrician. This final rule does not change the previous flexibility that states had to define pediatrician. In some states, pediatric ophthalmologists are eligible for the program, but that is entirely dependent on how the state has chosen to define pediatrician. This suggestion is also outside the scope of this rulemaking.

After consideration of the public comments received, we are finalizing the revised definition of ''practices predominantly'' at § 495.302 as proposed; this revised definition is applicable to providers attesting to meeting program requirements for the 2013 program year and subsequent program years.

5. Medicaid Hospital Incentive Payment Calculation

a. Discharge Related Amount

In order to ensure that Medicaid regulations are consistent with Medicare, we proposed that the Medicaid calculation should be consistent with the Medicare calculation found in § 495.104(c)(2). Our current regulations at § 495.310(g)(1)(i)(B) require the use of the ''12-month period selected by the state, but ending in the Federal fiscal year before the hospital's fiscal year that serves as the first payment year.'' We also published a tip sheet with additional guidance on the Medicaid hospital incentive payment calculation, which can be found at: (*https://www.cms.gov/MLNProducts/downloads/Medicaid_Hosp_Incentive_Payments_Tip_Sheets.pdf*). However, some hospitals may not have a full 12 months of data ending with the Federal fiscal year immediately preceding the first payment year, or they may have a slightly older 12-month period that could be used. Therefore, we have revised our regulations at § 495.310(g)(1)(i)(B) to allow states to use, for the purpose of calculating the discharge related amount, and other determinations (such as inpatient bed days), the most recent continuous 12-month period for which data are available prior to the payment year. If such 12-month period is a cost report, it should be one, single 12-month cost reporting period (and not a consolidation of two separate cost reporting periods). If it is an alternative source different from the cost report, we will rely on the state to ensure that the source is an appropriate source, and that the period is a continuous 12 months, and that the state is using the most recent data that are available. States should implement these changes only for hospitals that begin participation in the program starting in federal fiscal year 2013 or subsequent federal fiscal years. Hospitals that began participation before federal fiscal year 2013 must use discharge data from the hospital fiscal year that ends during the federal fiscal year prior to the hospital fiscal year that serves as the first payment year.

Comment: Commenters were concerned that hospitals may not have a full 12 months of data available ending with the Federal fiscal year immediately preceding the first payment year, thus restricting hospitals participation in the program.

Response: We appreciate the commenters concern; however, the change in regulatory language does not require hospitals to use data immediately preceding the first payment year, but rather the most recent 12 consecutive months of data available to the hospital prior to the payment year. The intent of this regulatory change was to encourage timely participation in the program. For the base year, the former policy required hospitals to initiate participation using a 12-month period ending in the Federal fiscal year before the hospital's fiscal year that serves as the first payment year. In recognition of this challenge, we are changing the regulation at § 495.310(g)(1)(i)(B) to allow hospitals to use, for purposes of determining the base year for the Medicaid incentive payment calculation, the most recent continuous 12-month period for which data are available prior to the payment year. Only those hospitals that begin participation in program year 2013 and beyond will be affected by this change. Hospitals that began participation in the program before 2013 will not have to adjust previous calculations.

Comment: A commenter suggested that ''the most recent data that are available'' is ambiguous. Hospital cost report data are subject to significant audit and adjustments subsequent to their submission to the state, so the definition of ''available'' has a large impact on the reliability of the data used to calculate the incentive payment amount. The commenter noted that the state and CMS have a strong interest in ensuring that the data used to calculate

the hospital incentive payment is accurate, defensible, and final, and the use of data that are not properly audited would create a significant potential for issuing incentive payments that would later need to be adjusted. The commenter suggested that CMS clarify ''the most recent data that are available'' means the most recent data that, in the judgment of the state, are properly audited and finalized.

Response: We appreciate the commenters concern; however, we do not agree that the data needs to be audited and finalized in order to be used for the incentive payment calculation. It is our expectation that the hospital incentive payment is calculated using the most accurate data available at the time of calculation and it is the responsibility of the state to make the determination of which source is most accurate. We do not restrict data sources, as we believe the states are best positioned to balance the accuracy and timeliness of the data available. Medicare pays hospitals using preliminary, filed, cost report data and reconciles payment when the data is audited and finalized. Similarly, we allow states to adjust calculations and reconcile payments when audited and finalized data are available. State policy changes or proposals regarding reconciliation of hospital incentive payments must be reflected in the state' Medicaid Health Information Technology Plan (SMHP) and must be reviewed and approved by CMS.

b. Acute Care Inpatient Bed Days and Discharges for the Medicaid Share and Discharge-Related Amount

In order to ensure that the regulations accurately reflect our current policy, we proposed to amend the hospital payment regulations at § 495.310(g)(1)(i)(B) and (g)(2) to recognize that only acute-care discharges and bed-days are included in our calculations. We currently require that only discharges from the acute care part of the hospital may be counted in both the discharge-related amount and the Medicaid share. For example, in response to a frequently asked question (*https://questions.cms.gov*, FAQ #2991), we explained that nursery days and nursery discharges (for newborns) could not be counted in both the Medicare and Medicaid EHR incentive programs. We stated: ''[N]ursery days and discharges are not included in inpatient bed-day or discharge counts in calculating hospital incentives * * * because they are not considered acute inpatient services based on the level of care provided during a normal nursery stay.''

Such regulatory amendments do not represent a change in policy but rather a clarification of existing policy. The Medicaid share will count only those days that will count as inpatient-bed days for Medicare purposes under section 1886(n)(2)(D) of the Act. (See 75 FR 44498). In addition, in determining the overall EHR amount, section 1903(t)(5)(B) of the Act requires the use of applicable amounts specified in section 1886(n)(2)(A) of the Act.

Comment: A commenter expressed concern with the perceived removal of newborn nursery days from the hospital calculation. The commenter stated that this would create a disadvantage for some hospitals.

Response: We wish to be clear our policy on nursery days is not a new policy or a proposed change. The change in regulatory language on the use of acute inpatient bed days is to ensure that our regulation text clearly reflects our existing policy. The requirement to exclude non-acute inpatient bed days from the incentive payment calculation is consistent with both the Medicare and Medicaid regulations under Stage 1, as stated in our frequently asked questions (available at *https://questions.cms.gov*, FAQ #2991). In that FAQ, we explain that the Medicaid payment to hospitals is based largely on the method that applies to Medicare incentive payments. Because such nursery discharges and bed days would not be included in the Medicare calculation, and because the Medicaid statute incorporates Medicare concepts, they also would not be counted in the Medicaid formula. We are simply adding additional language to clarify that all bed days and discharges used in the calculation are strictly limited to the acute-inpatient portion of the hospital. All hospitals will continue to exclude nonacute bed days and discharges from the hospital incentive calculation.

Comment: A commenter suggested that CMS clarify and inform states and providers that neonatal intensive care days are considered acute, and should be included in the Medicaid hospital incentive payment calculation.

Response: We appreciate the commenter's suggestion and recognize that neonatal intensive care days are considered acute inpatient services that should be included in the hospital incentive calculation.

c. Hospitals Switching States

There may be a situation where a hospital changes participation in one state Medicaid EHR incentive program to participation in another state. We are clarifying that in no case will a hospital receive more than the aggregate incentive amount calculated by the state from which the hospital initiated participation in the program. Section 495.310(e) requires a hospital to choose only one state per payment year from which to receive an incentive payment. Additionally, § 495.310(f)(2) states that in no case can total incentives received by a hospital exceed the aggregate EHR incentive amount, as calculated in § 495.310(g).

In this scenario, both states will be required to work together to determine the remaining payments due to the hospital based on the aggregate incentive amount and incentive amounts already paid. The hospital will then assume the second state's payment cycle, less the money paid from the first state. States should consult with CMS before addressing this specific scenario.

We did not receive any comments and we are finalizing these provisions as proposed for the reasons provided in the proposed rule.

6. Hospital Demonstrations of Meaningful Use—Auditing and Appeals

We proposed revisions to § 495.312 under which states would have the option for CMS to conduct audits and handle any subsequent appeals of whether eligible hospitals are meaningful EHR users, on the state's behalf. (We note that the preamble text (at 77 FR 13788) did not reflect the proposed regulations.) We also proposed revisions to the SMHP requirements in § 495.332 by adding a new paragraph (g) that would allow the state, at the state's option, to include a signed agreement if the state has opted for CMS to conduct such audits and appeals. Under these proposals, the state electing the option would be required to (1) designate CMS to conduct all audits and appeals of eligible hospitals' meaningful use attestations; (2) be bound by the audit and appeal findings; (3) perform any necessary recoupments arising from the audits; and (4) be liable for any FFP granted the state to pay eligible hospitals that, upon audit (and any subsequent appeal) are determined not to have been meaningful EHR users. Finally, we proposed to revise our regulations at § 495.370 to make clear that results of any adverse CMS audits (for states that have made the election) would be subject to the CMS administrative appeals process and not the state appeals process.

Most hospitals are eligible for both Medicare and Medicaid incentive payments, submit attestations on meaningful use to us under the Medicare attestation system, and, if

successful, under the authority of section 1903(t)(8) of the Act, are deemed to have met the meaningful use requirements for Medicaid. Thus, we believe the revisions that were included in our proposed regulation text would provide states with the option to alleviate their burden to develop an audit process for hospitals and then perform audits on hospitals' meaningful use attestations. Because the regulation text made the CMS audits and appeals a state option, no state would be required to delegate the responsibility to CMS.

As discussed in the proposed rule preamble, many states indicated an interest in having CMS audit all hospitals' meaningful use attestations, and a majority of states have two or fewer Medicaid-only hospitals applying for incentive payments. Therefore, a state option for CMS to conduct audits and appeals will leverage the resources already devoted to auditing the vast majority of hospitals that are eligible for both incentive programs while retaining state flexibility to perform their own meaningful use audits and appeals for the Medicaid-only hospitals in states that choose to do so. (In cases where a state has made the election, meaningful use attestation data collected by states for the Medicaid-only eligible hospitals would be shared with our auditors to enable this process).

As discussed in the proposed rule, we note that this policy does not extend to Medicaid eligible professionals, given the anticipated large number of Medicaid eligible professionals demonstrating meaningful use solely under the Medicaid program. In addition, states that opt for CMS to conduct audits and appeals will remain responsible for auditing all other aspects of eligibility for both EPs and eligible hospitals for incentive payments, including, but not limited to—(1) adopt, implement or upgrade; (2) patient volume; (3) average stay length; and (4) calculation of payment amounts. States will also remain responsible for auditing EPs for compliance with meaningful use of certified EHR technology.

We did not receive any comments on either the preamble or the regulation text, and we are finalizing the proposed regulations for the reasons discussed previously.

7. State Flexibility for Stage 2 of Meaningful Use

We proposed to offer states flexibility with the public health measures in Stage 2, similar to that of Stage 1, subject to the same conditions and standards as the Stage 1 flexibility policy. This applies to the public health measures as well as the measure to generate lists of specific conditions to use for quality improvement, reduction of disparities, research or outreach. In addition, we proposed that whether moved to the core or left in the menu, states could also 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 ONC EHR certification criteria as finalized for Stage 2 of meaningful use.

We did not receive any comments on this policy. Although § 495.316(d)(2) already contains provisions for state flexibility, there are new public health measures for Stage 2 of meaningful use and some of the descriptions are changing slightly for Stage 2. Therefore, in this final rule, we have amended § 495.316(d)(2) to ensure that the objectives for which states will have flexibility are adequately represented for both Stage 1 and Stage 2.

8. State Medicaid Health Information Technology Plan (SMHP) and Implementation Advance Planning Document (IAPD)

a. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates

We proposed to revise § 495.342 regarding the frequency of HIT IAPD updates. Rather than requiring each state to submit an annual HIT IAPD within 60 days from the HIT IAPD approved anniversary date, we proposed to require that a state's annual IAPD (also known as an IAPD Update (IAPD–U)) be submitted a minimum of 12 months from the date of the last CMS approved HIT IAPD. For example, if the initial HIT IAPD or previous IAPD–U was approved by CMS effective July 25, 2011, the state must submit their next HIT IAPD–U on or before July 25, 2012. Therefore, annual IAPD updates are required only if the state has not submitted an IAPD–U in the past 12 months, rather than on a fixed annual basis as currently reflected in § 495.342. We did not propose to change the requirements of the circumstances of ''as needed'' IAPD updates as defined by § 495.340.

Comment: Comments received on the change to the annual HIT IAPD submission deadline requirements were supportive of the change and the idea of reducing the administrative burden on states. A commenter requested that the phrase, ''minimum of 12 months'' be changed to ''maximum of 12 months.''

Response: We believe that a better solution would be to remove the word ''minimum'' from the text so it reads, ''Each state is required to submit the HIT IAPD Updates 12 months from the date of the last CMS approved HIT IAPD and must contain the following.'' This more accurately describes the intent to clarify the timeline in which the state must submit the annual HIT IAPD. Therefore, § 495.342 is revised accordingly.

b. Requirements of States Transitioning From HIT Planning Advanced Planning Documents (P–APDs) to HIT IAPDs

We proposed the following process for states that have an approved HIT P–APD and are ready to submit a HIT IAPD for review and approval. We do not allow states to have more than one HIT Advance Planning Document (APD) open at a time. If planning activities from the HIT P–APD have been completed, in their HIT IAPD the state should explain in a narrative format that all planning activities have been completed and the planning advanced planning document can be closed out. If there are HIT planning activities that the state determines will continue during the implementation period, these planning activities must be included as line items within the HIT IAPD budget.

We did not receive any comments on this discussion of the process states should use. We will use the previously-described process for states transitioning from a HIT P–APD to a HIT IAPD.

III. Waiver of Delayed Effective Date

We ordinarily provide a 60-day delay in the effective date of the provisions of a major rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in effective date if the Secretary finds, for good cause, that such delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued under 5 U.S.C. 553(d)(3) and 5 U.S.C. 808(2).

The Secretary finds that good cause exists to make certain regulatory provisions effective upon publication in the **Federal Register**.

Our revisions to § 495.6(f) and (g) change certain criteria for meaningful use beginning with FY 2013. Some eligible hospitals and CAHs will begin their EHR reporting period using the criteria under § 495.6(f) and (g)

beginning October 1, 2012. All of these changes are optional and are meant to provide greater flexibility in meeting these criteria. Because these revisions relieve a restriction on eligible hospitals and CAHs, a waiver of the delayed effective date is in order. It is both unnecessary to delay the effective date, and in the public's best interest to waive the delay in effective date for these changes. Furthermore, ensuring that these provisions are effective beginning with FY 2013 would mitigate any disadvantage experienced by eligible hospitals and CAHs beginning their EHR reporting periods at the beginning of the fiscal year, because it would allow them to use these revised criteria at the beginning of such period. Our revisions to § 495.6(f) include eliminating the reporting of clinical quality measures as a separate objective of meaningful use and instead including this reporting requirement as part of the definition of ''meaningful EHR user'' under § 495.4. Accordingly, the delayed effective date must also be waived with regard to the definition of ''meaningful EHR user'' under § 495.4 and the revisions to § 495.8. To allow these provisions to take effect with the beginning of FY 2013, it is impracticable to delay the effective date, which would occur after the beginning of the fiscal year.

We have also made a technical correction to § 495.102(c) so that it correctly reflects the policy we adopted in the Stage 1 final rule for EPs who predominantly furnish services in a geographic HPSA. This change is technical in nature and merely codifies our existing policy. Retaining current regulatory language would allow an error to persist. Therefore, it is unnecessary, impracticable, and contrary to the public interest to delay the effective date of this codification.

We are also waiving the delay in effective date for all of the changes we are making to subpart D of part 495. Some of these changes either codify or more clearly specify already existing policy (deletions of § 495.310(a)(1)(ii), § 495.310(a)(2)(ii), and § 495.332(d)(9) to reflect the existing policy on net average allowable cost under the Medicare and Medicaid Extenders Act of 2010; changes to § 495.310(g) to clarify that the rules are for ''acute-care inpatient discharges'' and ''acute care inpatient bed-days''; changes to § 495.310 to clarify policy on hospitals switching states). Therefore, it is unnecessary, impracticable, and contrary to the public interest to delay the effective date of these provisions as they are already in effect as CMS policies.

Others of these changes merely provide states or eligible providers with additional flexibility to adopt policies that will be of benefit to the states or providers, thus relieving a restriction (§ 495.302 change in definition for children's hospital and practices predominantly; § 495.304 regarding allowing EPs and eligible hospitals to include individuals enrolled in a Medicaid program in 2013; changes to § 495.306 regarding additional flexibility for determining patient volume in 2013; changes to § 495.312 and § 495.332(c) and (g) and § 495.370 regarding additional options for states in conducting audits and appeals of eligible hospitals' meaningful use; and changes to § 495.342 adding flexibility on submission of the HIT IAPD). These changes will be in the public interest of states or eligible providers or both, because they provide additional flexibility allowing states to relieve their burdens, or allowing additional providers to qualify for Medicaid incentives under the program. It is important that these changes be in place as soon as possible, and especially as of October 1, 2012 for eligible hospitals beginning their fiscal years. Therefore, a waiver in the delay in the effective date is both impracticable and contrary to the public interest, and the Secretary finds good cause not to delay the effective date of these provisions.

The final change to subpart D (in § 495.304(f) and § 495.332(b)(6)) applies to EPs, who will not begin payment year 2013 until the beginning of the calendar year in any case. However, in the interest of ensuring that states have a reasonable opportunity to amend their SMHPs and to ensure consistency in effective date for the entire subpart it is in the public interest to waive the delay in effective date for these changes as well. Again, the effect on EPs would not take place until January of 2013 in any case—well after a 60-day delay has occurred.

For all these reasons, we believe that a 60-day delay in the effective date of the previously discussed provisions would be unnecessary, impracticable, and contrary to the public interest. Therefore, we find good cause for waiving the 60-day delay in the effective date for these provisions and making the provisions effective upon publication.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

The following is a discussion of the requirements we believe are subject to the PRA and collection of information requirements (ICRs) as a result of this final rule. This analysis finalizes our projections which were proposed in the March 7, 2012 **Federal Register** (77 FR 13790 through 13800) in which we proposed a revision to the existing PRA package approved under OMB control number 0938–1158. The projected numbers of EPs, eligible hospitals, CAHs, MA organizations, MA EPs, and MA-affiliated hospitals are based on the numbers used in the impact analysis assumptions as well as estimated federal costs and savings in section V. of this final rule. The actual burden will remain constant for all of Stage 2 as EPs, eligible hospitals, and CAHs will only need to attest that they have successfully demonstrated meaningful use one time per year. The only variable from year to year in Stage 2 will be the number of respondents, as noted in the impact analysis assumptions. For the purposes of this analysis, we are focusing only on 2014, the first year in which a provider may participate in Stage 2 of the Medicare EHR Incentive Program. We do not believe the burden for EPs, eligible hospitals, and CAHs participating in Stage 1 prior to 2014 will be different from the agency information collection activities (75 FR 65354) based on this final rule. Beginning in 2012, Medicare EPs, eligible hospitals, and CAHs have the option to electronically report their clinical quality measures through the respective electronic reporting pilots. The burden for the EP pilot is discussed in the CY 2012 Medicare PFS final rule with comment period (76 FR 73450 through 73451). For eligible hospitals and CAHs, the burden is discussed in the CY 2012 OPPS final rule with comment period (76 FR 74489 through 74492).

A. ICR Regarding Demonstration of Meaningful Use Criteria (§ 495.6 and § 495.8)

In § 495.6 of the proposed rule, we proposed that to successfully demonstrate meaningful use of CEHRT for Stage 2, 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 § 495.6. In § 495.8, we proposed that a provider must also successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable. We assumed that the CEHRT adopted by the provider would capture many of the objectives and associated measures and generate automated numerator and denominator information where required, or generate automated summary reports. 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 EPs would be required to report on a total of 17 core objectives and associated measures, 3 of 5 menu set objectives and associated measures, and 12 ambulatory clinical quality measures. We estimated the total average annual cost burden for all 198,912 nonhospital-based EPs who may attest in 2014 to be $186,098,885 (198,912 EPs × 10 hours 24 minutes × $89.96 (mean hourly rate for physicians based on May 2010 Bureau of Labor Statistics (BLS) data)). We proposed that eligible hospitals and CAHs would be required to report on a total of 16 core objectives and associated measures, 2 of the 4 menu set objectives and associated measures, and 24 clinical quality measures. We estimated the total 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 would be $2,375,564 (4,993 eligible hospitals and CAHs × $62.23 (12 hours 14 minutes × $62.23 (mean hourly rate for lawyers based on May 2010 BLS) data)).

Comment: A commenter suggested CMS account for Web site responsiveness when estimating the burden for providers as they enter attestation data. The commenter noted that the Web site would take several minutes after entering data until the next page would become available.

Response: We cannot forecast technical difficulties with our Web sites, but strive to maintain a high level of responsiveness.

Comment: Some commenters suggested CMS underestimated the amount of time it takes providers to attest that they have successfully demonstrated meaningful use. They noted that providers see attestation as more than just reporting their data at the end of the reporting period, rather, a process that is continuously monitored throughout that time. Others noted that the operational burden that providers encounter on a per-patient basis will increase significantly in Stage 2.

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 individual providers' workflows or training needs to participate in these programs.

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.

In this final rule, there are 13 core objectives and up to 3 menu set objectives that will require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs will have to attest they have met 10 core objectives and 3 menu set 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 CEHRT. 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 their 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 3 core objectives and up to 3 menu set objectives that will require a ''yes'' or ''no'' response during attestation. For eligible hospitals and CAHs, there are 5 core objectives and that will require a ''yes'' or ''no'' response during attestation and no such menu set objectives. We expect that it will take a provider or their designee 1 minute to attest to each objective that requires a ''yes'' or ''no'' response.

Providers will also be required to attest that they are protecting electronic health information. We estimate completion of the analysis required to successfully meet the associated measure for this objective will take approximately 6 hours, which is identical to our estimate for the Stage 1 requirement. 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.

Table 20 lists those objectives and associated measures for EPs, eligible hospitals and CAHs. We estimate the core set of objectives and associated measures will take an EP 8 hours and 13 minutes to complete, and will take an eligible hospital or CAH 7 hours and 45 minutes to complete. For EPs, we estimate the completion of 3 menu set objectives and associated measures will take between 3 minutes and 30 minutes to complete, depending on the combination of objectives they choose to attest to. We estimate the selection, preparation, and electronic submission of the 9 ambulatory clinical quality measures will take EPs 1 hour and 30 minutes. We estimate it will take eligible hospitals and CAHs 30 minutes to attest to the 3 menu set objectives they choose. For eligible hospitals and CAHs, we estimate the selection, preparation, and electronic submission of 16 required clinical quality measures will take 2 hours and 40 minutes.

TABLE 20—BURDEN ESTIMATES

Eligible professionals	Eligible hospitals and CAHs	Stage 2 measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
CORE SET				
Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	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, or all prescriptions written by the EP and queried for a drug formulary and transmitted electronically using CEHRT.	10 minutes.	
Record the following demographics. • Preferred language • Sex • Race • Ethnicity • Date of birth	Record the following demographics. • Preferred language • Sex • Race • Ethnicity • Date of birth • Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data.	10 minutes	10 minutes.
Record and chart changes in vital signs:. • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0–20 years, including BMI	Record and chart changes in vital signs:. • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0–20 years, including BMI	More than 80% of all unique patients 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 blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.	10 minutes	10 minutes.
Record smoking status for patients 13 years old or older.	Record smoking status for patients 13 years old or older.	More than 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) have smoking status recorded as structured data.	10 minutes	10 minutes.
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 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 improving healthcare efficiency.		

TABLE 20—BURDEN ESTIMATES—Continued

Eligible professionals	Eligible hospitals and CAHs	Stage 2 measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
.....	.....	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.
Incorporate clinical lab-test results as structured data.	Incorporate clinical lab-test results as structured data.	More than 55% of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in CEHRT as structured data.	10 minutes	10 minutes.
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.	1 minute	1 minute.
Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder, per patient preference.	.....	More than 10% of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available.	10 minutes.	
	Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).	More than 10% 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 for which all doses are tracked using eMAR.	.....	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% 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. 2. More than 5% of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download, or transmit to a third party their health information.	10 minutes.	

TABLE 20—BURDEN ESTIMATES—Continued

Eligible professionals	Eligible hospitals and CAHs	Stage 2 measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
	Provide patients the ability to view online, download, and transmit information about a hospital admission.	1. More than 50% 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. 2. More than 5% of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period.	.....	10 minutes.
Provide clinical summaries for patients for each office visit.	.....	Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50% of office visits.	10 minutes.	
Use CEHRT to identify patient-specific education resources and provide those resources to the patient.	Use 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.
Use secure electronic messaging to communicate with patients on relevant health information.	.....	A secure message was sent using the electronic messaging function of CEHRT by more than 5% of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period.	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.

TABLE 20—BURDEN ESTIMATES—Continued

Eligible professionals	Eligible hospitals and CAHs	Stage 2 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 provides a summary of care record for more than 50% of transitions of care and referrals. 2. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. 3. An EP, eligible hospital or CAH must satisfy one of the two following criteria: (A) conducts one or more successful electronic exchanges of a summary of care document, as part of which is counted in "measure 2" (for EPs the measure at § 495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs the measure at § 495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was developed designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2).	10 minutes	10 minutes.
Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic immunization data from CEHRT to an immunization registry or immunization information system for the entire EHR reporting period.	1 minute	1 minute.
	Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic reportable laboratory results from CEHRT to public health agencies for the entire EHR reporting period.		1 minute.
	Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period.		1 minute.

TABLE 20—BURDEN ESTIMATES—Continued

Eligible professionals	Eligible hospitals and CAHs	Stage 2 measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
Protect electronic health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	Protect electronic health information 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 encryption/security 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.
Core Set Burden			8 hours 13 minutes	7 hours 45 minutes.
MENU SET				
	Record whether a patient 65 years old or older has an advance directive.	More than 50% of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.		10 minutes.
Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT.	Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT.	More than 10% of all tests whose result is one or moreimages ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through CEHRT.	10 minutes	10 minutes.
Record patient family health history as structured data.	Record patient family health history as structured data.	More than 20% of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.	10 minutes	10 minutes.
	Generate and transmit permissible discharge prescriptions electronically (eRx).	More than 10% 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.		10 minutes

TABLE 20—BURDEN ESTIMATES—Continued

Eligible professionals	Eligible hospitals and CAHs	Stage 2 measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
Record electronic notes in patient records.	Record electronic notes in patient records.	Enter at least one electronic progress note created, edited, and signed by an eligible professional for more than 30 percent of unique patients with at least one office visit during the EHR reporting period. Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. Electronic progress notes must be text-searchable. Nonsearchable, notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be included with searchable notes under this measure.	10 minutes	10 minutes.
	Provide structured electronic lab results to ambulatory providers.	Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20% of electronic lab orders received.		10 minutes
Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period.	1 minute.	
Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period.	1 minute.	
Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of specific case information from CEHRT to a specialized registry for the entire EHR reporting period.	1 minute.	
Menu Set Least Burdensome Criteria			3 minutes.	
Menu Set Most Burdensome Criteria			30 minutes	30 minutes.
Time to Attest and Report Clinical Quality Measures			1 hour 30 minutes	2 hours 40 minutes.
Total—Core Set (including CQMs) + Least Burdensome Menu Set Criteria			9 hours 46 minutes.	
Total—Core Set (including CQMs) + Most Burdensome Menu Set Criteria			10 hours 13 minutes.	10 hours 55 minutes.

First, we will discuss the burden associated with the EP attestation to meeting the core meaningful use objectives and associated measures. We estimate that it will take no longer than 8 hours and 13 minutes to attest that

during the EHR reporting period, they used the CEHRT, specify the EHR technology used, and satisfy each of the applicable core objectives and associated measures. We estimate it will take an EP 30 minutes if they choose to submit the most burdensome objectives and associated measures from the menu set. If an EP chooses to attest to the least burdensome menu set objectives and associated measures, we estimate this will take approximately 3 minutes. We also estimate that it will take an EP an additional 1 hour and 30 minutes to select, prepare, and electronically submit the ambulatory clinical quality measures. The total burden hours for an EP to attest to the most burdensome criteria previously specified is 10 hours and 13 minutes. The total burden hours for an EP to attest to the least burdensome criteria previously specified is 9 hours and 46 minutes. We estimate that there could be approximately 537,600 nonhospital-based Medicare and Medicaid EPs in 2014. We anticipate approximately 37 percent (198,912) of these EPs may attest to the information previously specified (after registration and completion of Stage 1) in CY 2014 to receive an incentive payment. We estimate the burden for the approximately 13,000 MA EPs in the MAO burden section. We estimate the total burden associated with these requirements for an EP is 10 hours and 13 minutes (8 hours 13 minutes + 30 minutes + 1 hour 30 minutes). The total estimated annual cost burden for all EPs to attest to EHR technology, meaningful use core set and most burdensome menu set criteria, and electronically submit the ambulatory clinical quality measures is $182,877,942 (198,912 EPs × 10 hours 13 minutes × $89.96 (mean hourly rate for physicians based on May 2010 Bureau of Labor Statistics (BLS) data)). We estimate the total burden associated with these requirements for an EP is 9 hours and 46 minutes (8 hours 13 minutes + 3 minutes + 1 hour 30 minutes). The total estimated cost burden for all EPs to attest to EHR technology, meaningful use core set and least burdensome menu set criteria, and electronically submit the ambulatory clinical quality measures is $174,825,587 (198,912 EPs × 9 hours 46 minutes × $89.96 (mean hourly rate for physicians based on May 2010 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 7 hours and 45 minutes to attest that during the EHR reporting period, they used the CEHRT, specify the EHR technology used, and satisfied each of the applicable core objectives and associated measures. We estimate it will take an eligible hospital or CAH 30 minutes to choose and submit the objectives and associated measures from the menu set. We also estimate that it will take an eligible hospital or CAH an additional 2 hours and 40 minutes to select, prepare, and electronically submit the clinical quality measures. Therefore, the total burden hours for an eligible hospital or CAH to attest to the aforementioned criteria is 10 hours, 55 minutes. We estimate that there are about 4,993 eligible hospitals and CAHs (3,573 acute care hospitals, 1,325 CAHs, 84 children's hospitals, and 11 cancer hospitals) that may attest to the aforementioned criteria (after registration and completion of Stage 1) in FY 2014 to receive an incentive payment. We estimate the burden for the 30 MA-affiliated hospitals in section III.B. of this final rule. We estimate the total burden associated with these requirements for an eligible hospital or CAH is 10 hours and 55 minutes (7 hours 45 minutes + 30 minutes + 2 hours 40 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 is $2,069,061 (4,993 eligible hospitals and CAHs × $62.23 (11 hours 4 minutes × $62.23 (mean hourly rate for lawyers based on May 2010 BLS) data)).

B. 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 in Stage 2, because—(1) qualifying MA organizations do not have to report the ambulatory clinical quality measures for their qualifying MA EPs; and (2) 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 en 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 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 eligible professionals, but non-clinical staff. We believe that the individual gathering the information could be equivalent to a GS 9, step 1, 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, or approximately $59.00/hour. Therefore, for the approximately 13,000 potentially qualifying MA EPs, we believe it will cost the participating qualifying MA organizations approximately $435,500 annually to make the attestations ([9,750 hours × $25.00] + [3,250 hours × $59.00]).

Furthermore, MA-affiliated eligible hospitals will be able to complete the attestations slightly faster than eligible hospitals because MA-affiliated eligible hospitals do not have to report the hospital clinical quality measures. While it is estimated that it will take an eligible hospital or CAH approximately between 16 hours, 24 minutes and 16 hours, 33 minutes to attest to the applicable meaningful use objectives and associated measures, 8 of those hours are attributed to reporting clinical quality measures, which MA organizations do not have to report. Therefore, we estimate that it will take between 8 hours, 24 minutes and 8 hours, 33 minutes (which on average is 8 hours 29 minutes) for an MA organization's MA-affiliated eligible hospitals to make the attestations. We believe that the individual gathering the information could be equivalent to a GS 9, step 1, 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, or approximately $59.00/hour. We believe that the person gathering the information could dedicate 7 of the estimated hours to gathering the information, and the individual certifying could take 1 hour and 29 minutes of the estimated time. Therefore, for the approximately 30 potentially qualifying MA-affiliated eligible hospitals, we believe it will cost the participating qualifying MA organizations in the aggregate approximately $7,870 annually to

successfully attest ([210 hrs × $25.00] + [44 hrs × $59.00]).

We did not receive any comments and we are finalizing these estimates as proposed.

C. ICRs Regarding State Medicaid Agency and Medicaid EP and Hospital Activities (§ 495.332 Through § 495.344)

The burden associated with this section is the time and effort associated with completing the single provider election repository and each state's process for the administration of the Medicaid incentive payments, including tracking of attestations and oversight; the submission of the state Medicaid HIT Plan and the additional planning and implementation documents; enrollment or reenrollment of providers, and collection and submission of the data for providers to demonstrate that they have adopted, implemented, or upgraded CEHRT or that they are meaningful users of such technology. We believe the burden associated with these requirements has already been accounted for in our discussion of the burden for § 495.316 in the Stage 1 final rule. However, we proposed to revise 42 CFR 495 regarding the frequency of HIT IAPD updates. Rather than requiring each state to submit an annual HIT IAPD within 60 days from the HIT IAPD approved anniversary date, we proposed to require that a state's annual IAPD or IAPD Update (IAPD–U) be submitted at a minimum of 12 months from the date of the last CMS approval. We are finalizing our proposed revision to 42 CFR 495; therefore, annual IAPD updates are only required if a state has not submitted an IAPD–U in the past 12 months, which will create less of a burden on the states. We expect that it will take a state 70 hours to update an annual IAPD. We believe that the requirement for states to agree to have CMS conduct audits and appeals for hospitals for meaningful use will reduce state burden, as they will not conduct their own audits. Also, the alternatives for calculating patient volume will alleviate state burden as patient volume will be more easily calculated.

We did not receive any comments and we are finalizing these estimates as proposed.

TABLE 21—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING REQUIREMENTS

Reg section	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
§ 495.6—EHR Technology Used, Core Set Objectives/Measures (EPs)	???-New	198,912	198,912	8.22	1,635,057	89.96	147,089,695.33
§ 495.6—Menu Set Objectives/Measures (EPs) HIGH	???-New	198,912	198,912	0.50	99,456	89.96	8,947,061.76
§ 495.6—Menu Set Objectives/Measures (EPs) LOW	???-New	198,912	198,912	0.05	9,946	89.96	894,706.18
§ 495.6—Menu Set Objectives/Measures (EPs) AVERAGE	???-New	198,912	198,912	0.28	54,701	89.96	4,920,883.97
§ 495.8—CQMs for EPs	???-New	198,912	198,912	1.50	298,368	89.96	26,841,185.28
§ 495.6—EHR Technology Used, Core Set Objectives/Measures (hospitals/CAHs)	???-New	2,696	2,696	7.75	20,894	62.23	1,300,233.62
§ 495.6—Menu Set Objectives/Measures (hospitals/CAHs)	???-New	2,696	2,696	0.50	1,348	89.96	121,266.08
§ 495.8—CQMs for hospitals/CAHs	???-New	2,696	2,696	2.67	7,198	89.96	647,560.87
§ 495.210—Gather information for attestation (MA EPs)	???-New	13,000	13,000	0.75	9,750	25.00	243,750.00
§ 495.210—Attesting on behalf of MA EPs	???-New	13,000	13,000	0.25	3,250	59.00	191,750.00
§ 495.210—Total cost of attestation for Stage 2 (MA EPs)	???-New	13,000	13,000	1.00	13,000	n/a	435,500.00
§ 495.210—Gather information for attestation (MA-affiliated hospitals)	???-New	30	30	7.00	210	25.00	5,250.00

TABLE 21—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING REQUIREMENTS—Continued

Reg section	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
§ 495.210—Attesting on behalf of MA-affiliated hospitals	???-New	30	30	1.48	44	59.00	2,619.60
§ 495.210—Total cost of attestation for Stage 2 (MA-affiliated hospitals)	???-New	30	30	8.48	254	n/a	7,869.60
§ 495.342–1. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates	???-New	56	56	70.00	3,920	56.24	220,460.80
Burden Total for 2014					2,034,740.16		181,584,656

Note: All nonwhole numbers in this table are rounded to 2 decimal places.

If you would like to comment on these information collection and recordkeeping requirements, submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–0044–F], Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule will implement the provisions of the ARRA that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and meaningfully use CEHRT. The final rule specifies applicable criteria for earning incentives and avoiding payment adjustments.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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 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 that to the best of our ability presents the costs and benefits of the final rule.

As noted in section I. of this final rule, this final rule is one of two coordinated rules related to the adoption and meaningful use of CEHRT. The other is ONC's final rule, 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'' published elsewhere in this **Federal Register**. This analysis focuses on the impact associated with Stage 1 meaningful use participation in 2014, Stage 2 requirements for meaningful use, the changes in quality measures that will take effect beginning in 2014, and other changes in the Medicare and Medicaid EHR Incentive Programs.

A number of factors will affect the adoption of EHR systems and demonstration of meaningful use. Many of these factors are addressed in this analysis and in the provisions of the final rule 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'' published elsewhere in this **Federal Register**. Readers should understand that these forecasts are also subject to substantial uncertainty since demonstration of meaningful use will depend not only on the standards and requirements for FYs 2014 and 2015 for eligible hospitals and CYs 2014 and 2015 for EPs, but on future rulemakings issued by the HHS.

The Act 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 CEHRT. Payment adjustments are incorporated into the Medicare 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 disadvantaged 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

incentives 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.

One legislative uncertainty arises because under current law, physicians are scheduled for payment reductions under the sustainable growth rate (SGR) formula for determining Medicare payments. The current override of SGR payment reductions prevents any further reductions of Medicare physician payments throughout the rest of 2012. Any payment reductions implemented in CY 2013 and subsequent calendar years could cause major changes in physician behavior, enrollee care, and other Medicare provider payments, but the specific nature of these changes is exceptionally uncertain. Under a current law scenario, the EHR incentives or payment adjustments will exert only a minor influence on physician behavior relative to any large payment reductions. However, the Congress has legislatively avoided physician payment reductions for each year since 2002.

All of these factors taken together make it difficult to predict with precision the timing or rates of adoption and ultimately meaningful use. Further, new data regarding rates of adoption or costs of implementation is just starting to emerge. Because of this continued uncertainty, these estimates for adoption rates should be used with caution. Our estimate of meaningful use demonstration assumes that by 2019 nearly 100 percent of hospitals and nearly 70 percent of EPs will be meaningful users. This estimate is based on the substantial economic incentives created by the combined direct and indirect factors affecting providers.

Data from the EHR Incentive Program to date has shown that about 12 percent of EPs and 8 percent of hospitals received incentive payments in 2011, the first year. This may be because providers have taken a ''wait and see approach'' in the first year of implementation or that they have had problems receiving certified systems. Two thousand eleven was the first year of the program and saw initially slow, but rapidly accelerating, growth in qualification for and payment of meaningful use incentives. Given that this is very early data, and given the differences between Stage 1 and Stage 2 requirements, this data only indicates preliminary penetration rates.

Overall, we expect spending under the EHR incentive program for transfer payments to Medicare and Medicaid providers between 2014 and 2019 to be $15.4 billion (these estimates include payment adjustments for Medicare providers who do not achieve meaningful use in 2015 and subsequent years in the amount of $2.1 billion). 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 also that adopting entities will achieve dollar savings at least equal to their total costs, and that there will be additional benefits to society. We believe that implementation costs are significant for each participating entity because providers must purchase CEHRT to qualify as meaningful users of EHRs. However, we believe that providers who have already purchased CEHRT and participated in Stage 1 of meaningful use will experience significantly lower costs for participation in the program. We continue to believe that the short-term costs to demonstrate meaningful use of CEHRT are 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 to the best of our ability presents the costs and benefits of this final rule.

Previously, the Stage 2 proposed rule and the Stage 1 final rule impact analyses showed two plausible scenarios for program costs. In this RIA, we are showing a scenario based on the FY 2013 Mid-Session Review of the President's budget. The estimates are based on the limited actual historical data that is now available for the EHR Incentive Programs. The new projections differ somewhat from the two scenarios presented previously. The major reasons for the differences are different assumed penetration rates based on more recent data and analysis, and revised assumptions as to the timing of payments in relation to when meaningful use is achieved based on the actual experience of the programs to date. When compared with the two illustrations from the Stage 2 proposed rule and Stage 1 final rule, the penetration rates for the current estimates are generally closer to those in the high cost scenario. In general, the actual program experience, which is included in the new estimates, showed somewhat lower payments early in the first year, and somewhat higher payments towards the end of the first year than assumed in the two previously-used scenarios. The accounting statement numbers under the 7-percent discount for the two scenarios from the previous estimates were $706 million and $2,346 million. The current accounting statement number under the 7-percent discount is $2,558 million. The current projections, while based on more up-to-date information, are still very uncertain and actual future outcomes are likely to differ somewhat from these projections.

Comment: A commenter suggested that the impact analysis should only address Stage 2 of the EHR Incentive Programs.

Response: Although we considered the idea of only addressing Stage 2 in this impact analysis, we do not believe that such an analysis would provide a comprehensive impact of this final rule. This final rule establishes not only Stage 2 criteria but also changes to Stage 1 criteria and both payment adjustments and hardship exceptions that could affect providers at all stages of meaningful use. In addition, providers in all payment years will be at differing stages of meaningful use, and any impact analysis that focused on a single stage would not accurately capture the costs and benefits that accrue from all providers who are participating in the EHR Incentive Programs during a given payment year. Therefore, we include all providers in this impact analysis.

C. Anticipated Effects

The objective of the remainder of this 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 industry for implementation of this technology.

1. Overall Effects

a. Regulatory Flexibility Analysis and Small Entities

The Regulatory Flexibility Act (RFA) requires agencies to prepare a Final 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 million and $34 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 will be economically significant. Accordingly, this RIA section, in conjunction with the remainder of the preamble, constitutes the required Regulatory Flexibility Analysis. 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 will make it attractive to virtually all eligible entities. Furthermore, entities that do not demonstrate meaningful use of EHR technology for an applicable reporting period will be subject to significant Medicare payment reductions beginning with 2015. The anticipation of 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 they currently have could be upgraded to meet the criteria for certified EHR technology 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 noncertified 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.

The most recent data available suggests that more providers have adopted EHR technology since the publication of the Stage 1 final rule. A 2011 survey conducted by the ONC and the AHA found that the percentage of U.S. hospitals which had adopted EHRs doubled from 16 to 35 percent between 2009 and 2011. In November 2011, a CDC survey found the percentage of physicians who adopted basic EHRs in their practice had doubled from 17 to 34 percent between 2008 and 2011, with the percent of primary care doctors using this technology nearly doubling from 20 to 39 percent. While these numbers are encouraging, they are still low relative to the overall population of providers. The majority of EPs still need to purchase certified EHR technology, implement this new technology, and train their staff on its use. The costs for implementation and complying with the criteria of meaningful use could lead to higher operational expenses. However, we believe that the combination of payment incentives and long-term overall gains in efficiency will compensate for the initial expenditures.

(1) Number of Small Entities

In total, we estimate that there are approximately 624,000 healthcare organizations (EPs, practices, eligible hospitals or CAHs) that will be affected by the incentive program. These include hospitals and physician practices as well as doctors of medicine or osteopathy, dental surgery or dental medicine, podiatric medicine, optometry or a chiropractor. Additionally, as many as 47,000 nonphysician practitioners (such as certified nurse-midwives, etc) will be eligible to receive the Medicaid incentive payments.

Of the 624,000 healthcare organizations we estimate will be affected by the incentive program, we estimate that 94.71 percent will be EPs, 0.8 percent will be hospitals, and 4.47 percent will be MA organization physicians or hospitals. We further estimate that EPs will 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). 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, 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. 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 to achieve meaningful use. We estimate $1 million for maintenance, upgrades, and training each year.

(2) Conclusion

As discussed later in this analysis, we believe that there are many positive effects of adopting EHR on health care providers, quite apart from the incentive payments to be provided under this rule. While economically significant, we do not believe that the net effect on individual providers will be negative over time except in very rare cases. Accordingly, we believe that the object of the RFA to minimize burden on small entities is met by this rule.

b. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a 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. This final rule 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 certified EHR technology by the applicable reporting period. As stated previously, we have determined that this final rule 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 will arise from the implementation of certified EHR technology in a rural eligible hospital will 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, we have statutory authority to make case-by-case exceptions for significant hardship, and proposed certain case-by-case applications that may be made when there are barriers to internet connectivity that will impact health information exchange.

c. 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 2012, that threshold is approximately $139 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 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 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 will be required to invest in systems and technology to comply. States will have to identify and educate providers, evaluate their attestations and pay the incentive. However, the Federal government will fund 90 percent of the State's related administrative costs, providing controls on the total State outlay.

The investments needed to meet the meaningful use standards 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 will have a negative impact on providers that fail to meaningfully use certified EHR technology for the applicable 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 $139 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.

d. 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 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 this final rule does add a new business requirement for States, because of the existing systems that will need to be modified to track and report on the new meaningful use requirements for provider attestations. We are providing 90 percent 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.

2. Effects on Eligible Professionals, Eligible Hospitals, and CAHs

a. Background and Assumptions

The principal costs of this final rule are the additional expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt, implement or upgrade and/or demonstrate 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 somewhat uncertain for several reasons: (1) 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 reporting period; (2) the Stage 1 and Stage 2 criteria for the demonstration of meaningful use of CEHRT has been finalized, but will change in Stage 3 and over time; and (3) the impact of the financial incentives and payment adjustments on the rate of adoption of certified EHR technology by EPs, eligible hospitals, and CAHs is difficult to predict based on the information we have currently collected. The net costs and savings shown for this program represent a possible scenario and actual impacts could differ substantially.

Based on input from a number of internal and external sources, including the Government Accountability Office (GAO) and CBO, we estimated the numbers of EPs and eligible hospitals, including CAHs under Medicare, Medicaid, and MA and used them throughout the analysis.

- About 568,900 Medicare FFS EPs in 2014 (some of whom will also be Medicaid EPs).
- About 14 percent of the total EPs are hospital-based Medicare EPs, and are not eligible for the program. This leaves approximately 491,000 nonhospital-based Medicare EPs in 2014.
- About 20 percent of the nonhospital-based Medicare EPs (approximately 98,200 Medicare EPs in 2014) are *also* eligible for Medicaid (meet the 30 percent Medicaid patient volume criteria), but can only be paid under one program. We assume that any EP in this situation will choose to receive the Medicaid incentive payment, because it is larger.
- About 46,600 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible nonphysicians such as certified nurse-midwives, nurse practitioners and physicians assistants) will be eligible to receive the Medicaid incentive payments.
- 4,993 eligible hospitals comprised of the following:
  - ++ 3,573 acute care hospitals.
  - ++ 1,325 CAHs.
  - ++ 84 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.
- 12 MA organizations (about 28,000 EPs, and 29 hospitals) will be eligible for incentive payments.

b. Industry Costs and Adoption Rates

In the Stage 1 final rule (75 FR 44545 through 44547), we estimated the impact on healthcare providers using information from the same four studies cited previously in this final rule. Based on these studies and current average costs for available certified EHR technology 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, the range is from $1 million to $100 million. Although reports vary widely, we anticipate that the average will be $5 million to achieve meaningful use, because providers who will like to 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 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. 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. These estimates are similar to estimates made in the Stage 1 final rule. 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.

Comment: Some commenters suggested that specific costs and financial gains for each provider be recorded as part of attestation to inform the overall impact analysis. Another commenter suggested that the analysis should include costs associated with unintended consequences of the regulation, such as the loss of revenue to providers through the elimination of unnecessary or duplicative tests and the resistance of the market to improving patient care under such circumstances. The commenter also suggested that the impact analysis should be stratified according to primary care and specialty providers.

Response: Although we agree that a system that records the specific costs and benefits for each provider would yield a more accurate financial analysis, we believe that such a requirement would place a significant burden on providers and potentially limit participation in the EHR Incentive Programs. We also do not believe that there is an accurate method to calculate the loss of revenue due to the elimination of unnecessary or duplicative tests or market resistance to improving patient care. The reduction of costs while improving patient care is one of the goals of the EHR Incentive Programs, and we do not believe that these reductions should be classified as negative impacts for the healthcare system as they would also lead to lower overall health care costs. Nor do we believe it is possible for us to proactively estimate such savings at this time. Because both primary-care and specialty providers receive the same incentive payment amounts under this program, we do not believe there is a benefit to stratifying the impact analysis in this way.

d. Costs of EHR Adoption for Eligible Hospitals

AHA conducts annual surveys that among other measures, track hospital spending. This data reflects the latest figures from the 2008 AHA Survey. Costs at these levels of adoption were significantly higher in 2008 than in previous years. This may better reflect the costs of implementing additional functionalities. The range in yearly information technology spending among hospitals is large, from $36,000 to over $32 million based on the AHA data. EHR system costs specifically were reported by experts to run as high as $20 million to $100 million. HHS discussions with experts led to cost ranges for adoption that varied by hospital size and level of EHR system sophistication. Research to date has shown that adoption of comprehensive EHR systems is limited. In the aforementioned AHA study, 1.5 percent of these organizations had comprehensive systems, which were defined as hospital-wide clinical documentation of cases, test results, prescription and test ordering, plus support for decision-making that included treatment guidelines. Some 10.9 percent have a basic system that does not include physician and nursing notes, and can only be used in one area of the hospital. Applying a similar standard to the 2008 AHA data, results in roughly 3 to 4 percent of hospitals having comprehensive systems and 12 to 13 percent having basic systems. According to hospital CEOs, the main barrier to adoption is the cost of the systems, and the lack of capital. Hospitals have been concerned that they will not be able to recoup their investment, and they are already operating on limited margins. Because uptake of advanced systems is low, it is difficult to get a solid average estimate for implementation and maintenance costs that can be applied across the industry. In addition, we recognize that there are additional industry costs associated with adoption and implementation of EHR technology that are not captured in our estimates that eligible entities will incur. Because the impact of those activities, such as reduced staff productivity related to learning how to use the EHR technology, the need to add additional staff to work with HIT issues, and administrative costs related to reporting are unknown at this time and difficult to quantify.

Comment: Some commenters suggested that overall IT operating costs should be included as part of the analysis. These commenters also suggested that estimates for costs related to staff training were too low and should include time and resources devoted to understanding the EHR Incentive Programs regulations. Other commenters suggested that costs associated with the time and resources related to registration and attestation should be included as part of the analysis. Finally, some commenters suggested that costs associated with EHR products, consultants, and trained IT professionals have increased since the start of the EHR Incentive Programs and should be reflected in the analysis.

Response: As noted in this impact analysis, we based cost estimates for IT on peer-reviewed studies of EHR and health IT costs. These cost estimates included maintenance and operating costs specific to EHRs and staff training. There are many aspects of IT operating costs that are not directly related to the maintenance or operation of CEHRT, and we do not believe it would be appropriate to include those costs as part of the impact analysis of this regulation. We are not aware of any new data that suggests an overall increase in the costs of CEHRT or related implementation and maintenance costs since the start of the EHR Incentive Programs, and in many cases we believe that the product and maintenance costs of CEHRT can be significantly lower than our estimates. Therefore, we are continuing to use the estimates we proposed for this impact analysis. We also do not believe it is appropriate to include additional costs related to registration and attestation, as the cost for dedicating resources to these activities is addressed earlier in this final rule in our discussion of information collection requirements.

3. Medicare Incentive Program Costs

a. Medicare Eligible Professionals (EPs)

We continue the method of cost estimation we used to determine the estimated costs of the Medicare incentives for EPs in our Stage 1 final rule (75 FR 44549). In order to determine estimated costs, we first needed to determine the EPs with Medicare claims. Then, we calculated that about 14 percent of those EPs are hospital based according to the definition in § 495.4 (finalized in our Stage 1 final rule), and therefore, do not qualify for incentive payments. This percent of EPs was subtracted from the

total number of EPs who have claims with Medicare. These numbers were tabulated from Medicare claims data.

In the Stage 1 final rule, we also estimated that about 20 percent of EPs that were not hospital based will qualify for Medicaid incentive payments and will choose that program because the payments are higher. Current program data does not provide additional evidence regarding this, so we continued to use the 20 percent estimation in the current projections. Of the remaining EPs, we estimated the percentage which will be meaningful users each calendar year. As discussed previously, our estimates for the number of EPs that will successfully demonstrate meaningful use of CEHRT are uncertain. The percentage of Medicare EPs who will satisfy the criteria for demonstrating meaningful use of CEHRT and will qualify for incentive payments is a key, but a highly uncertain factor. Accordingly, the estimated number of nonhospital based Medicare EPs who will demonstrate meaningful use of CEHRT over the period CYs 2014 through 2019 is as shown in Table 22.

TABLE 22—MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

	Calendar year					
	2014	2015	2016	2017	2018	2019
EPs who have claims with Medicare (thousands)	568.9	574.8	580.8	586.8	592.7	598.6
Nonhospital Based EPs (thousands)	491.0	496.1	501.3	506.4	511.5	516.7
EPs that are both Medicare and Medicaid EPs (thousands)	98.2	99.2	100.3	101.3	102.3	103.3
Percent of EPs who are Meaningful Users	37	46	52	57	62	67
Meaningful Users (thousands)	147.1	184.2	206.5	229.3	252.5	276.1

Our estimates of the incentive payments and payment adjustment savings are presented in Table 23. These payments reflect the Medicare and Medicaid incentive payments and payment adjustments included in 42 CFR Part 495 of our regulations. They reflect our assumptions about the proportion of EPs who will demonstrate meaningful use of CEHRT. These assumptions were developed based on a review of the studies presented in the Stage 1 impact analysis.

Specifically, our assumptions are based on literature estimating current rates of physician EHR adoption and rates of diffusion of EHRs and similar technologies. There are a number of studies that have attempted to measure the rate of adoption of electronic medical records (EMR) among physicians prior to the enactment of the HITECH Act (see, for example, Funky and Taylor (2005) The State and Pattern of Health Information Technology Adoption. RAND Monograph MG–409. Santa Monica: The RAND Corporation; Ford, E.W., Menachemi, N., Peterson, L.T., Huerta, T.R. (2009) ''Resistance is Futile: But it is Slowing the Pace of EHR Adoption Nonetheless'' Journal of the American Informatics Association 16(3): 274–281). More recently, there is also some data available to suggest that more providers have adopted EHR technology since the start of the EHR Incentive Programs. The 2011 ONC–AHA survey cited earlier found that the percentage of U.S. hospitals which had adopted EHRs increased from 16 to 35 percent between 2009 and 2011. In November 2011, the CDC survey cited earlier found the percentage of physicians who adopted basic (EHRs in their practice had doubled from 17 to 34 percent between 2008 and 2011. These survey results are in line with the estimated rate of EHR adoption presented in the Stage 1 impact analysis, but they constitute a relatively small sample on which to base new estimates. Therefore we maintain the estimates that were based on the study with the most rigorous definition, though we note again that neither the Stage 1 nor the Stage 2 meaningful use criteria are equivalent to a fully functional system as defined in this study. (DesRoches, CM, Campbell, EG, Rao, SR et al (2008) ''Electronic Health Records in Ambulatory Care-A National Survey of Physicians'' New England Journal of Medicine 359(1): 50–60. In addition, we note that the final penetration rates used in the initial estimates were developed in consensus with industry experts relying on the studies. Actual adoption trends could be different from these assumptions, given the elements of uncertainty we describe throughout this analysis.

Estimated net costs of the Medicare EP portion of the HITECH Act are shown in Table 23.

TABLE 23—ESTIMATED COSTS (+) AND SAVINGS (−) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

[In billions]

Fiscal year	Incentive payments ($)	Payment adjustment receipts	Benefit payments	Net total ($)
2014	1.9			1.9
2015	2.0	−0.1		1.9
2016	0.8	−0.1		0.6
2017	0.3	−0.2		0.1
2018		−0.2		−0.2
2019		−0.2		−0.2

b. Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital adoption were developed by calculating projected incentive payments (which are driven by discharges), comparing them to projected costs of attaining meaningful use, and then making assumptions about how rapidly hospitals will adopt given the fraction of their costs that were covered.

Specifically, the first step in preparing estimates of Medicare program costs for eligible hospitals was to determine the amount of Medicare incentive payments that each hospital in the country could potentially receive under the statutory formula, based on its discharge numbers (total patients and Medicare patients). The total incentive payments potentially payable over a 4-year period vary significantly by hospitals' inpatient caseloads, ranging from a low of about $11,000 to a high of $12.9 million, with the median being $3.8 million. The potential Medicare incentive payments for each eligible hospital were compared with the hospital's expected cost of purchasing and operating certified EHR technology. Costs of adoption for each hospital were estimated using data from the 2009 AHA survey and IT supplement. Estimated costs varied by size of hospital and by the likely status of EHR adoption in that class of hospitals. Hospitals were grouped first by size (CAHs, non-CAH hospitals under 400 beds, and hospitals with 400 or more beds) because EHR adoption costs do vary by size: namely, larger hospitals with more diverse service offerings and large physician staffs generally implement more customized systems than smaller hospitals that might purchase off-the-shelf products. We then calculated the proportion of hospitals within each class that were at one of three levels of EHR adoption: (1) Hospitals which had already implemented relatively advanced systems that included CPOE systems for medications; (2) hospitals which had implemented more basic systems through which lab results could be shared, but not CPOE for medications; and (3) hospitals starting from a base level with neither CPOE or lab reporting. The CPOE for medication standard was chosen for this estimate because expert input indicated that the CPOE standard in the final meaningful use definition will be the hardest one for hospitals to meet. Table 24 provides these proportions.

TABLE 24—HOSPITAL IT CAPABILITIES BY HOSPITAL SIZE

Hospital size	Levels of adoption							
	Any CPOE meds		Lab results		Neither		Total	
	Number of hospitals	Percentage	Number of hospitals	Percentage	Number of hospitals	Percentage	Number of hospitals	Percentage
CAHs	169	22	390	51	210	27	769	23
Small/Medium	834	37	1,051	47	348	16	2,233	67
Large (400+ beds)	200	56	145	41	10	3	355	10
Total	1,203	36	1,586	47	568	17	3,357	100

We then calculated the costs of moving from these stages to meaningful use for each class of hospital, assuming that even for hospitals with CPOE systems they will incur additional costs of at least 10 percent of their IT budgets. These costs were based on cross-sectional data from the AHA survey and thus do not likely represent the true costs of implementing systems. This data reflects the latest figures from the 2009 AHA Survey. Costs at these levels of adoption were significantly higher than in previous years. This may better reflect the costs of implementing additional functionalities. We have also updated the number of discharges using the most recent cost report data available. The payment incentives available to hospitals under the Medicare and Medicaid programs are included in our regulations at 42 CFR part 495. We estimate that there are 12 MAOs that might be eligible to participate in the incentive program. Those plans have 29 eligible hospitals. The costs for the MA program have been included in the overall Medicare estimates.

Our estimated net costs for section 4102 of the HITECH Act are shown in Table 25: Estimated costs (+) and savings (–) for eligible hospitals adopting certified EHRs. This provision is estimated to increase Medicare hospital expenditures by a net total of $5.3 billion during FYs 2014 through 2019.

TABLE 25—ESTIMATED COSTS (+) AND SAVINGS (−) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2014	$2.1	.....	(1)	$2.1
2015	2.2	−0.4	(1)	1.8
2016	1.7	−0.5	(1)	1.2
2017	0.5	−0.3	(1)	0.2
2018	.....	−0.1	(1)	−0.1
2019	.....	.....	(1)	(1)

[1] Savings of less than $50 million.

Based on the comparison of Medicare incentive payments and implementation/operating costs for each eligible hospital (described previously), we made the assumptions shown in Table 25, related to the prevalence of CEHRT for FYs 2014 through 2018. These assumptions are consistent with the actual program data for 2011. As indicated, eligible hospitals that could cover the full cost of an EHR system through Medicare incentive payments were assumed to implement them relatively rapidly, and vice versa. In other words, eligible hospitals will have an incentive to purchase and implement an EHR system if they perceive that a large portion of the costs will be covered by the incentive payments. Table 26 shows the assumptions that were used.

TABLE 26—ASSUMED PROPORTION OF ELIGIBLE HOSPITALS WITH CERTIFIED EHR TECHNOLOGY, BY PERCENTAGE OF SYSTEM COST COVERED BY MEDICARE INCENTIVE PAYMENTS

Fiscal year	Incentive payments as percentage of EHR technology cost				
	100+%	75–100%	50–75%	25–50%	0–25%
2014	1.0	0.95	0.85	0.5	0.3
2015	1.0	1.0	0.95	0.75	0.5
2016	1.0	1.0	1.0	0.9	0.75
2017	1.0	1.0	1.0	1.0	0.9
2018	1.0	1.0	1.0	1.0	1.0

For instance, 95 percent of eligible hospitals whose incentive payments will cover between 75 percent and 100 percent of the cost of a certified EHR system were assumed to have a certified system in FY 2014. All such hospitals were assumed to have a certified EHR system in FY 2015 and thereafter.

High rates of EHR adoption are anticipated in the years leading up to FY 2015 due to the payment adjustments that will be imposed on eligible hospitals. However, we know from industry experts that issues surrounding the capacity of vendors and expert consultants to support implementation, issues of access to capital, and competing priorities in responding to payer demand will limit the number of hospitals that can adopt advanced systems in the short term. Therefore, we cannot be certain of the adoption rate for hospitals due to these factors and others previously outlined in this preamble.

For large, organized facilities such as hospitals, we believe that the revenue losses caused by these payment adjustments will be a substantial incentive to adopt certified EHR technology, even in instances where the Medicare incentive payments will cover only a portion of the costs of purchasing, installing, populating, and operating the EHR system. Based on the assumptions about incentive payments as percentages of EHR technology costs in Table 26, we estimated that the great majority of eligible hospitals will qualify for at least a portion of the Medicare incentive payments that they could potentially receive, and only a modest number will incur payment adjustments. Nearly all eligible hospitals are projected to have implemented CEHRT by FY 2019. Table 27 shows our estimated percentages of the total potential incentive payments associated with eligible hospitals that could demonstrate meaningful use of EHR systems. Also shown are the estimated percentages of potential incentives that will actually be paid each year.

TABLE 27—ESTIMATED PERCENTAGE OF MEDICARE INCENTIVES WHICH COULD BE PAID FOR MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE IN YEAR

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2014	66.1	66.1
2015	80.2	72.2
2016	91.3	48.8
2017	97.7	.....
2018	100.0	.....

For instance in FY 2014, 66.1 percent of the total amount of incentive payments which could be payable in that year will be for eligible hospitals who have demonstrated meaningful use of CEHRT and therefore will be paid. In FY 2015, 80.2 percent of the total amount of incentive payments which could be payable will be for hospitals who have certified EHR systems, but some of those eligible hospitals will have already received 4 years of incentive payments, and therefore 72.2 percent of all possible incentive payments actually paid in that year.

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 nonqualifying 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 are discussed under ''general considerations'' at the end of 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.

c. Critical Access Hospitals (CAHs)

We estimate that there are 1,325 CAHs eligible to receive EHR incentive payments. In the Stage 1 impact analysis, we estimated that the 22 percent of CAHs with relatively advanced EHR systems will achieve meaningful use before 2016 given on the financial assistance available under HITECH for Regional Extension Centers, whose priorities include assisting CAHs in EHR adoption. We also estimated that most of the remaining CAHs that had already adopted some kind of EHR system at that time (51 percent of CAHs) will also achieve meaningful use by 2016. Current program payment data, as well as current data from the Regional Extension Centers, provides some more information for us to alter these estimates. Our new estimates regarding the incentives that will be paid to CAHs are incorporated into the overall Medicare and Medicaid program costs.

4. Medicaid Incentive Program Costs

Under section 4201 of the HITECH Act, states can voluntarily participate in the Medicaid incentive payment program. However, as of the writing of this final rule 48 states are already participating in the Medicaid incentive payment program and the remaining

states have indicated they will begin participation in 2012. Therefore we anticipate that all states will be participating by 2014, as we estimated in the Stage 1 impact analysis. The payment incentives available to EPs and hospitals under the Medicaid programs 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 hospital and EP. Table 28 shows our estimates for the net Medicaid costs for eligible hospitals and EPs.

TABLE 28—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (−) UNDER MEDICAID

[In billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2014	0.6	0.5	(1)	1.1
2015	0.4	0.8	(1)	1.2
2016	0.5	0.8	(1)	1.2
2017	0.5	0.7	(1)	1.2
2018	0.1	0.7	(1)	0.8
2019	0.0	0.5	(1)	0.5

[1] Savings of less than $50 million.

a. Medicaid EPs

To determine the Medicaid EP incentive payments, we first determined the number of qualifying EPs. As indicated previously, we assumed that 20 percent of the nonhospital-based Medicare EPs will meet the requirements for Medicaid incentive payments (30 percent of patient volume from Medicaid). All of these EPs were assumed to choose the Medicaid incentive payments, as they are larger. In addition, the total number of Medicaid EPs was adjusted to include EPs who qualify for the Medicaid incentive payments but not for the Medicare incentive payments, such as most pediatricians, dentists, certified nurse-midwives, nurse practitioners, and physicians assistants. As noted previously, there is much uncertainty about the rates of demonstration of meaningful use that will be achieved. Our estimates are listed in Table 29.

TABLE 29—ASSUMED NUMBER OF NONHOSPITAL-BASED MEDICAID EPS WHO WILL BE MEANINGFUL USERS OF CERTIFIED EHR TECHNOLOGY

[All population figures are in thousands]

		Calendar year					
		2014	2015	2016	2017	2018	2019
	EPs who have claims with Medicare	568.9	574.8	580.8	586.8	592.7	598.6
	Nonhospital-based EPs	491.0	496.1	501.3	506.4	511.5	516.7
A	EPs who meet the Medicaid patient volume threshold.	98.2	99.2	100.3	101.3	102.3	103.3
B	Medicaid[1] only EPs	46.6	47.4	48.1	48.9	49.7	50.4
	Total Medicaid EPs (A + B)	144.8	146.6	148.4	150.2	152.0	153.8
	Percent of EPs receiving incentive payment during year.	49.2%	58.8%	64.0%	52.9%	29.5%	22.6%
	Number of EPs receiving incentive payment during year.	71.2	86.3	95.0	79.4	44.8	34.8
	Percent of EPs who have ever received incentive payment.	49.2%	58.8%	64.0%	68.9%	73.5%	77.9%
	Number of EPs who have ever received incentive payment.	71.2	86.3	95.0	103.4	111.7	119.8

It should be noted that since the Medicaid EHR incentive payment program provides that a Medicaid EP can receive an incentive payment in their first year because he or she has demonstrated a meaningful use or because he or she has adopted, implemented, or upgraded certified EHR technology, these participation rates include not only meaningful users but eligible providers implementing CEHRT as well.

b. Medicaid Hospitals

Medicaid incentive payments to most acute-care hospitals were estimated using the same adoption assumptions and method as described previously for Medicare eligible hospitals and shown in Table 30. Because hospitals' Medicare and Medicaid patient loads differ, we separately calculated the range of percentage of total potential incentives that could be associated with qualifying hospitals, year by year, and the corresponding actual percentages payable each year. Acute care hospitals may qualify to receive both the Medicare and Medicaid incentive payments.

As stated previously, the estimated eligible hospital incentive payments were calculated based on the hospitals' qualifying status and individual incentive amounts payable under the statutory formula. The estimated savings in Medicaid benefit expenditures resulting from the use of CEHRT are discussed under ''general considerations.'' Since we were using

Medicare cost report 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 nonchildren's hospitals.

TABLE 30—ESTIMATED PERCENTAGE OF POTENTIAL MEDICAID INCENTIVES ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE EACH YEAR

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2014	67.5	59.3
2015	81.1	37.9
2016	91.8	33.7
2017	97.7	24.3
2018	100.0	10.7
2019	100.0	0.0

5. Benefits for All EPs and All Eligible Hospitals

In this final rule we have not quantified 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, certified EHR technology) has not yet been collected, and although some studies question the benefits of health information technology, a 2011 study completed by ONC (Buntin et al. 2011 ''The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results'' *Health Affairs*.) found that 92 percent of 154 articles published from July 2007 up to February 2010 reached conclusions that showed the overall positive effects of health information technology on key aspects of care, including quality and efficiency of health care. 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. 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 ROI within 16 months and annual savings thereafter (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-1s*.) A study that 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 (DeLeon et al. 2010, ''The business end of health information technology. Can a fully integrated electronic health record increase provider productivity in a large community practice?'' *J Med Pract Manage*). Some vendors have estimated that EHRs could result in cost savings of between $100 and $200 per patient per year. At the time of the writing of this final rule, there was only limited information on participation in the EHR Incentive Programs and on adoption of Certified EHR Technology. As participation and adoption increases, there will be more opportunities to capture and report on cost savings and benefits. A number of relevant studies are required in the HITECH Act for this specific purpose, and the results will be made public, as they are available.

6. Benefits to Society

According to the recent CBO study ''Evidence on the Costs and Benefits of Health Information Technology'' (*http://www.cbo.gov//ftpdocs/91xx/doc9168/05-20-HealthIT.pdf*) when used effectively, EHRs can enable providers to deliver health care more efficiently. 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 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.

Since the CBO study, there has been additional research that has emerged documenting the association of EHRs with improved outcomes among diabetics (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) and trauma patients (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), enhanced efficiencies in ambulatory care settings (Chen, C et al. (2009) ''The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities of Care.''Health Affairs 28(2):323–333), and improved outcomes and lower costs in hospitals (Amarasingham, R. et al. (2009) ''Clinical information technologies and inpatient outcomes: A multiple hospital study'' Archives of Internal Medicine 169(2):108–14). However, data relating specifically to the EHR Incentive Programs is limited at this time.

7. General Considerations

The estimates for the HITECH Act provisions were based on the economic assumptions underlying the President's 2013 Budget. Under the statute, Medicare incentive payments for CEHRT are excluded from the determination of MA capitation benchmarks. As noted previously, there is considerable uncertainty about the rate at which eligible hospitals, CAHs and EPs are adopting EHRs and other HIT. Nonetheless, we believe that the Medicare incentive payments and the prospect of significant payment adjustments for not demonstrating meaningful use will result in the great majority of hospitals implementing CEHRT in the early years of the Medicare EHR incentive program. We expect that a steadily growing proportion of practices will implement CEHRT over the next 10 years, even in the absence of the Medicare incentives.

Actual future Medicare and Medicaid costs for eligible hospital and EP incentives will depend in part on the standards developed and applied for assessing meaningful use of certified EHR technology. We are administering the requirements in such a way as to encourage adoption of CEHRT and facilitate qualification for incentive payments, and expect to adopt progressively demanding standards at each stage year. Certified EHR technology has the potential to help reduce medical costs through efficiency improvements, such as prompter treatments, avoidance of duplicate or otherwise unnecessary services, and reduced administrative costs (once systems are in place), with most of these savings being realized by the providers rather than by Medicare or Medicaid. To the extent that this technology will have a net positive effect on efficiency, then more rapid adoption of such EHR systems will achieve these efficiencies sooner than will otherwise occur, without the EHR incentives. As noted, the possible efficiency savings from the adoption of EHR is expected to be realized by the providers rather than the payers. We expect a negligible impact on benefit payments to hospitals and EPs from Medicare and Medicaid as a result of the implementation of EHR technology.

In the process of preparing the estimates for this rule, we consulted with and/or relied on internal CMS sources, as well as the following sources:

- Congressional Budget Office (staff and publications).
- American Medical Association (staff and unpublished data).
- American Hospital Association.
- Actuarial Research Corporation.
- CMS Statistics 2011.
- RAND Health studies on:

++ ''The State and Pattern of Health Information Technology Adoption'' (Fonkych & Taylor, 2005);

++ ''Extrapolating Evidence of Health Information Technology Savings and Costs'' (Girosi, Meili, & Scoville, 2005); and

++ ''The Diffusion and Value of Healthcare Information Technology'' (Bower, 2005).

- Kaiser Permanente (staff and publications).
- Miscellaneous other sources (Health Affairs, American Enterprise Institute, ONC survey, Journal of Medical Practice Management, news articles and perspectives).

As noted at the beginning of this analysis, it is difficult to predict the actual impacts of the HITECH Act with much 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.

8. Summary

The total cost to the Medicare and Medicaid programs between 2014 and 2019 is estimated to be $15.4 billion in transfers. We do not estimate total costs to the provider industry, but rather provide a possible per EP and per eligible hospital outlay for implementation and maintenance.

TABLE 31—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	
2014	$2.1	$1.9	$0.6	$0.5	$5.1
2015	1.8	1.9	0.4	0.8	4.9
2016	1.2	0.6	0.5	0.8	3.1
2017	0.2	0.1	0.5	0.7	1.5
2018	−0.1	−0.2	0.1	0.7	0.5
2019		−0.2	0.0	0.5	0.3

9. Explanation of Benefits and Savings Calculations

In our analysis, we assume that benefits to the program will accrue in the form of savings to Medicare, through the Medicare payment adjustments. Expected qualitative benefits, such as improved quality of care, better health outcomes, and the like, are unable to be quantified at this time.

D. Accounting Statement

Whenever 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. Monetary annualized benefits and nonbudgetary costs are presented as discounted flows using 3 percent and 7 percent factors. Additional expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt and demonstrate meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will ensue if they fail to do so are noted by a placeholder in the accounting statement. 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.

Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like. Private industry costs will 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.

TABLE 32—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES CYS 2014 THROUGH 2019

[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	
		Low estimate	High Estimate		
Annualized Monetized Costs to Private Industry Associated with Reporting Requirements.	2014	$178.0	$186.1	7%	CY 2014
		$178.0	$186.1	3%	
Qualitative—Other private industry costs associated with the adoption of EHR technology.	These costs will 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	2014	$2,558	7%	CYs 2014–2019	
		$2,441	3%		
From Whom To Whom?	Federal Government to Medicare- and Medicaid-eligible professionals and hospitals.				

E. Conclusion

The previous analysis, together with the remainder of this preamble, provides an RIA. We believe there are many positive effects of adopting EHR on health care providers, quite apart from the incentive payments to be provided under this rule. We believe there are benefits that can be obtained by eligible hospitals and EPs, including: reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, and reduced errors. When used effectively, EHRs can enable providers to deliver health care more efficiently. For example, 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. We also believe that internal savings will likely come through the reductions in the cost of providing care. While economically significant, we do not believe that the net effect on individual providers will be negative over time except in very rare cases. Accordingly, we believe that the RFA objective to minimize burden on small entities is met by this final rule.

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

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, 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 set forth 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).

Subpart D—Basic Method for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

■ 2. Section 412.64 is amended as follows:

■ A. Revising paragraph (d)(3) introductory text.

■ B. Adding paragraphs (d)(4) and (5).

The revision and addition read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(3) Beginning fiscal year 2015, in the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR) user as defined in part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the applicable percentage change specified in paragraph (d)(1) of this section is reduced—

* * * * *

(4) *Exception*–(i) *General rules.* The Secretary may, on a case-by-case basis, exempt an eligible hospital that is not a qualifying eligible hospital from the application of the reduction under paragraph (d)(3) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for the eligible hospital.

(ii) To be considered for an exception, a hospital must submit an application, in the manner specified by CMS, demonstrating that it meets one or more than one of the criteria specified in this paragraph (d)(4) of this section. These types of exceptions are subject to annual renewal, but in no case may a hospital be granted this type of exception for more than 5 years. (See § 495.4 for definitions of payment adjustment year, EHR reporting period, and meaningful EHR user.)

(A) During any 90-day period from the beginning of the fiscal year that is 2 years before the payment adjustment year to April 1 of the year before the payment adjustment year, the hospital was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring internet connectivity, and faced insurmountable barriers to obtaining such internet connectivity. Applications requesting this exception must be submitted by April 1 of the year before the applicable payment adjustment year.

(B)(*1*) During the fiscal year that is 2 fiscal years before the payment adjustment year, the hospital that has previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted by April 1 of the year before the applicable payment adjustment year.

(*2*) During the fiscal year preceding the payment adjustment year, the hospital that has not previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted by April 1 of the year before the applicable payment adjustment year.

(C) The hospital is new in the payment adjustment year, and has not previously operated (under previous or present ownership). This exception expires beginning with the first Federal fiscal year that begins on or after the hospital has had at least one 12-month (or longer) cost reporting period after they accept their first Medicare covered patient. For purposes of this exception, the following hospitals are not considered new hospitals:

(*1*) A hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(*2*) A hospital that closes and subsequently reopens.

(*3*) A hospital that changes its status from a CAH to a hospital that is subject to the Medicare hospital inpatient prospective payment systems.

(5) A State in which hospitals are paid for services under section 1814(b)(3) of the Act must—

(i) Adjust the payments to each eligible hospital in the State that is not a meaningful EHR user in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each eligible hospital in the State in a manner comparable to the reduction under paragraph (d)(3) of this section; and

(ii) Provide to the Secretary, by January 1, 2013, a report on the method that it proposes to employ in order to make the requisite payment adjustment described in paragraph (d)(5)(i) of this section.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 3. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–133 (113 Stat. 1501A–332).

■ 4. Section 413.70 is amended by revising paragraphs (a)(6)(i) introductory text, (a)(6)(ii), and (a)(6)(iii) to read as follows:

§ 413.70 Payment for services of a CAH.

(a) * * *

(6)(i) For cost reporting periods beginning in or after FY 2015, if a CAH is not a qualifying CAH for the applicable EHR reporting period, as defined in § 495.4 and § 495.106(a) of this chapter, then notwithstanding the percentage applicable in paragraph (a)(1) of this section, the reasonable costs of the CAH in providing CAH services to its inpatients are adjusted by the following applicable percentage:

* * * * *

(ii) The Secretary may on a case-by-case basis, exempt a CAH that is not a qualifying CAH from the application of the payment adjustment under paragraph (a)(6)(i) of this section if the Secretary determines that compliance with the requirement for being a meaningful user would result in a significant hardship for the CAH. In order to be considered for an exception, a CAH must submit an application demonstrating that it meets one or more of the criteria specified in this paragraph (a)(6) for the applicable payment adjustment year no later than November 30 after the close of the applicable EHR reporting period. The Secretary may grant an exception for one or more of the following:

(A) During any 90-day period from the beginning of the cost reporting period that begins in the fiscal year before the payment adjustment year to November 30 after the end of the payment adjustment year, the hospital was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring Internet connectivity, and faced insurmountable barriers to obtaining such Internet connectivity.

(B) A CAH that faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user during the payment adjustment year.

(C) The CAH is new in the payment adjustment year and has not previously operated (under previous or present ownership). This exception expires beginning with the first Federal fiscal year that begins on or after the hospital

has had at least one 12-month (or longer) cost reporting period after they accept their first Medicare-covered patient. For the purposes of this exception, the following CAHs are not considered new CAHs:

(*1*) A CAH that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(*2*) A CAH that closes and subsequently reopens.

(*3*) A CAH that has been converted from an eligible hospital as defined at § 495.4 of this chapter.

(iii) Exceptions granted under paragraph (a)(6)(ii) of this section are subject to annual renewal, but in no case may a CAH be granted such an exception for more than 5 years.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 5. 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).

Subpart A—General Provisions

■ 6. Section 495.4 is amended as follows:

■ A. Revising the definition of ''EHR reporting period''.

■ B. Adding the definition of ''EHR reporting period for a payment adjustment year'' in alphabetical order.

■ C. Revising the definition of ''Hospital-based EP''.

■ D. Revising paragraphs (1) and (3) of the definition of ''Meaningful EHR user''.

■ E. Adding the definition of ''Payment adjustment year'' in alphabetical order.

The revisions and additions read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. Except with respect to payment adjustment years, EHR reporting period means either of the following:

(1) For an eligible EP—

(i) 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;

(ii) Except as specified in paragraphs (1)(iii) and (1)(iv) of this definition, 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.

(iii) For an EP seeking to demonstrate he or she is a meaningful EHR user for the Medicare EHR incentive program for CY 2014, any of the following 3-month periods:

(A) January 1, 2014 through March 31, 2014.

(B) April 1, 2014 through June 30, 2014.

(C) July 1, 2014 through September 30, 2014.

(D) October 1, 2014 through December 31, 2014.

(iv) For an EP seeking to demonstrate he or she is a meaningful EHR user for the Medicaid EHR incentive program for CY 2014 any continuous 90-day period within CY 2014.

(2) For an eligible hospital or CAH—

(i) 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 Federal fiscal year;

(ii) Except as specified in paragraph (2)(iii) of this definition, 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 Federal fiscal year.

(iii) For an eligible hospital or CAH seeking to demonstrate it is a meaningful EHR user for FY 2014, any of the following 3-month periods:

(A) October 1, 2013 through December 31, 2013.

(B) January 1, 2014 through March 31, 2014.

(C) April 1, 2014 through June 30, 2014.

(D) July 1, 2014 through September 30, 2014.

EHR reporting period for a payment adjustment year. For a payment adjustment year, the EHR reporting period means the following:

(1) For an EP—

(i)(A) Except as provided in paragraphs (1)(i)(B), (ii), and (iii) of this definition, the calendar year that is 2 years before the payment adjustment year.

(B) The special EHR reporting period for CY 2014 (specified in paragraph (1)(iii) or (1)(iv) of this definition, as applicable) of the definition of ''EHR Reporting Period'' that occurs within the calendar year that is 2 years before the payment adjustment year and is only for EHR reporting periods in CY 2014.

(ii) If an EP is demonstrating he or she is a meaningful EHR user for the first time in the calendar year, that is 2 years before the payment adjustment year, then any continuous 90-day period within such (2 years prior) calendar year.

(iii)(A) If in the calendar year that is 2 years before the payment adjustment year and in all prior calendar years, the EP has not successfully demonstrated he or she is a meaningful EHR user, then any continuous 90-day period that both begins in the calendar year 1 year before the payment adjustment year and ends at least 3 months before the end of such prior year.

(B) Under this exception, the provider must successfully register for and attest to meaningful use no later than the date October 1 of the year before the payment adjustment year.

(2) For an eligible hospital—

(i)(A) Except as provided in paragraphs (2)(i)(B), (ii), and (iii) of this definition, the Federal fiscal year that is 2 years before the payment adjustment year.

(B) The special EHR reporting period for FY 2014 (defined in paragraph (2)(iii) of the definition ''EHR Reporting Period'') that occurs within the fiscal year that is 2 years before the payment adjustment year and is only for EHR reporting periods in fiscal year 2014.

(ii) If an eligible hospital is demonstrating it is a meaningful EHR user for the first time in the Federal fiscal year that is 2 years before the payment adjustment year, then any continuous 90-day period within such (2 years prior) Federal fiscal year.

(iii)(A) If in the Federal fiscal year that is 2 years before the payment adjustment year and for all prior Federal fiscal years the eligible hospital has not successfully demonstrated it is a meaningful EHR user, then any continuous 90-day period that both begins in the Federal fiscal year that is 1 year before the payment adjustment year and ends at least 3 months before the end of such prior Federal fiscal year.

(B) Under this exception, the eligible hospital must successfully register for and attest to meaningful use no later than July 1 of the year before the payment adjustment year.

(3) For a CAH—

(i) Except as provided in paragraph (3)(ii) of this definition, the Federal fiscal year that is the payment adjustment year.

(ii) If the CAH is demonstrating it is a meaningful EHR user for the first time in the payment adjustment year, any continuous 90-day period within the Federal fiscal year that is the payment adjustment year.

* * * * *

Hospital-based EP. Unless it meets the requirements of § 495.5 of this part, a hospital-based EP means an EP who furnishes 90 percent or more of his or her covered professional services in

sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before such payment adjustment year.

(1) For Medicare, this is calculated based on—

(i) The FFY preceding the payment year; and

(ii) For the payment adjustments, on the—

(A) FFY preceding the payment adjustment year; or

(B) FFY 2 years before the payment adjustment year.

(2) For Medicaid, it is at the State's discretion if the data is gathered on the Federal fiscal year or calendar year preceding the payment year.

* * * * *

Meaningful EHR user * * *

(1) Subject to paragraph (3) of this definition, an EP, eligible hospital or CAH that, for an EHR reporting period for a payment year or payment adjustment year, demonstrates in accordance with § 495.8 meaningful use of Certified EHR Technology by meeting the applicable objectives and associated measures under § 495.6 and successfully reporting the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable; and

* * * * *

(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during an EHR reporting period for a payment year (or, in the case of a payment adjustment year, during an applicable EHR reporting period for such payment adjustment year) must occur at a practice/location or practices/locations equipped with Certified EHR Technology.

* * * * *

Payment adjustment year means either of the following:

(1) For an EP, a calendar year beginning with CY 2015.

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2015.

* * * * *

■ 7. Section 495.5 is added to read as follows:

§ 495.5 Requirements for EPs seeking to reverse a hospital-based determination under § 495.4.

(a) *Exception for certain EPs.* Beginning with payment year 2013, an EP who meets the definition of hospital-based EP specified in § 495.4 but who can demonstrate to CMS that the EP funds the acquisition, implementation, and maintenance of Certified EHR Technology, including supporting hardware and interfaces needed for meaningful use without reimbursement from an eligible hospital or CAH, and uses such Certified EHR Technology in the inpatient or emergency department of a hospital (instead of the hospital's Certified EHR Technology), may be determined by CMS to be a nonhospital-based EP.

(b) *Process for determining a nonhospital-based EP.* When an EP registers for a given payment year they should receive a determination of whether they have been determined ''hospital-based.''

(1) An EP determined ''hospital-based,'' but who wishes to be determined nonhospital-based as specified in paragraph (a) of section, may use an administrative process to provide documentation and seek a nonhospital-based determination. Such administrative process will be available throughout the incentive payment year and including the 2 months following the incentive payment year in which the EP may attest to being a meaningful EHR user.

(2) If an EP is determined nonhospital-based under paragraph (a) of this section, to be considered nonhospital-based for subsequent payment years, the EP must attest in such payment year (or by the time the EP must attest it is a meaningful EHR user for such year) that the EP continues to meet the criteria of paragraph (a) of this section.

(c) *Requirements for nonhospital-based EPs.* An EP determined nonhospital-based must—

(1) Continue to meet all applicable requirements to receive an incentive payment, including meeting all requirements for meaningful use; and

(2) Demonstrate meaningful use using all encounters at all locations equipped with Certified EHR Technology, including those in the inpatient and emergency departments of the hospital.

■ 8. Section 495.6 is amended as follows:

■ A. Redesignating paragraph (a)(2)(ii) as paragraph (a)(2)(ii)(A).

■ B. Adding paragraph (a)(2)(ii)(B).

■ C. Redesignating paragraph (b)(2)(ii) as paragraph (b)(2)(ii)(A).

■ D. Adding paragraph (b)(2)(ii)(B).

■ E. In paragraphs (c) introductory text and (c)(1), the references ''paragraphs (d) through (g)'' are removed and the references ''paragraphs (d) through (m)'' is added in their place.

■ F. Redesignating paragraph (d)(1)(ii) as paragraph (d)(1)(ii)(A).

■ G. Adding paragraph (d)(1)(ii)(B).

■ H. Redesignating paragraph (d)(4)(iii) as paragraph (d)(4)(iii)(A).

■ I. Adding a paragraph (d)(4)(iii)(B).

■ J. Redesignating paragraph (d)(8)(i)(E) as paragraph (d)(8)(i)(E)(*1*).

■ K. Adding paragraphs (d)(8)(i)(E)(*2*) and (*3*).

■ L. Redesignating paragraph (d)(8)(ii) as paragraph (d)(8)(ii)(A).

■ M. Adding paragraphs (d)(8)(ii)(B) and (C).

■ N. Redesignating paragraph (d)(8)(iii) as paragraph (d)(8)(iii)(A).

■ O. Adding paragraphs (d)(8)(iii)(B) and (C).

■ P. Redesignating paragraph (d)(10)(i) as paragraph (d)(10)(i)(A).

■ Q. Adding paragraph (d)(10)(i)(B).

■ R. Redesignating paragraph (d)(10)(ii) as paragraph (d)(10)(ii)(A).

■ S. Adding a paragraph (d)(10)(ii)(B).

■ T. Redesignating paragraph (d)(12)(i) as paragraph (d)(12)(i)(A).

■ U. Adding a paragraph (d)(12)(i)(B).

■ V. Redesignating paragraph (d)(12)(ii) as paragraph (d)(12)(ii)(A).

■ W. Adding a paragraph (d)(12)(ii)(B).

■ X. Redesignating paragraph (d)(12)(iii) as paragraph (d)(12)(iii)(A).

■ Y. Adding a paragraph (d)(12)(iii)(B).

■ Z. Redesignating paragraph (d)(14)(i) as paragraph (d)(14)(i)(A).

■ AA. Adding a paragraph (d)(14)(i)(B).

■ BB. Redesignating paragraph (d)(14)(ii) as paragraph (d)(14)(ii)(A).

■ CC. Adding a paragraph (d)(14)(ii)(B).

■ DD. In paragraph (e) introductory text—

■ i. Removing the colon and adding a period in its place.

■ ii. Adding a sentence at the end of the paragraph.

■ EE. Redesignating paragraph (e)(5)(i) as paragraph (e)(5)(i)(A).

■ FF. Adding a paragraph (e)(5)(i)(B).

■ GG. Redesignating paragraph (e)(5)(ii) as paragraph (e)(5)(ii)(A).

■ HH. Adding paragraph (e)(5)(ii)(B).

■ II. Redesignating paragraph (e)(9)(i) as (e)(9)(i)(A).

■ JJ. Adding paragraph (e)(9)(i)(B).

■ KK. Redesignating paragraph (e)(10)(i) as (e)(10)(i)(A).

■ LL. Adding paragraph (e)(10)(i)(B).

■ MM. Redesignating paragraph (f)(1)(ii) as paragraph (f)(1)(ii)(A).

■ NN. Adding paragraphs (f)(1)(ii)(B) and (C).

■ OO. Redesignating paragraph (f)(7)(i)(E) as paragraph (f)(7)(i)(E)(*1*).

■ PP. Adding a paragraphs (f)(7)(i)(E)(*2*) and (*3*).

■ QQ. Redesignating paragraph (f)(7)(ii) as (f)(7)(ii)(A).

■ RR. Adding paragraphs (f)(7)(ii)(B) and (C).

■ SS. Redesignating paragraph (f)(9)(i) as paragraph (f)(9)(i)(A).
■ TT. Adding a paragraph (f)(9)(i)(B).
■ UU. Redesignating paragraph (f)(9)(ii) as paragraph (f)(9)(ii)(A).
■ VV. Adding a paragraph (f)(9)(ii)(B).
■ WW. Redesignating paragraphs (f)(11)(i) and (ii) as paragraphs (f)(11)(i)(A) and (ii)(A), respectively.
■ XX. Adding paragraphs (f)(11)(i)(B) and (ii)(B).
■ YY. Redesignating paragraph (f)(12)(i) as paragraph (f)(12)(i)(A).
■ ZZ. Adding a paragraph (f)(12)(i)(B).
■ AAA. Redesignating paragraph (f)(12)(ii) as paragraph (f)(12)(ii)(A).
■ BBB. Adding a paragraph (f)(12)(ii)(B).
■ CCC. Redesignating paragraph (f)(12)(iii) as paragraph (f)(12)(iii)(A).
■ DDD. Adding a paragraph (f)(12)(iii)(B).
■ EEE. Redesignating paragraph (f)(13)(i) as paragraph (f)(13)(i)(A).
■ FFF. Adding a paragraph (f)(13)(i)(B).
■ GGG. Redesignating paragraph (f)(13)(ii) as paragraph (f)(13)(ii)(A).
■ HHH. Adding a paragraph (f)(13)(ii)(B).
■ III. In paragraph (g) introductory text—
■ i. Removing the colon and adding a period in its place.
■ ii. Adding a sentence at the end of the paragraph.
■ JJJ. Redesignating paragraph (g)(8)(i) as paragraph (g)(8)(i)(A).
■ KKK. Adding a paragraph (g)(8)(i)(B).
■ LLL. Redesignating paragraph (g)(9)(i) as paragraph (g)(9)(i)(A).
■ MMM. Adding a paragraph (g)(9)(i)(B).
■ NNN. Redesignating paragraph (g)(10)(i) as paragraph (g)(10)(i)(A).
■ OOO. Adding a paragraph (g)(10)(i)(B).
■ PPP. Revising paragraphs (h) and (i).
■ QQQ. Adding new paragraphs (j) through (m).

The additions and revisions read as follows:

§ 495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(B) Beginning 2014, an exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (e) of this section unless five or more objectives can be excluded. An EP must meet five of the objectives and associated measures specified in paragraph (e) of this section, one of which must be either paragraph (e)(9) or (10) of this section, unless the EP has an exclusion from five or more objectives specified in paragraph (e) of this section, in which case the EP must meet all remaining objectives and associated measures in paragraph (e) of this section.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(B) Beginning 2014, an exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (g) of this section. Eligible hospitals or CAHs must meet five of the objectives and associated measures specified in paragraph (g) of this section, one which must be specified in paragraph (g)(8), (9), or (10) of this section.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(B) Subject to paragraph (c) of this section, more than 30 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry, or the measure specified in paragraph (d)(1)(ii)(A) of this section.

* * * * *

(4) * * *

(iii) * * *

(B) Beginning 2013, any EP who 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/her EHR reporting period, or the exclusion specified in (d)(4)(iii)(A) of this section.

* * * * *

(8)(i) * * *

(E) * * *

(*2*) For 2013, plot and display growth charts for patients 0–20 years, including body mass index, or paragraph (d)(8)(i)(E)(*1*) of this section.

(*3*) Beginning 2014, plot and display growth charts for patients 0–20 years, including body mass index.

(ii) * * *

(B) For 2013—(*1*) Subject to paragraph (c) of this section, more than 50 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data; or

(*2*) The measure specified in paragraph (d)(8)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (d)(8)(ii)(B)(*1*) of this section.

(iii) * * *

(B) For 2013, either of the following:

(*1*) The exclusion specified in paragraph (d)(8)(iii)(A) of this section.

(*2*) The exclusion for an EP who—

(*i*) Sees no patients 3 years or older is excluded from recording blood pressure;

(*ii*) Believes that all three vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them;

(*iii*) Believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or

(*iv*) Believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

(C) Beginning 2014, only the exclusion specified in paragraph (d)(8)(iii)(B)(*2*) of this section.

* * * * *

(10)(i) * * *

(B) Beginning 2013, this objective is reflected in the definition of a meaningful EHR user in § 495.4 and is no longer listed as an objective in this paragraph (d).

(ii) * * *

(B) Beginning 2013, this measure is reflected in the definition of a meaningful EHR user in § 495.4 and no longer listed as a measure in this paragraph (d).

* * * * *

(12)(i) * * *

(B) Beginning 2014, 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.

(ii) * * *

(B) Beginning 2014, subject to paragraph (c) of this section, more than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient 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.

(iii) * * *

(B) Beginning 2014, any EP who neither orders nor creates any of the information listed for inclusion as part of this measure.

* * * * *

(14)(i) * * *

(B) Beginning 2013, this objective is no longer required as part of the core set.

(ii) * * *

(B) Beginning 2013, this measure is no longer required as part of the core set.

* * * * *

(e) * * * Beginning 2014, an EP must meet five of the following objectives and associated measures, one of which must be either paragraph (e)(9) or (10) of this section unless the EP has an exclusion from five or more objectives in this paragraph (e), in which case the EP must meet all remaining objectives and associated measures in paragraph (e) of this section.

* * * * *

(5)(i) * * *

(B) Beginning 2014, this objective is no longer included in the menu set.

(ii) * * *

(B) Beginning 2014, this measure is no longer included in the menu set.

* * * * *

(9)(i) * * *

(B) Beginning 2013, capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited and according to applicable law and practice.

* * * * *

(10)(i) * * *

(B) Beginning 2013, capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(B) Subject to paragraph (c) of this section, 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, or the measure specified in paragraph (f)(1)(ii)(A) of this section.

* * * * *

(7) * * *

(i) * * *

(E) * * *

(*2*) For 2013, plot and display growth charts for patients 0–20 years, including body mass index, or paragraph (f)(*7*)(i)(E)(*1*) of this section.

(*3*) Beginning 2014, plot and display growth charts for patients 0–20 years, including body mass index.

(ii) * * *

(B) For 2013—(*1*) Subject to paragraph (c) of this section, more than 50 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 have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data; or

(*2*) The measure specified in paragraph (f)(7)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (f)(7)(ii)(B)(*1*) of this section.

* * * * *

(9) * * *

(i) * * *

(B) Beginning 2013, this objective is reflected in the definition of a meaningful EHR user in § 495.4 and no longer listed as an objective in this paragraph (f).

(ii) * * *

(B) Beginning 2013, this measure is reflected in the definition of a meaningful EHR user in § 495.4 and no longer listed as a measure in this paragraph (f).

* * * * *

(11) * * *

(i) * * *

(B) Beginning 2014, this objective is no longer required as part of the core set.

(ii) * * *

(B) Beginning 2014, this measure is no longer required as part of the core set.

(12) * * *

(i) * * *

(B) Beginning 2014, provide patients the ability to view online, download, and transmit information about a hospital admission.

(ii) * * *

(B) Beginning 2014, subject to paragraph (c) of this section, 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.

(iii) * * *

(B) Beginning 2014, this exclusion is no longer available.

* * * * *

(13) * * *

(i) * * *

(B) Beginning 2013, this objective is no longer required as part of the core set.

(ii) * * *

(B) Beginning 2013, this measure is no longer required as part of the core set.

* * * * *

(g) * * * Beginning 2014, eligible hospitals or CAHs must meet five of the following objectives and associated measures, one which must be specified in paragraph (g)(8), (9), or (10) of this section:

* * * * *

(8)(i) * * *

(B) Beginning 2013, Capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited and according to applicable law and practice.

(9)(i) * * *

(B) Beginning 2013, capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission except where prohibited according to applicable law and practice.

(10)(i) * * *

(B) Beginning 2013, capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

* * * * *

(h) *Stage 2 criteria for EPs*–(1) *General rule regarding Stage 2 criteria for meaningful use for EPs.* Except as specified in paragraph (h)(2) of this section, EPs must meet all objectives and associated measures of the Stage 2 criteria specified in paragraph (j) of this section and 3 objectives of the EP's choice from paragraph (k) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusion for nonapplicable objectives.* (i) An EP may exclude a particular objective contained in paragraph (j) or (k) of this section, if the EP meets all of the following requirements:

(A) Must ensure that the objective in paragraph (j) or (k) 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.

(C) Attests.

(ii)(A) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (j) of this section. For example, an EP that has an exclusion from one of the objectives in paragraph (j) of this section must meet 16 objectives from such paragraph to meet the definition of a meaningful EHR user.

(B) An exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (k) of this section unless four or more exclusions apply. For example, an EP that has an exclusion for one of the objectives in paragraph (k) of this section must meet three of the five nonexcluded objectives from such paragraph to meet the definition of a meaningful EHR user. If an EP has an exclusion for four of the objectives in paragraph (k) of this

section, then he or she must meet the remaining two nonexcluded objectives from such paragraph to meet the definition of a meaningful EHR user.

(i) *Stage 2 criteria for eligible hospitals and CAHs*–(1) *General rule regarding Stage 2 criteria for meaningful use for eligible hospitals or CAHs.* Except as specified in paragraph (i)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 2 criteria specified in paragraph (l) of this section and three objectives of the eligible hospital's or CAH's choice from paragraph (m) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusions for nonapplicable objectives.* (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraphs (l) or (m) of this section, if the hospital meets all of the following requirements:

(A) The hospital meets the criteria in the applicable objective that would permit an exclusion.

(B) The hospital so attests.

(ii)(A) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (l) of this section. For example, an eligible hospital that has an exclusion from 1 of the objectives in paragraph (l) of this section must meet 15 objectives from such paragraph to meet the definition of a meaningful EHR user.

(B) An exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (m) of this section. For example, an eligible hospital that has an exclusion for one of the objectives in paragraph (m) of this section must meet three of the five nonexcluded objectives from such paragraph to meet the definition of a meaningful EHR user.

(j) *Stage 2 core criteria for EPs.* An EP must satisfy the following objectives and associated measures, except those objectives and associated measures for which an EP qualifies for an exclusion under paragraph (h)(2) of this section specified in this paragraph (j).

(1)(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) *Measures.* Subject to paragraph (c) of this section—

(A) More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry;

(B) More than 30 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry; and

(C) More than 30 percent of radiology orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(iii) *Exclusions in accordance with paragraph (h)(2) of this section.* (A) For the measure specified in paragraph (j)(1)(ii)(A) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(B) For the measure specified in paragraph (j)(1)(ii)(B) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(C) For the measure specified in paragraph (j)(1)(ii)(C), any EP who writes fewer than 100 radiology orders during the EHR reporting period.

(2)(i) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(ii) *Measure.* Subject to paragraph (c) of this section, 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 Certified EHR Technology.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who—

(A) Writes fewer than 100 permissible prescriptions during the EHR reporting period; or (B) 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.

(3)(i) *Objective.* Record all of the following demographics:

(A) Preferred language.

(B) Sex.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP during the EHR reporting period have demographics recorded as structured data.

(4)(i) *Objective.* Record and chart changes in the following vital signs:

(A) Height/Length.

(B) Weight.

(C) Blood pressure (ages 3 and over).

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for patients 0–20 years, including body mass index.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 80 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who—

(A) Sees no patients 3 years or older is excluded from recording blood pressure;

(B) Believes that all three vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them;

(C) Believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or

(D) Believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

(5)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 80 percent of all unique patients 13 years old or older seen by the EP during the EHR reporting period have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who sees no patients 13 years old or older.

(6)(i) *Objective.* Use clinical decision support to improve performance on high priority health conditions.

(ii) *Measures.* (A) 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

(B) The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section for paragraph (j)(6)(ii)(B) of this section.* An EP who writes fewer than 100 medication orders during the EHR reporting period.

(7)(i) *Objective.* Incorporate clinical lab test results into Certified EHR Technology as structured data.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 55 percent of all clinical lab tests results ordered by the EP during the EHR reporting period whose results are either in a positive/

negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who orders no lab tests whose results are either in a positive/negative affirmation or numerical format during the EHR reporting period.

(8)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(ii) *Measure.* Generate at least one report listing patients of the EP with a specific condition.

(9)(i) *Objective.* Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder, per patient preference.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 10 percent of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has had no office visits in the 24 months before the beginning of the EHR reporting period.

(10)(i) *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.

(ii) *Measures.* (A) More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient 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; and

(B) More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who—

(A) Neither orders nor creates any of the information listed for inclusion as part of the measures in paragraphs (j)(10)(ii)(A) and (B) of this section, except for ''Patient name'' and ''Provider's name and office contact information,'' is excluded from both paragraphs (j)(10)(ii)(A) and (B) of this section; 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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (j)(10)(ii)(B) of this section.

(11)(i) *Objective.* Provide clinical summaries for patients for each office visit.

(ii) *Measure.* Subject to paragraph (c) of this section, clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(12)(i) *Objective.* Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

(ii) *Measure.* Patient-specific education resources identified by Certified EHR Technology 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.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(13)(i) *Objective.* 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.

(ii) *Measure.* Subject to paragraph (c) 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.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who was not the recipient of any transitions of care during the EHR reporting period.

(14)(i) *Objective.* 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.

(ii) *Measures.* (A) Subject to paragraph (c) of this section, the EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals;

(B) Subject to paragraph (c) of this section, the EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either—

(*1*) Electronically transmitted using Certified EHR Technology to a recipient; or

(*2*) Where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network, and

(C) Subject to paragraph (c) of this section an EP must satisfy one of the following:

(*1*) Conducts one or more successful electronic exchanges of a summary of care record meeting the measure specified in paragraph (j)(14)(ii)(B) of this section with a recipient using technology to receive the summary of care record that was designed by a different EHR developer than the sender's EHR technology certified at 45 CFR 107.314(b)(2); or

(*2*) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(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.

(15)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP that meets one or more of the following criteria:

(A) Does not administer any of the 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.

(B) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for Certified EHR Technology at the start of his or her EHR reporting period.

(C) Operates in a jurisdiction where no immunization registry or immunization information system provides information timely on capability to receive immunization data.

(D) Operates in a jurisdiction for which no immunization registry or immunization information system that is capable of accepting the specific standards required by Certified EHR Technology at the start of his or her EHR reporting period can enroll additional EPs.

(16)(i) *Objective.* Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

(ii) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data stored in Certified EHR Technology 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.

(17)(i) *Objective.* Use secure electronic messaging to communicate with patients on relevant health information.

(ii) *Measure.* A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who meets one or more of the following criteria:

(A) Has no office visits during the EHR reporting period.

(B) 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 3Mbps broadband availability according to the latest information available from the FCC on the first day of their EHR reporting period.

(k) *Stage 2 menu set criteria for EPs.* An EP must meet 3 of the following objectives and associated measures, unless the EP has an exclusion from 4 or more objectives in this paragraph (k) of this section, in which case the EP must meet all remaining objectives and associated measures.

(1)(i) *Objective.* Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 10 percent of all tests whose result is one or more images ordered by the EP during the EHR reporting period are accessible through Certified EHR Technology.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who meets one or more of the following criteria.

(A) Orders less than 100 tests whose result is an image during the EHR reporting period.

(B) Has no access to electronic imaging results at the start of the EHR reporting period.

(2)(i) *Objective.* Record patient family health history as structured data.

(ii) *Measure.* More than 20 percent of all unique patients seen by the EP during the EHR reporting period have a structured data entry for one or more first-degree relatives.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(3)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP that meets one or more of the following criteria:

(A) Is not in a category of providers who collect ambulatory syndromic surveillance information on their patients during the EHR reporting period.

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) Operates in a jurisdiction where no public health agency provides information timely on capability to receive syndromic surveillance data.

(D) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional EPs.

(4)(i) *Objective.* Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of cancer case information from Certified EHR Technology to a public health central cancer registry for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who meets one or more of the following—

(A) Does not diagnose or directly treat cancer.

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic cancer case information in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) Operates in a jurisdiction where no public health agency provides information timely on capability to receive electronic cancer case information.

(D) Operates in a jurisdiction for which no public health agency that is capable of receiving electronic cancer case information in the specific standards required for Certified EHR Technology at the beginning of their EHR reporting period can enroll additional EPs.

(5)(i) *Objective.* Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who meets one or more of the following criteria:

(A) Does not diagnose or directly treat any disease associated with a specialized registry sponsored by a national specialty society for which the EP is eligible, or the public health agencies in their jurisdiction;

(B) Operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible is capable of receiving electronic specific case information in the specific standards required by Certified EHR Technology at the beginning of their EHR reporting period;

(C) Operates in a jurisdiction where no public health agency or national specialty society for which the EP is eligible provides information timely on capability to receive information into their specialized registries; or

(D) Operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible that is capable of receiving electronic specific case information in the specific standards required by

Certified EHR Technology at the beginning of his or her EHR reporting period can enroll additional EPs.

(6)(i) *Objective.* Record electronic notes in patient records.

(ii) *Measure.* Enter at least one electronic progress note created, edited, and signed by an EP for more than 30 percent of unique patients with at least one office visit during the EHR reporting period. The text of the electronic note must be text-searchable and may contain drawings and other content.

(l) *Stage 2 core criteria for eligible hospitals or CAHs.* An eligible hospital or CAH must meet the following objectives and associated measures except those objectives and associated measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (i)(2) of this section.

(1)(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) *Measures.* Subject to paragraph (c) of this section, more than—

(A) Sixty 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,

(B) Thirty 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

(C) Thirty 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.

(2)(i) *Objective.* Record all of the following demographics:

(A) Preferred language.

(B) Sex.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(F) Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

(ii) *Measure.* More than 80 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 have demographics recorded as structured data.

(3)(i) *Objective.* Record and chart changes in the following vital signs:

(A) Height/Length.

(B) Weight.

(C) Blood pressure (ages 3 and over).

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for patients 0–20 years, including body mass index.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 80 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 have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

(4)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 80 percent of all unique patients 13 years old or older admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that admits no patients 13 years old or older to their inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(5)(i) *Objective.* Use clinical decision support to improve performance on high priority health conditions.

(ii) *Measures.* (A) 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

(B) 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.

(6)(i) *Objective.* Incorporate clinical lab test results into Certified EHR Technology as structured data.

(ii) *Measure.* More than 55 percent of all clinical lab tests results ordered by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.

(7)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.

(ii) *Measure.* Generate at least one report listing patients of the eligible hospital or CAH with a specific condition.

(8)(i) *Objective.* Provide patients the ability to view online, download, and transmit information about a hospital admission.

(ii) *Measures.* (A) 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; and

(B) More than 5 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or their authorized representative) view, download or transmit to a third party their information during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (l)(8)(ii)(B) of this section.

(9)(i) *Objective.* Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

(ii) *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 Certified EHR Technology.

(10)(i) *Objective.* The eligible hospital or CAH that receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure.* Subject to paragraph (c) 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).

(11)(i) *Objective.* The eligible hospital or CAH that 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.

(ii) *Measures.* (A) Subject to paragraph (c) in this section, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals,

(B) Subject to paragraph (c) in this section, the eligible hospital or CAH that transitions their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either—

(*1*) Electronically transmitted using Certified EHR Technology to a recipient; or

(*2*) Where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network; and

(C) Subject to paragraph (c) of this section an eligible hospital or CAH must satisfy one of the following:

(*1*) Conducts one or more successful electronic exchanges of a summary of care record meeting the measure specified in paragraph (l)(11)(ii)(B) of this section with a recipient using technology to receive the summary of care record that was designed by a different EHR developer than the sender's EHR technology certified at 45 CFR 107.314(b)(2); or

(*2*) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

(12)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that meets one or more of the following criteria:

(A) The eligible hospital or CAH does not administer any of the 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.

(B) The eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) The eligible hospital or CAH operates in a jurisdiction where no immunization registry or immunization information system provides information timely on capability to receive immunization data.

(D) Operates in a jurisdiction for which no immunization registry or immunization information system that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

(13)(i) *Objective.* Capability to submit electronic reportable laboratory results to public health agencies, where except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that meets one or more of the following criteria:

(A) Operates in a jurisdiction for which no public health agency is capable of receiving electronic reportable laboratory results in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(B) Operates in a jurisdiction for which no public health agency provides information timely on capability to receive electronic reportable laboratory results.

(C) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

(14)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that meets one or more of the following criteria:

(A) Does not have an emergency or urgent care department.

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period or can enroll additional eligible hospitals or CAHs.

(C) Operates in a jurisdiction for which no public health agency provides information timely on capability to receive syndromic surveillance data.

(D) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

(15)(i) *Objective.* Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

(ii) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data stored in Certified EHR Technology 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.

(16)(i) *Objective.* Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

(ii) *Measure.* Subject to paragraph (c) of this section, more than 10 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 for which all doses are tracked using eMAR.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH with an average daily inpatient census of fewer than 10 patients.

(m) *Stage 2 menu set criteria for eligible hospitals or CAHs.* An eligible hospital or CAH must meet the measure criteria for three of the following objectives and associated measures.

(1)(i) *Objective.* Record whether a patient 65 years old or older has an advance directive.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that admits no patients age 65 years old or older during the EHR reporting period.

(2)(i) *Objective.* Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 10 percent of all tests whose result is an image ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period are accessible through Certified EHR Technology.

(3)(i) *Objective.* Record patient family health history as structured data.

(ii) *Measure.* More than 20 percent of all unique patients admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.

(4)(i) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(ii) *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 Certified EHR Technology.

(iii) *Exclusion in accordance with paragraph (i)(2) 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 its EHR reporting period.

(5)(i) *Objective.* Record electronic notes in patient records.

(ii) *Measure:* Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. The text of the electronic note must be text-searchable and may contain drawings and other content.

(6)(i) *Objective.* Provide structured electronic lab results to ambulatory providers.

(ii) *Measure.* Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received.

■ 9. Section 495.8 is amended as follows:

■ A. Revising paragraph (a)(2)(i)(B) and (a)(2)(ii).

■ B. Revising paragraphs (b)(2)(i)(B) and (b)(2)(ii).

§ 495.8 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(i) * * *

(B) Satisfied the required objectives and associated measures under § 495.6 for the EP's stage of meaningful use.

* * * * *

(ii) *Reporting clinical quality information.* Successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) Satisfied the required objectives and associated measures under § 495.6 for the eligible hospital or CAH's stage of meaningful use.

* * * * *

(ii) *Reporting clinical quality information.* Successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

* * * * *

§ 495.10 [Amended]

■ 10. In § 495.10, paragraph (a)(3) is amended by removing the phrase ''Business address and'' and adding in its place the phrase ''Business address, business email address, and''.

■ 11. Section 495.100 is amended by revising the definitions of ''Qualifying CAH,'' ''Qualifying eligible professional (qualifying EP),'' and ''Qualifying hospital'' to read as follows:

§ 495.100 Definitions.

* * * * *

Qualifying CAH means a CAH that is a meaningful EHR user for the EHR reporting period applicable to a payment year or payment adjustment year in which a cost reporting period begins.

Qualifying eligible professional (qualifying EP) means an EP who is a meaningful EHR user for the EHR reporting period applicable to a payment or payment adjustment year and who is not a hospital-based EP, as determined for that payment or payment adjustment year.

Qualifying hospital means an eligible hospital that is a meaningful EHR user for the EHR reporting period applicable to a payment or payment adjustment year.

■ 10. Section 495.102 is amended as follows:

■ A. Revising paragraphs (c), (d)(1), and (d)(2)(iii).

■ B. Adding paragraph (d)(2)(iv).

■ C. Revising paragraph (d)(3).

■ D. Adding paragraphs (d)(4) and (5).

The revisions and additions read as follows:

§ 495.102 Incentive payments to EPs.

* * * * *

(c) *Increase in incentive payment limit for EPs who predominantly furnish services in a geographic HPSA.* In the case of a qualifying EP who furnishes more than 50 percent of his or her covered professional services during the payment year in a geographic HPSA that is designated as of December 31 of the prior year, the incentive payment limit determined under paragraph (b) of this section is to be increased by 10 percent.

(d) *Payment adjustment effective in CY 2015 and subsequent years for nonqualifying EPs.* (1)(i) Subject to paragraphs (d)(3) and (4) of this section, beginning 2015, for covered professional services furnished by an EP who is not hospital-based, and who is not a qualifying EP by virtue of not being a meaningful EHR user (for the EHR reporting period applicable to the payment adjustment year), the payment amount for such services is equal to the product of the applicable percent specified in paragraph (d)(2) of this section and the Medicare physician fee schedule amount for such services.

(2) * * *

(iii) For 2017, 97 percent.

(iv) For 2018 and subsequent years, 97 percent, except as provided in paragraph (d)(3) of this section.

(3) *Decrease in applicable percent in certain circumstances.* If, beginning CY 2018 and for each subsequent year, the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent must be decreased by 1 percentage point for EPs from the applicable percent in the preceding year, but in no case will the applicable percent be less than 95 percent.

(4) *Exceptions.* The Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustment under paragraph (d)(1) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for the EP. To be considered for an exception, an EP must submit, in the manner specified by CMS, an application

demonstrating that it meets one or more of the criteria in this paragraph (d)(4) unless otherwise specified in the criteria. The Secretary's determination to grant an EP an exemption may be renewed on an annual basis, provided that in no case may an EP be granted an exemption for more than 5 years.

(i) During any 90-day period from the beginning of the year that is 2 years before the payment adjustment year to July 1 of the year preceding the payment adjustment year, the EP was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring internet connectivity, and faced insurmountable barriers to obtaining such internet connectivity. Applications requesting this exception must be submitted no later than July 1 of the year before the applicable payment adjustment year.

(ii) The EP has been practicing for less than 2 years.

(iii)(A) During the calendar year that is 2 calendar years before the payment adjustment year, the EP that has previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted no later than July 1 of the year before the applicable payment adjustment year.

(B) During the calendar year preceding the payment adjustment year, the EP that has not previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted by July 1 of the year before the applicable payment adjustment year.

(iv) An EP may request an exception through an application submitted by July 1 of the year before the applicable payment adjustment year due to difficulty in meeting meaningful use based on any one of the following during the period that begins 2 calendar years before the payment adjustment year through the application deadline:

(A) The EP practices at multiple locations and can demonstrate inability to control the availability of Certified EHR Technology at one such practice location or a combination of practice locations, and where the location or locations constitute more than 50 percent of their patient encounters.

(B) The EP can demonstrate difficulty in meeting meaningful use on the basis of lack of face-to-face or telemedicine interaction with patients and lack of need for follow up with patients.

(C) The EP 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. Such an EP may be deemed to qualify for this exception, subject to the 5-year limit that applies to all exceptions under this paragraph.

(5) *Payment adjustments not applicable to hospital-based EPs.* No payment adjustment under paragraphs (d)(1) through (3) of this section may be made in the case of a hospital-based eligible professional, as defined in § 495.4.

§ 495.106 [Amended]

■ 12. In § 495.106, paragraph (e) is amended by removing the phrase ''for a payment year'' and adding the phrase ''for a payment adjustment year'' in its place.

■ 13. Section 495.200 is amended by—

■ A. Adding definitions for ''MA payment adjustment year,'' and ''Potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals'' in alphabetical order.

■ B. Revising paragraph (5) of the definition of ''Qualifying MA EP''.

The additions and revision read as follows:

§ 495.200 Definitions.

* * * * *

MA payment adjustment year means—(1) For qualifying MA organizations that receive an MA EHR incentive payment for at least 1 payment year, calendar years beginning with CY 2015.

(2) For MA-affiliated eligible hospitals, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the federal fiscal year ending in the MA payment adjustment year.

(3) For MA EPs, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the calendar year concurrent with the payment adjustment year.

* * * * *

Potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals are defined for purposes of this subpart in § 495.202(a)(4).

* * * * *

Qualifying MA EP * * *

(5) Is not a ''hospital-based EP'' (as defined in § 495.4 of this part) and in determining whether 90 percent or more of his or her covered professional services were furnished in a hospital setting, only covered professional services furnished to MA plan enrollees of the qualifying MA organization, in lieu of FFS patients, will be considered.

* * * * *

■ 14. Section 495.202 is amended as follows:

■ A. Revising paragraph (b)(1).

■ B. In paragraph (b)(2) introductory text, removing the cross-reference ''(b)(3)'' and adding the cross-reference ''(4)'' in its place.

■ C. Revising paragraph (b)(2)(iii).

■ D. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5).

■ E. Adding a new paragraph (b)(3).

■ F. Revising newly redesignated paragraph (b)(4).

■ G. Revising newly redesignated paragraphs (b)(5)(i) and (ii).

The addition and revisions read as follows:

§ 495.202 Identification of qualifying MA organizations, MA–EPs and MA-affiliated eligible hospitals.

* * * * *

(b) * * *

(1) A qualifying MA organization, as part of its initial bid starting with plan year 2012, must make a preliminary identification of MA EPs and MA-affiliated eligible hospitals that the MA organization believes will be qualifying MA EPs and MA-affiliated eligible hospitals for which the organization is seeking incentive payments for the current plan year.

(2) * * *

(iii) NPI or CCN.

* * * * *

(3) When reporting under either paragraph (b)(1) or (4) of this section for purposes of receiving an incentive payment, a qualifying MA organization must also indicate whether more than 50 percent of the covered Medicare professional services being furnished by a qualifying MA EP to MA plan enrollees of the MA organization are being furnished in a designated geographic HPSA (as defined in § 495.100 of this part).

(4) Final identification of qualifying and potentially qualifying, as applicable, MA EPs and MA-affiliated eligible hospitals must be made within 2 months of the close of the payment year or the EHR reporting period that applies to the payment adjustment year as defined in § 495.200.

(5) * * *

(i) Identify all MA EPs and MA-affiliated eligible hospitals of the MA organization that the MA organization believes will be either qualifying or potentially qualifying;

(ii) Include information specified in paragraph (b)(2)(i) through (iii) of this section for each professional or hospital; and

* * * * *

■ 15. Section 495.204 is amended as follows:

■ A. Revising the section heading.

■ B. Revising paragraphs (b)(2) and (b)(4) introductory text, and (b)(4)(i) and (ii).

■ C. Redesignating paragraph (e) as paragraph (f).

■ D. Adding new paragraphs (e), (f)(5), and (g).

The revisions and additions read as follows:

§ 495.204 Incentive payments to qualifying MA organizations for qualifying MA–EPs and qualifying MA-affiliated eligible hospitals.

* * * * *

(b) * * *

(2) The qualifying MA organization must report to CMS within 2 months of the close of the calendar year, the aggregate annual amount of revenue attributable to providing services that would otherwise be covered as professional services under Part B received by each qualifying MA EP for enrollees in MA plans of the MA organization in the payment year.

* * * * *

(4) CMS requires the qualifying MA organization to develop a methodological proposal for estimating the portion of each qualifying MA EP's salary or revenue attributable to providing services that would otherwise be covered as professional services under Part B to MA plan enrollees of the MA organization in the payment year. The methodological proposal—

(i) Must be approved by CMS; and

(ii) May include an additional amount related to overhead, where appropriate, estimated to account for the MA-enrollee related Part B practice costs of the qualifying MA EP.

* * * * *

(e) *Potential increase in incentive payment for furnishing services in a geographic HPSA.* In the case of a qualifying MA EP who furnishes more than 50 percent of his or her covered professional services to MA plan enrollees of the qualifying MA organization during a payment year in a geographic HPSA, the maximum amounts referred to in paragraph (b)(3) of this section are increased by 10 percent.

(f) * * *

(5) If an MA EP, or entity that employs an MA EP, or in which an MA EP has a partnership interest, MA-affiliated eligible hospital, or other party contracting with the MA organization, fails to comply with an audit request to produce applicable documents or data, CMS recoups all or a portion of the incentive payment, based on the lack of applicable documents or data.

(g) *Coordination of payment with FFS or Medicaid EHR incentive programs.* (1) If, after payment is made to an MA organization for an MA EP, it is determined that the MA EP is eligible for the full incentive payment under the Medicare FFS EHR Incentive Program or has received a payment under the Medicaid EHR Incentive Program, CMS recoups amounts applicable to the given MA EP from the MA organization's monthly MA payment, or otherwise recoups the applicable amounts.

(2) If, after payment is made to an MA organization for an MA-affiliated eligible hospital, it is determined that the hospital is ineligible for the incentive payment under the MA EHR Incentive Program, or has received a payment under the Medicare FFS EHR Incentive Program, or if it is determined that all or part of the payment should not have been made on behalf of the MA-affiliated eligible hospital, CMS recoups amounts applicable to the given MA-affiliated eligible hospital from the MA organization's monthly MA payment, or otherwise recoups the applicable amounts.

■ 16. Section 495.208 is amended as follows:

■ A. Redesignating paragraphs (a) through (c) as paragraphs (d) through (f).

■ B. Adding new paragraphs (a) through (c).

The additions read as follows:

§ 495.208 Avoiding duplicate payment.

(a) CMS requires a qualifying MA organization that registers MA EPs for the purpose of participating in the MA EHR Incentive Program to notify each of the MA EPs for which it is claiming an incentive payment that the MA organization intends to claim, or has claimed, the MA EP for the current plan year under the MA EHR Incentive Program.

(b) The notice must make clear that the MA EP may still directly receive an EHR incentive payment if the MA EP is entitled to a full incentive payment under the FFS portion of the EHR Incentive Program, or if the MA EP registered to participate under the Medicaid portion of the EHR Incentive Program and is entitled to payment under that program—in both of which cases no payment would be made for the EP under the MA EHR incentive program.

(c) An attestation by the qualifying MA organization that the qualifying MA organization provided notice to its MA EPs in accordance with this section must be required at the time that meaningful use attestations are due with respect to MA EPs for the payment year.

* * * * *

■ 17. Section 495.210 is amended by revising paragraphs (b) and (c) to read as follows:

§ 495.210 Meaningful EHR user attestation

* * * * *

(b) Qualifying MA organizations are required to attest within 2 months after the close of a calendar year whether each qualifying MA EP is a meaningful EHR user.

(c) Qualifying MA organizations are required to attest within 2 months after close of the FY whether each qualifying MA-affiliated eligible hospital is a meaningful EHR user.

■ 18. Add § 495.211 to subpart C to read as follows:

§ 495.211 Payment adjustments effective for 2015 and subsequent MA payment years with respect to MA EPs and MA-affiliated eligible hospitals.

(a) *In general.* Beginning for MA payment adjustment year 2015, payment adjustments set forth in this section are made to prospective payments (issued under section 1853(a)(1)(A) of the Act) of qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program, if all or a portion of the MA–EPs and MA-affiliated eligible hospitals that would meet the definition of qualifying MA–EPs or qualifying MA-affiliated eligible hospitals (but for their demonstration of meaningful use) are not meaningful EHR users.

(b) *Adjustment based on payment adjustment year.* The payment adjustment is calculated based on the payment adjustment year.

(c) *Separate application of adjustments for MA EPs and MA-affiliated eligible hospitals.* The payment adjustments identified in paragraphs (d) and (e) of this section are applied separately. Paragraph (d) of this section applies only to qualifying MA organizations that received payment for any MA payment year for qualifying MA EPs under § 495.204. Paragraph (e) of this section applies only to qualifying MA organizations that received payment for any MA payment year for qualifying MA-affiliated eligible hospitals under § 495.204.

(d) *Payment adjustments effective for 2015 and subsequent years with respect to MA EPs.* (1) For payment adjustment year 2015, and subsequent payment

adjustment years, if a qualifying MA EP is not a meaningful EHR user during the payment adjustment year, CMS—

(i) Determines a payment adjustment based on data from the payment adjustment year; and

(ii) Collects the payment adjustment owed by adjusting a subsequent year's prospective payment or payments (issued under section 1853(a)(1)(A) of the Act), or by otherwise collecting the payment adjustment, if, in the year of collection, the MA organization does not have an MA contract with CMS.

(2) Beginning for payment adjustment year 2015, a qualifying MA organization that previously received incentive payments must, for each payment adjustment year, report to CMS the following:

[the total number of potentially qualifying MA EPs]/[(the total number of potentially qualifying MA EPs) + (the total number of qualifying MA EPs)].

(3) The monthly prospective payment amount paid under section 1853(a)(1)(A) of the Act for the payment adjustment year is adjusted by the product of—

(i) The percent calculated in accordance with paragraph (d)(2) of this section;

(ii) The Medicare Physician Expenditure Proportion percent, which is CMS's estimate of proportion of expenditures under Parts A and B that are not attributable to Part C that are attributable to expenditures for physicians' services, adjusted for the proportion of expenditures that are provided by EPs that are neither qualifying nor potentially qualifying MA EPs with respect to a qualifying MA organization; and

(iii) The applicable percent identified in paragraph (d)(4) of this section.

(4) *Applicable percent.* The applicable percent is as follows:

(i) For 2015, 1 percent;

(ii) For 2016, 2 percent;

(iii) For 2017, 3 percent.

(iv) For 2018, 3 percent, except, in the case described in paragraph (d)(4)(vi) of this section, 4 percent.

(v) For 2019 and each subsequent year, 3 percent, except, in the case described in paragraph (d)(4)(vi) of this section, the percent from the prior year plus 1 percent. In no case will the applicable percent be higher than 5 percent.

(vi) Beginning with payment adjustment year 2018, if the percentage in paragraph (d)(2) of this section is more than 25 percent, the applicable percent is increased in accordance with paragraphs (d)(4)(iv) and (v) of this section.

(e) *Payment adjustments effective for 2015 and subsequent years with respect to MA-affiliated eligible hospitals.* (1)(i) The payment adjustment set forth in this paragraph (e) applies if a qualifying MA organization that previously received an incentive payment (or a potentially qualifying MA-affiliated eligible hospital on behalf of its qualifying MA organization) attests that a qualifying MA-affiliated eligible hospital is not a meaningful EHR user for a payment adjustment year.

(ii) The payment adjustment is calculated by multiplying the qualifying MA organization's monthly prospective payment for the payment adjustment year under section 1853(a)(1)(A) of the Act by the percent set forth in paragraph (e)(2) of this section.

(2) The percent set forth in this paragraph (e) is the product of—

(i) The percentage point reduction to the applicable percentage increase in the market basket index for the relevant Federal fiscal year as a result of § 412.64(d)(3) of this chapter;

(ii) The Medicare Hospital Expenditure Proportion percent specified in paragraph (e)(3) of this section; and

(iii) The percent of qualifying and potentially qualifying MA-affiliated eligible hospitals that are not meaningful EHR users. Qualifying MA organizations are required to report to CMS

[the number of potentially qualifying MA-affiliated eligible hospitals]/[(the total number of potentially qualifying MA-affiliated eligible hospitals) + (the total number of qualifying MA-affiliated eligible hospitals)].

(3) The Medicare Hospital Expenditure Proportion for a year is the Secretary's estimate of expenditures under Parts A and B that are not attributable to Part C, that are attributable to expenditures for inpatient hospital services, adjusted for the proportion of expenditures that are provided by hospitals that are neither qualifying nor potentially qualifying MA-affiliated eligible hospitals with respect to a qualifying MA organization.

■ 19. Section 495.302 is amended as follows:

■ A. In the definition of ''Adopt, implement or upgrade,'' by revising paragraph (1).

■ B. In the definition of ''Children's hospital,'' by revising paragraph (1), redesignating paragraph (2) as paragraph (3), and adding a new paragraph (2).

■ C. In the definition of ''Practices predominantly,'' by removing the phrase ''in the most recent calendar year'' and adding the phrase ''(within the most recent calendar year or, as an optional State alternative beginning for payment year 2013, within the 12-month period preceding attestation)''.

The revisions and addition read as follows:

§ 495.302 Definitions.

* * * * *

Adopt, implement or upgrade * * *

(1) Acquire, purchase, or secure access to certified EHR technology capable of meeting meaningful use requirements;

* * * * *

Children's hospital * * *

(1) Has a CMS certification number (CCN), (previously known as the Medicare provider number), that has the last 4 digits in the series 3300–3399; or

(2) Does not have a CCN but has been provided an alternative number by CMS for purposes of enrollment in the Medicaid EHR Incentive Program as a children's hospital and;

* * * * *

■ 20. Section 495.304 is amended as follows:

■ A. In paragraphs (c)(1) and (2), by removing the phrase ''individuals receiving Medicaid'' and adding the phrase '' individuals enrolled in a Medicaid program'' in its place.

■ B. Adding paragraph (f).

The addition reads as follows:

§ 495.304 Medicaid provider scope and eligibility.

* * * * *

(f) *Further patient volume requirements for the Medicaid EP.* For payment year 2013 and all subsequent payment years, at least one clinical location used in the calculation of patient volume must have Certified EHR Technology—

(1) During the payment year for which the EP attests to having adopted, implemented or upgraded Certified EHR Technology (for the first payment year); or

(2) During the payment year for which the EP attests it is a meaningful EHR user.

■ 21. Section 495.306 is amended as follows;

■ A. Revising paragraphs (b), (c)(1)(i), (c)(2)(i), (c)(3)(i), (d)(1)(i)(A), (d)(1)(ii)(A), (d)(2)(i)(A), (d)(2)(ii)(A), and (e)(1) introductory text.

■ B. In paragraph (e)(1)(i), by removing ''; or'' and adding a period in its place.

■ C. Adding paragraph (e)(1)(iii).

■ D. Revising paragraph (e)(2)(i) introductory text.

■ E. In paragraph (e)(2)(i)(A), by removing ''; or'' and adding a period in its place.

■ F. Adding paragraph (e)(2)(i)(C).
■ G. Revising paragraph (e)(2)(ii) introductory text.
■ H. In paragraph (e)(2)(ii)(A), by removing ''; or'' and adding a period in its place.
■ I. Adding paragraph (e)(2)(ii)(C).
■ J. Revising paragraph (e)(3) introductory text.
■ K. In paragraphs (e)(3)(i) and (ii), by removing the semicolon and adding a period in its place.
■ L. In paragraph (e)(3)(iii), by removing ''; or'' and adding a period in its place.
■ M. Redesignating paragraphs (e)(3)(iii) and (e)(3)(iv) as paragraphs (e)(3)(iv) and (e)(3)(v).
■ N. Adding a new paragraph (e)(3)(iii).

The revisions and additions read as follows:

§ 495.306 Establishing patient volume.

* * * * *

(b) *State option(s) through SMHP.* (1) A State must submit through the SMHP the option or options it has selected for measuring patient volume.

(2)(i) A State must select the method described in either paragraph (c) or paragraph (d) of this section (or both methods).

(ii) Under paragraphs (c)(1)(i), (c)(2)(i), (c)(3)(i), (d)(1)(i), and (d)(2)(i) of this section, States may choose whether to allow eligible providers to calculate total Medicaid or total needy individual patient encounters in any representative continuous 90-day period in the 12 months preceding the EP or eligible hospital's attestation or based upon a representative, continuous 90-day period in the calendar year preceding the payment year for which the EP or eligible hospital is attesting.

(3) In addition, or as an alternative to the method selected in paragraph (b)(2) of this section, a State may select the method described in paragraph (g) of this section.

(c) * * *

(1) * * *

(i) The total Medicaid patient encounters in any representative, continuous 90-day period in the calendar year preceding the EP's payment year, or in the 12 months before the EP's attestation; by

* * * * *

(2) * * *

(i) The total Medicaid encounters in any representative, continuous 90-day period in the fiscal year preceding the hospitals' payment year or in the 12 months before the hospital's attestation; by

* * * * *

(3) * * *

(i) The total needy individual patient encounters in any representative, continuous 90-day period in the calendar year preceding the EP's payment year, or in the 12 months before the EP's attestation; by

* * * * *

(d) * * *

(1) * * *

(i)(A) The total Medicaid patients assigned to the EP's panel in any representative, continuous 90-day period in either the calendar year preceding the EP's payment year, or the 12 months before the EP's attestation when at least one Medicaid encounter took place with the individual in the 24 months before the beginning of the 90-day period; plus

* * * * *

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the 24 months before the beginning of the 90-day period; plus

* * * * *

(2) * * *

(i)(A) The total Needy Individual patients assigned to the EP's panel in any representative, continuous 90-day period in the either the calendar year preceding the EP's payment year, or the 12 months before the EP's attestation when at least one Needy Individual encounter took place with the individual in the 24 months before the beginning of the same 90-day period; plus

* * * * *

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the 24 months before the beginning of the 90-day period, plus

* * * * *

(e) * * *

(1) A Medicaid encounter means services rendered to an individual on any one day where:

* * * * *

(iii) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(2) * * *

(i) A Medicaid encounter means services rendered to an individual per inpatient discharge when any of the following occur:

(C) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(ii) A Medicaid encounter means services rendered in an emergency department on any 1 day if any of the following occur:

* * * * *

(C) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(3) For purposes of calculating needy individual patient volume, a needy patient encounter means services rendered to an individual on any 1 day if any of the following occur:

* * * * *

(iii) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

* * * * *

■ 22. Section 495.310 is amended as follows:
■ A. Removing and reserving paragraphs (a)(1)(ii) and (a)(2)(ii).
■ B. Adding paragraph (f)(8).
■ C. Revising paragraph (g)(1)(i)(B) introductory text.
■ D. In paragraphs (g)(1)(i)(B)(*1*) through (g)(1)(i)(B)(*3*), by removing the term ''discharge'' wherever it appears and adding the term ''acute-care inpatient discharge'' in its place.
■ E. In paragraph (g)(1)(i)(C), by removing the term ''discharges'' and adding the term ''acute-care inpatient discharges'' in its place.
■ F. In paragraphs (g)(2)(i)(A) and (B), (g)(2)(ii)(A), and (g)(2)(iii), by removing the phrase ''inpatient-bed-days'' wherever it appears and adding the phrase ''acute care inpatient-bed-days'' in its place.

The addition and revision read as follows:

§ 495.310 Medicaid provider incentive payments.

* * * * *

(f) * * *

(8) The aggregate EHR hospital incentive amount calculated under paragraph (g) of this section is determined by the State from which the eligible hospital receives its first payment year incentive. If a hospital receives incentive payments from other States in subsequent years, total incentive payments received over all payment years of the program can be no greater than the aggregate EHR incentive amount calculated by the initial State.

(g) * * *

(1) * * *

(i) * * *

(B) The discharge-related amount for the most recent continuous 12-month period selected by the State, but ending before the federal fiscal year that serves

as the first payment year. The discharge-related amount is the sum of the following, with acute-care inpatient discharges over the 12-month period and based upon the total acute-care inpatient discharges for the eligible hospital (regardless of any source of payment):

* * * * *

■ 23. Section 495.312 is amended by revising paragraph (c) to read as follows:

§ 495.312 Process for payments.

* * * * *

(c) *State's role.* (1) Except as specified in paragraph (c)(2) of this section, the State determines the provider's eligibility for the EHR incentive payment under subparts A and D of this part and approves, processes, and makes timely payments using a process approved by CMS.

(2) At the State's option, CMS conducts the audits and handles any subsequent appeals, of whether eligible hospitals are meaningful EHR users on the States' behalf.

* * * * *

■ 24. Section 495.316 is amended by revising paragraph (d)(2) to read as follows:

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

* * * * *

(d) * * *

(2)(i) Subject to § 495.332, the State may propose a revised definition for Stage 1 of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the following objectives:

(A) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.

(B) Capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited, and according to applicable law and practice.

(C) Capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission except where prohibited according to applicable law and practice.

(D) Capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

(ii) Subject to § 495.332, the State may propose a revised definition for Stage 2 of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the following objectives:

(A) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(B) Capability to submit electronic data to immunization registries or immunization information systems, except where prohibited, and in accordance with applicable law and practice.

(C) Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(D) Capability to provide electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(E) Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.

(F) Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

* * * * *

■ 23. Section 495.332 is amended by:

■ A. Adding paragraph (b)(6).

■ B. Revising paragraph (c) introductory text.

■ C. Removing paragraph (d)(9).

■ D. Adding paragraph (g).

The additions and revisions read as follows:

§ 495.332 State Medicaid health information technology (HIT) plan requirements.

* * * * *

(b) * * *

(6) For ensuring that at least one clinical location used for the calculation of the EP's patient volume has Certified EHR Technology during the payment year for which the EP is attesting.

(c) *Monitoring and validation.* Subject to paragraph (g) of this section, for monitoring and validation of information States must include the following:

* * * * *

(g) *Optional—signed agreement.* At the State's option, the State may include a signed agreement indicating that the State does all of the following:

(1) Designates CMS to conduct all audits and appeals of eligible hospitals' meaningful use attestations.

(2) Is bound by the audit and appeal findings described in paragraph (g)(1) of this section.

(3) Performs any necessary recoupments if audits (and any subsequent appeals) described in paragraph (g)(1) of this section determine that an eligible hospital was not a meaningful EHR user.

(4) Is liable for any FFP granted to the State to pay eligible hospitals that, upon audit (and any subsequent appeal) are determined not to have been meaningful EHR users.

■ 26. Section 495.342 is amended by revising the introductory text to read as follows:

§ 495.342 Annual HIT IAPD requirements.

Each State is required to submit the HIT IAPD Updates 12 months from the date of the last CMS approved HIT IAPD and must contain the following:

* * * * *

■ 27. Section 495.370 is amended by adding paragraph (d) to read as follows:

§ 495.370 Appeals process for a Medicaid provider receiving electronic health record incentive payments.

* * * * *

(d) This section does not apply in the case that CMS conducts the audits and handles any subsequent appeals under § 495.312(c)(2) of this part.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 21, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 21, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991–AB82

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

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: With this final rule, the Secretary of Health and Human Services adopts certification criteria that establish the technical capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record (EHR) Technology will need to include to, at a minimum, support the achievement of meaningful use by eligible professionals, eligible hospitals, and critical access hospitals under the Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in fiscal year and calendar year 2014. This final rule also makes changes to the permanent certification program for health information technology, including changing the program's name to the ONC HIT Certification Program.

DATES: These regulations are effective October 4, 2012. The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of October 4, 2012.

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION: This final rule is issued under section 3004 of the Public Health Service Act.

Commonly Used Acronyms

CAH Critical Access Hospital
CDA Clinical Document Architecture
CDC Centers for Disease Control and Prevention
CDS Clinical Decision Support
CEHRT Certified EHR Technology
CFR Code of Federal Regulations
CHPL Certified HIT Products List
CMS Centers for Medicare & Medicaid Services
CQM Clinical Quality Measure
CY Calendar Year
EH Eligible Hospital
EHR Electronic Health Record
EP Eligible Professional
FY Fiscal Year
HHS Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health
HITPC HIT Policy Committee
HITSC HIT Standards Committee
HL7 Health Level Seven
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
ICD–10 International Classification of Diseases, 10th Revision
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, 10th Revision, Procedure Coding System
IHE Integrating the Healthcare Enterprise®
LOINC® Logical Observation Identifiers Names and Codes
MU Meaningful Use
ONC Office of the National Coordinator of Health Information Technology
NCPDP National Council for Prescription Drug Programs
NIST National Institute of Standards and Technology
PHSA Public Health Service Act
SNOMED CT® Systematized Nomenclature of Medicine Clinical Terms

I. Executive Summary
A. Purpose of Regulatory Action
B. Summary of Major Provisions
1. Overview of the 2014 Edition EHR Certification Criteria
2. Certified EHR Technology
3. ONC HIT Certification Program
C. Costs and Benefits
II. Background
A. Statutory Basis
1. Standards, Implementation Specifications, and Certification Criteria
2. HIT Certification Programs
B. Regulatory History
1. Standards, Implementation Specifications, and Certification Criteria Rules
2. Medicare and Medicaid EHR Incentive Programs Rules
3. HIT Certification Programs Rules
III. Provisions of the Final Rule Affecting Standards, Implementation Specifications and Certification Criteria
A. 2014 Edition EHR Certification Criteria
1. Certification Criteria Relationship to MU
2. Applicability
3. Scope of a Certification Criterion for Certification
4. Explanation and Revision of Terms Used in Certification Criteria
5. Consensus-Based Standards
6. Adopting Versions of Standards
7. Display of Vocabulary Standards
8. Common Data Elements in Certification Criteria
9. New Certification Criteria
a. Ambulatory and Inpatient Setting
b. Ambulatory Setting
c. Inpatient Setting
10. Revised Certification Criteria
a. Ambulatory and Inpatient Setting
b. Ambulatory Setting
c. Inpatient Setting
11. Unchanged Certification Criteria
a. Refinements to Unchanged Certification Criteria
b. Unchanged Certification Criteria Without Refinements
12. Gap Certification
13. ''Disability'' Status
B. Redefining Certified EHR Technology and Related Terms
1. Certified EHR Technology (CEHRT) Definition
2. Base EHR Definition
3. Complete EHR Definition
4. Certifications Issued for Complete EHRs and EHR Modules
5. Adaptations of Certified Complete EHRs or Certified EHR Modules
IV. Provisions of the Final Rule Affecting the Permanent Certification Program for HIT (''ONC HIT Certification Program'')
A. Program Name Change
B. ''Minimum Standards'' Code Sets
C. Revisions to EHR Module Certification Requirements
1. Privacy and Security Certification
2. Certification to Certain New Certification Criteria
D. ONC–ACB Reporting Requirements
E. Continuation and Representation of Certified Status
1. 2011 or 2014 Edition EHR Certification Criteria Compliant
2. Updating a Certification
3. Representation of Meeting the Base EHR Definition
F. EHR Technology Price Transparency
G. Certification and Certification Criteria for Other Health Care Settings
V. Collection of Information Requirements
VI. Regulatory Impact Statement
A. Statement of Need
B. Overall Impact
1. Comment and Response
2. Executive Orders 12866 and 13563—Regulatory Planning and Review Analysis
a. Costs
i. Development and Preparation Costs for 2014 Edition EHR Certification Criteria
ii. Overall Development and Preparation Estimated Costs Over a 3-Year Period
iii. Costs for Reporting Test Results Hyperlinks
b. Benefits
3. Regulatory Flexibility Act Analysis
4. Executive Order 13132—Federalism
5. Unfunded Mandates Reform Act of 1995
Regulation Text

I. Executive Summary

A. Purpose of Regulatory Action

The HIT Standards Committee (HITSC) issued recommendations for standards, implementation specifications, and certification criteria to the National Coordinator for Health Information Technology (the National Coordinator) on September 28, 2011 and

October 21, 2011. In fulfilling his duties under sections 3001(c)(1)(A) and (B) of the Public Health Service Act (PHSA), the National Coordinator reviewed the recommendations made by the HITSC, endorsed certain standards, implementation specifications, and certification criteria, and reported his determinations to the Secretary for consideration. On March 7, 2012, the Secretary published a proposed rule (77 FR 13832) with her determinations regarding the standards, implementation specifications, and certification criteria endorsed by the National Coordinator, as required by section 3004(a)(3) of the PHSA. The proposed rule solicited public comment on the standards, implementation specifications, and certification criteria the Secretary proposed for adoption.

This final rule addresses comments received on the proposed rule and specifies the adoption by the Secretary, under sections 3004(a)(3) and 3004(b)(3) of the PHSA, of the standards, implementation specifications, and certification criteria that will establish the technical capabilities that electronic health record (EHR) technology must include to be certified. EHR technology certified to these standards, implementation specifications, and certification criteria makes it possible for eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) to adopt Certified EHR Technology (CEHRT) and subsequently attempt to demonstrate its meaningful use (MU) under the Medicare and Medicaid EHR Incentive Programs (the ''EHR Incentive Programs'').

Consistent with Executive Order 13563, we have undertaken a retrospective review of our regulations. The final rule establishes multiple means for reducing regulatory burden and increasing regulatory flexibility for stakeholders, including changes to current regulatory requirements and approaches.

B. Summary of Major Provisions

1. Overview of the 2014 Edition EHR Certification Criteria

We have adopted certification criteria that will support the changes to the EHR Incentive Programs, including the new and revised objectives and measures for Stages 1 and 2 of MU finalized by CMS. The adopted certification criteria also enhance care coordination, patient engagement, and the security, safety, and efficacy of EHR technology. We refer to the adopted certification criteria as the 2014 Edition EHR certification criteria and the certification criteria previously adopted through rulemaking (75 FR 2014, 75 FR 44590) as the 2011 Edition EHR certification criteria. To permit efficient certification methods and reduce regulatory burden, we have identified those certification criteria that we have adopted as part of the 2014 Edition EHR certification criteria that include unchanged capabilities that were also included in the 2011 Edition EHR certification criteria. For EHR technology previously certified to the 2011 Edition EHR certification criteria, this will permit, where applicable, the use of prior test results for certification to the 2014 Edition EHR certification criteria (see the discussion of ''gap certification'' in section III.A.12 of this preamble).

2. Certified EHR Technology

Since the publication of the Standards and Certification Criteria final rule in July 2010, 75 FR 44590 (July 28, 2010) (the ''S&CC July 2010 final rule''), HHS received significant feedback from stakeholders which suggested that we change our CEHRT policy (and definition) to one that would provide EPs, EHs, and CAHs the flexibility to have only the EHR technology they need to demonstrate MU. Consistent with stakeholder feedback and recommendations received from the HITSC, we proposed to revise the CEHRT definition to offer the requested flexibility. Based on comments received, we have finalized a CEHRT definition that provides even more flexibility for EPs, EHs, and CAHs than we originally proposed. In order to have EHR technology that meets the CEHRT definition for FY and CY 2014 and subsequent years, EPs, EHs, and CAHs must have EHR technology certified to the 2014 Edition EHR certification criteria that meets the Base EHR definition (EHR technology that includes fundamental capabilities all providers would need to have) as well as the additional EHR technology certified to the 2014 Edition EHR certification criteria necessary to meet the MU objectives and measures for the stage of MU that they seek to meet and to capture, calculate, and electronically submit clinical quality measures. In addition, this final rule permits EPs, EHs, and CAHs to adopt EHR technology that meets the FY/CY 2014 CEHRT definition and use it in their attempts to achieve MU prior to FY/CY 2014. We further discuss the new dynamic CEHRT definition, including the Base EHR definition in section III.B (''Redefining Certified EHR Technology and Related Terms'').

We note that we continue to permit only two types of EHR technology, Complete EHRs and EHR Modules, to be certified to meet these definitions under the ''ONC HIT Certification Program.'' A Complete EHR requires EHR technology to meet, at a minimum, all the mandatory certification criteria for either the ambulatory or inpatient setting, while an EHR Module can be any EHR technology certified to one less than all the mandatory certification criteria for either the ambulatory or inpatient setting (as noted, it would be a Complete EHR if it was certified to all the mandatory certification criteria for a setting). A Complete EHR, by definition, would meet the Base EHR definition and could be used to meet the CEHRT definition, but we note that an EP may need EHR technology certified to the optional ''cancer registries'' certification criteria to support their attempt to achieve MU. A single EHR Module could also be developed to meet the Base EHR definition and CEHRT definition for an EP, EH, or CAH. Additionally, an EP, EH, or CAH could use multiple certified EHR Modules or a certified EHR Module(s) in conjunction with a certified Complete EHR to meet the Base EHR definition and CEHRT definition.

3. ONC HIT Certification Program

This final rule revises the permanent certification program in ways that increase regulatory clarity and transparency, reduce regulatory burden, and add flexibility for the health information technology (HIT) community. One of these revisions includes changing the permanent certification program title to the ''ONC HIT Certification Program,'' which provides clearer attribution to the agency responsible for the program and an appropriate description of the program's scope, covering both current and potential future activities. The final rule also revises the process for permitting the use of newer versions of ''minimum standard'' code sets. The new approach is expected to reduce regulatory complexity and burden by providing the industry with the flexibility to utilize newer versions of adopted ''minimum standard'' code sets in a timelier manner.

The final rule modifies the certification processes ONC-Authorized Certification Bodies (ONC–ACBs) will need to follow for certifying EHR Modules in a manner that provides clear implementation direction and compliance with the new certification criteria. It also reduces regulatory burden by eliminating the certification requirement that every EHR Module be certified to the ''privacy and security'' certification criteria. Instead, the privacy and security capabilities are

included in the Base EHR definition that every EP, EH, and CAH must meet as part of meeting the CEHRT definition.

To increase clarity for purchasers in the HIT market, we have established methods for representing certified Complete EHRs and certified EHR Modules, including when Complete EHRs and EHR Modules meet the Base EHR definition. We also require that test results used for EHR technology certification be made publicly available in an effort to increase transparency and provide EPs, EHs, and CAHs a potential starting point from which to assess any implementation issues associated with certified Complete EHRs and certified EHR Modules. Finally, as another means of increasing transparency and mitigating any potential confusion in the market, we require that ONC–ACBs ensure that EHR technology developers include in their marketing materials and communications notification to potential purchasers any additional types of costs that an EP, EH, or CAH would pay to implement their certified Complete EHR or certified EHR Module in order to attempt to meet MU objectives and measures.

C. Costs and Benefits

We determined that this final rule is not an economically significant rule as its overall costs will be less than $100 million in any one year. We have, however, estimated the costs and benefits of the final rule. The final rule does not account for the estimated costs that EPs, EHs, and CAHs will incur in adopting and implementing certified Complete EHRs and certified EHR Modules. Those costs are estimated in the CMS Medicare and Medicaid EHR Incentive Programs Stage 2 final rule (Stage 2 final rule) published elsewhere in this issue of the **Federal Register.** The estimated costs expected to be incurred by EHR technology developers to develop and prepare EHR technology (i.e., Complete EHRs and EHR Modules) to be tested and certified in accordance with the 2014 Edition EHR certification criteria are represented in monetary terms in Table 1 below. We believe that there will be market pressures to have certified Complete EHRs and certified EHR Modules ready and available prior to when EPs, EHs, and CAHs must meet the revised CEHRT definition for FY/CY 2014, particularly with the option provided by this final rule for EPs, EHs, and CAHs to adopt EHR technology that meets the FY/CY 2014 CEHRT definition and use it in their attempts to achieve MU in FY/CY 2013. Due to these market pressures, we believe that most of the estimated costs for developing EHR technology to meet the 2014 Edition EHR certification criteria will be incurred during the remainder of 2012 and throughout 2013, rather than in 2014. As a result, as represented in Table 1, the estimated costs attributable to this final rule are distributed as follows: 45% for 2012, 45% for 2013, and 10% for 2014. The dollar amounts expressed in Table 1 are expressed in 2012 dollars.

There are multiple potential benefits that stem from the 2014 Edition EHR certification criteria. Foremost, the 2014 Edition EHR certification criteria promote enhanced interoperability, functionality, utility, and security of EHR technology through the capabilities they include and the standards they require EHR technology to meet for certification. EHR technology certified to the 2014 Edition EHR certification criteria also will be capable of supporting EPs, EHs, and CAHs' attempts to demonstrate MU under the EHR Incentive Programs. The revised CEHRT definition, the availability of gap certification, and the revisions to the ONC HIT Certification Program, will, as noted, increase regulatory clarity, improve transparency, and add flexibility, while also reducing the regulatory burden on the HIT industry. Last, the provisions of this final rule are supportive of other initiatives, such as the Partnership for Patients, Medicare Shared Savings Program, and other quality measure programs administered by CMS.

TABLE 1—ESTIMATED COSTS OF THE FINAL RULE: DISTRIBUTED TOTAL DEVELOPMENT AND PREPARATION COSTS FOR COMPLETE EHR AND EHR MODULE DEVELOPERS (3-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (percent)	Total low cost estimate ($M)	Total high cost estimate ($M)	Primary mid-point total cost estimate ($M)
2012	45	45.85	130.02	87.93
2013	45	45.85	130.02	87.93
2014	10	10.20	28.90	19.56
3-Year Totals		101.90	288.94	195.42

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 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

With the passage of the HITECH Act, two new Federal advisory committees were established, the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC) (sections 3002 and 3003 of the PHSA, respectively). Each is responsible for advising the National Coordinator 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. The HITPC also considers and provides recommendations to ONC and CMS on meaningful use (MU) policy under the EHR Incentive Programs. The HITSC is responsible for recommending standards, implementation specifications, and certification criteria for adoption by the Secretary under section 3004 of the PHSA consistent with the ONC-coordinated Federal Health IT Strategic Plan.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary to adopt such standards, implementation

specifications, and certification criteria. As specified in section 3004(a)(1), the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register.**

Section 3004(b)(3) of the PHSA titled ''Subsequent Standards Activity'' provides that the ''Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent'' with the schedule published by the HITSC. We consider this provision in the broader context of the HITECH Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITSC and endorsed by the National Coordinator, as well as other appropriate and necessary HIT standards, implementation specifications, and certification criteria. Throughout this process, the Secretary intends to continue to seek the insights and recommendations of the HITSC.

2. HIT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. Specifically, section 3001(c)(5)(A) specifies that the ''National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle'' (i.e., certification criteria adopted by the Secretary under section 3004 of the PHSA). The certification program(s) must also ''include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act.''

Section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HITSC, ''shall support the establishment of a conformance testing infrastructure, including the development of technical test beds.'' The HITECH Act also indicates that ''[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.''

B. Regulatory History

1. Standards, Implementation Specifications, and Certification Criteria Rules

The Secretary issued an interim final rule with request for comments titled ''Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology'' (75 FR 2014, Jan. 13, 2010) (the ''S&CC January 2010 interim final rule''), which adopted an initial set of standards, implementation specifications, and certification criteria. After consideration of the public comments received on the S&CC January 2010 interim final rule, a final rule was issued to complete the adoption of the initial set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for MU Stage 1. 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). On October 13, 2010, an interim final rule with a request for comment was issued to remove certain implementation specifications related to public health surveillance that had been previously adopted in the S&CC July 2010 final rule (75 FR 62686).

The standards, implementation specifications, and certification criteria adopted by the Secretary in the S&CC July 2010 final rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of MU Stage 1 by EPs, EHs, and CAHs under the Medicare and Medicaid EHR Incentive Programs Stage 1 final rule (the ''Stage 1 final rule'') (see 75 FR 44314 for more information about MU and the Stage 1 requirements).

On March 7, 2012, ONC published a proposed rule (''the Proposed Rule'') (77 FR 13832) in the **Federal Register** that proposed new and revised certification criteria that would support the achievement of MU beginning with the EHR reporting periods in FY/CY 2014. These certification criteria are referred to as the 2014 Edition EHR certification criteria. The rule also proposed revisions to the CEHRT definition.

2. Medicare and Medicaid EHR Incentive Programs Rules

On January 13, 2010, CMS published the EHR Incentive Programs Stage 1 proposed rule (75 FR 1844). The rule proposed a definition for Stage 1 MU of CEHRT and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act. Subsequently, CMS published a final rule (75 FR 44314) for the EHR Incentive Programs on July 28, 2010, simultaneously with the publication of the S&CC July 2010 final rule. The Stage 1 final rule established the objectives, associated measures, and other requirements that EPs, EHs, and CAHs must satisfy to demonstrate MU during Stage 1.

On March 7, 2012, CMS published a proposed rule (77 FR 13698) in the **Federal Register** for MU Stage 2 that included proposed revisions to MU Stage 1 beginning with the EHR reporting periods in FY/CY 2013 (Stage 2 proposed rule).

3. HIT Certification Programs Rules

On March 10, 2010, ONC published a proposed rule (75 FR 11328) titled ''Proposed Establishment of Certification Programs for Health Information Technology'' (the ''Certification Programs proposed rule''). The rule proposed both a temporary and permanent certification program for the purposes of testing and certifying HIT. It also specified the processes the National Coordinator would follow to authorize organizations to perform the certification of HIT. A final rule establishing the temporary certification program was published on June 24, 2010 (75 FR 36158) (the ''Temporary Certification Program final rule'') and a final rule establishing the permanent certification program was published on January 7, 2011 (76 FR 1262) (''the Permanent Certification Program final rule'').

In the Proposed Rule mentioned above, ONC also proposed revisions to the permanent certification program, including changing the program's name to the ONC HIT Certification Program.

III. Provisions of the Final Rule Affecting Standards, Implementation Specifications, and Certification Criteria

To make a clear distinction between previously adopted certification criteria and the ones proposed for adoption in the Proposed Rule, we stated we would refer to and define the certification criteria adopted in the S&CC July 2010 final rule and included in §§ 170.302, 170.304, and 170.306 collectively as the

''2011 Edition EHR certification criteria.'' We proposed to revise § 170.102 to add this definition.

Comments. Commenters expressed support for ''editions'' of certification criteria, particularly the use of ''2011 Edition EHR certification criteria'' for collectively referencing §§ 170.302, 170.304, and 170.306.

Response. We appreciate the expression of support and have revised § 170.102 to include the definition of 2011 Edition EHR certification criteria as proposed.

A. 2014 Edition EHR Certification Criteria

In the Proposed Rule, we proposed new, revised, and unchanged certification criteria that would establish the technical capabilities and specify the related standards and implementation specifications that CEHRT would need to include to, at a minimum, support the achievement of MU by EPs, EHs, and CAHs under the EHR Incentive Programs beginning with the EHR reporting periods in FY/CY 2014. We referred to these new, revised, and unchanged certification criteria as the ''2014 Edition EHR certification criteria'' and proposed to add this term and its definition to § 170.102. Additionally, we proposed to include all of the 2014 Edition EHR certification criteria in § 170.314 to set them apart and make it easier for stakeholders to quickly determine which certification criteria would be required beginning with the EHR reporting periods that start in FY/CY 2014.

Comments. Commenters expressed support for ''editions'' of certification criteria, particularly the use of ''2014 Edition EHR certification criteria'' to reference the certification criteria adopted in § 170.314. One commenter, however, did not agree with our approach to include all of the 2014 Edition EHR certification criteria in § 170.314. The commenter suggested that we should maintain the approach used for the 2011 Edition EHR certification criteria (i.e., to separate general, ambulatory, and inpatient certification criteria into three sections of the Code of Federal Regulations (CFR)).

Response. We appreciate the expression of support for our ''editions'' approach and have revised § 170.102 to include the definition of 2014 Edition EHR certification criteria as proposed. Use of ''2014 Edition EHR certification criteria'' coupled with our use of ''2011 Edition EHR certification criteria'' should eliminate any ambiguity and provide a clear distinction between the certification criteria that are part of the 2011 Edition EHR certification criteria and those in the 2014 Edition EHR certification criteria.

We believe by including all the 2014 Edition EHR certification criteria in one section of the CFR is a better approach than our previous approach of separating general, ambulatory, and inpatient certification criteria into three sections of the CFR. As noted in the Proposed Rule, the inclusion of all 2014 Edition EHR certification criteria in one regulatory section will simplify the regulatory framework for stakeholders.

1. Certification Criteria Relationship to MU

Many of the certification criteria that we proposed supported the MU objectives and measures proposed by CMS in the Stage 2 proposed rule as well as the reporting of MU objectives and measures and clinical quality measures (CQMs). To the extent CMS has changed (e.g., added, revised, or removed) the MU objectives, measures, or reporting requirements in its final rule, we have made appropriate changes to the associated certification criteria so that they continue to support the MU objectives, measures, and reporting requirements.

We received many comments on the 2014 Edition EHR certification criteria that were not within this rulemaking's scope. These comments focused on the MU objectives, measures, CQM measures, and reporting requirements. For responses to such comments, we direct readers to the Stage 2 final rule published elsewhere in this issue of the **Federal Register**.

We reiterate and emphasize for commenters to remember that certification is a floor not a ceiling. It does not specify an exhaustive set of capabilities that EHR technology must include. Rather, certification assesses a subset of capabilities (generally capabilities that support MU requirements) that may be part of the overall EHR technology that an EP, EH, or CAH adopts. In this regard, certification focuses on providing assurance to EPs, EHs, and CAHs that EHR technology certified to a certification criterion includes the specified capabilities, that those capabilities perform correctly and, where applicable, that those capabilities properly utilize/support adopted standards.

We discuss the new, revised, and unchanged certification criteria that we are adopting as the 2014 Edition EHR certification criteria in sections A.8 through A.10 below. We include a table at the beginning of the discussion of each certification criterion or criteria that specifies the MU objective that the 2014 Edition EHR certification criterion or criteria support. The objective cited is either a Stage 1 or Stage 2 objective that will be effective for the EHR reporting periods in FY/CY 2014. We provide this frame of reference because beginning in FY/CY 2014 EHR technology will need to be certified to the 2014 Edition EHR certification criteria to meet the CEHRT definition and the tables clearly associate the certification criterion or criteria with the MU objective it supports. The tables also specify the CFR location for each certification criterion adopted in § 170.314.

2. Applicability

Section 170.300 establishes the applicability of subpart C—Certification Criteria for Health Information Technology. Section 170.300(a) establishes the applicability of the adopted certification criteria to the testing and certification of Complete EHRs and EHR Modules. Section 170.300(b) specifies that when a certification criterion refers to two or more standards as alternatives, the use of at least one of the alternative standards will be considered compliant. Section 170.300(c) specifies that Complete EHRs and EHR Modules are not required to be compliant with certification criteria that are designated as optional.

We proposed to revise § 170.300 to reflect our proposed regulatory structure for the 2014 Edition EHR certification criteria. We proposed to revise paragraph (c) to add that Complete EHRs and EHR Modules are also not required to be certified to specific capabilities within a certification criterion that are designated as optional. We also proposed to add a paragraph (d) that would clarify which certification criteria or specific capabilities within a certification criterion included in § 170.314 have general applicability (i.e., apply to both ambulatory and inpatient settings) or apply only to an inpatient setting or an ambulatory setting.

Comments. Comments asked for clarification on how the optionality provided for capabilities within certification criteria would be clearly identified to purchasers of certified EHR technology.

Response. We expect that the certifications issued to EHR technology will clearly indicate whether the EHR technology was certified to any optional capability within a certification criterion or, for that matter, any optional certification criterion. The Certified HIT Product List (CHPL) will also indicate

whether a certified Complete EHR or certified EHR Module was certified to an optional certification criterion or an optional specific capability within a certification criterion.

3. Scope of a Certification Criterion for Certification

In the Proposed Rule, based on our proposal to codify all the 2014 Edition EHR certification criteria in § 170.314, we clarified that certification to the certification criteria at § 170.314 would occur at the second paragraph level of the regulatory section. We noted that the first paragraph level in § 170.314 organizes the certification criteria into categories. These categories include: clinical (§ 170.314(a)); care coordination (§ 170.314(b)); clinical quality measures (§ 170.314(c)); privacy and security (§ 170.314(d)); patient engagement (§ 170.314(e)); public health (§ 170.314(f)); and utilization (§ 170.314(g)). Thus, we stated that a certification criterion in § 170.314 is at the second paragraph level and would encompass all of the specific capabilities in the paragraph levels below with, as noted in our discussion of ''applicability,'' an indication if the certification criterion or the specific capabilities within the criterion only apply to one setting (ambulatory or inpatient).

Comments. We received no comments on this clarification.

Response. Having adopted the 2014 Edition EHR certification criteria in § 170.314 as we proposed, our clarification remains accurate. Additionally, we offer further clarity with an illustration of this principle using the ''demographics'' certification criterion adopted at § 170.314(a)(3) (second paragraph level). The certification criterion includes two specific capabilities at (3)(i) and (ii) (third paragraph level): ''(i)'' enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth (in accordance with the specified standards for race, ethnicity, and preferred language (§ 170.314(3)(i)(A) and (B)); and, ''(ii)'' for the inpatient setting only, enable a user to electronically record, change, and access preliminary cause of death in the event of mortality. Consequently, to meet the demographics certification criterion, for example, EHR technology designed for the inpatient setting would need to meet § 170.314(a)(3)(i)(A) and (B) and (ii), while EHR technology designed for the ambulatory setting would only need to meet (3)(i)(A) and (B) because the capability at (3)(ii) only applies to the inpatient setting.

4. Explanation and Revision of Terms Used in Certification Criteria

In the Proposed Rule, we noted that certain terms are repeatedly used in the proposed 2014 Edition EHR certification criteria. We stated that, based on our experience and stakeholder feedback related to how terms in the 2011 Edition EHR certification criteria have been interpreted, it was necessary in certain cases to select different terms. Therefore, we provided the following list of terms that are repeatedly used in the 2014 Edition EHR certification criteria and the intended meaning for each term.

''User'' is used to mean a health care professional or his or her office staff or a software program or service that would interact directly with the CEHRT. This is essentially the same description that we gave to ''user'' in the S&CC July 2010 final rule (75 FR 44598). We clarified that, unless expressly stated otherwise, ''user'' does not mean a patient.

''*Record*'' is used to mean the ability to capture and store information in EHR technology. We consider this meaning complementary to and consistent with related terms, namely ''change and ''access,'' and their associated capabilities.

''*Change*'' is used to mean the ability to alter or edit information previously recorded in EHR technology. We proposed to replace the term ''modify'' used in the 2011 Edition EHR certification criteria with ''change.'' Although we interpret both terms to have essentially the same meaning, we believe ''change'' connotes a more plain language meaning as recommended by *plainlanguage.gov.*[1] In certification criteria in which this term is used, we stated that we do not intend for it to be interpreted to mean that information previously recorded would be able to be changed without the retention of prior value(s). Rather, a change must be retained as an audited event and in a viewable format that identifies the changed information in a patient's record (similar to how one might see changes represented in a word-processing application). How such changes are displayed is a design decision left to EHR technology developers.

''*Access*'' is used to mean the ability to examine or review information in or through EHR technology. We proposed to replace the term ''retrieve'' used in the 2011 Edition EHR certification criteria with ''access'' because we believe it is clearer and more accurately expresses the capability we intend for EHR technology to include. We noted that some stakeholders had interpreted ''retrieve'' to suggest that the EHR technology also needed to be able to obtain data from external sources. Nevertheless, we stated that we interpret both ''access'' and ''retrieve'' to have essentially the same meaning, but note that ''access'' should not be interpreted to include necessarily the capability of obtaining or transferring the data from an external source.

''*Incorporate*'' is used to mean to electronically import, attribute, associate, or link information in EHR technology. With the exception of import, we previously used these terms to describe the ''incorporate'' capability included in certification criteria as illustrated by the capability specified at § 170.302(h)(3). We proposed to revise its unique meaning for the 2014 Edition EHR certification criteria and the purposes of certification to account for the ability to electronically import information.

''*Create*'' is used to mean to electronically produce or generate information. We proposed to replace the term ''generate'' used in the 2011 Edition EHR certification criteria with ''create.'' We stated that ''create'' is clearer and is a better word choice than generate from a plain language perspective.

''*Transmit*'' is used to mean to send from one point to another.

Comments. Commenters expressed general support for our proposed replacement of terms in certification criteria with the proposed terms described above. A few commenters, however, expressed confusion about our description of ''incorporate'' as we described it and used it in different certification criteria such as the proposed ''transitions of care–incorporate summary care record'' certification criterion (§ 170.314(b)(1)) and the ''incorporate laboratory tests and values/results'' certification criterion (§ 170.314(b)(5)).

Response. We appreciate the support for the proposed term replacements and are replacing the terms as proposed, except for the term ''incorporate.'' We agree with commenters that our description of incorporate could create confusion based on the context in which we proposed to use it in different certification criteria. In consideration of comments received, we have revised our description of incorporation to reflect the common interpretation commenters stated they assigned to the term. Thus,

[1] *http://www.plainlanguage.gov/howto/wordsuggestions/simplewords.cfm#lm*

when the term incorporate is used within a certification criterion it is intended to mean to electronically process structured information from another source such that it is combined (in structured form) with information maintained by EHR technology and is subsequently available for use within the EHR technology by a user. As part of the 2014 Edition EHR certification criteria, the ''transitions of care'' and ''incorporate laboratory tests and values/results'' certification criteria at § 170.314(b)(2) and (b)(5), respectively, reference this term in the context of a specific capability that would require EHR technology to be able to incorporate information.

Comments. Commenters expressed confusion about how to interpret our use of the phrase ''included in one or any combination of the following'' in certification criteria.

Response. To eliminate any potential confusion, we have revised the certification criteria containing this phrase to read ''each one and at least one combination of the following data.'' We use this phrase to mean that the capability for which certification is required must be able to individually address each of the data specified in the certification criterion and at least one combination of those data. ''One combination'' means a combination of two or more of the data listed in the certification criterion. For example, in the clinical decision support (CDS) certification criterion six categories of data are listed in paragraphs § 170.314 (a)(8)(i)(A) through (F). The certification criterion states ''enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions … based on each one and at least one combination of the following data.'' Thus, to meet this certification criterion EHR technology must be able to enable the selection of CDS interventions that would be separately applicable to the data listed in (A) through (F) and at least one combination of the data listed in (A) through (F), such as (A) and (D) (problems and demographics).

To provide further clarity for the 2014 Edition EHR certification criteria, we have revised a number of certification criteria to now begin with ''EHR technology must be able to * * *'' rather than ''Enable a user to * * *.'' We believe this approach more clearly communicates that the *EHR technology* must demonstrate the capability to be certified to the certification criterion. As one last point of clarification, we replaced ''data element'' references in certification criteria, where appropriate, with simply ''data.'' We believe this clarifies when we intend to mean data that includes types and elements. We also believe this will prevent confusion when the reference point is solely a ''data element.''

Comments. Commenters asked how terms used in MU objectives and measures are defined for the purposes of the 2014 Edition EHR certification criteria, such as ''electronic notes,'' ''images,'' ''care plan,'' and ''care team.''

Response. We incorporate in our certification criteria the terms used in MU objectives and measures as they are defined or described in the Stage 2 final rule.

5. Consensus-Based Standards

Comments. Commenters stated that for interoperability to be successful, it was essential that standards be created through collaborative, consensus-based processes that take into consideration the needs and concerns of all interested stakeholders. *Response.* Federal agencies are required under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. § 3701 et seq.) and OMB Circular A–119 [2] to use, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. Both the NTTAA and OMB Circular A–119 provide for certain 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 have adopted or refer to voluntary consensus standards, except for the following government-unique standards: the Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity; the three transport standards adopted in § 170.202; the standard that identifies the data elements referenced by clinical quality measures (adopted at § 170.204(c)); and certain standards related to the protection of electronic health information adopted in § 170.210. We are aware of no voluntary consensus standards that would serve as alternatives to these standards for the purposes that we have identified.

Comments. A commenter suggested that we incorporate the HL7 EHR System Functional Model (ISO/HL7 10781 standard) into certification. The commenter noted that is a long-standing international consensus standard for EHR System functionality and that Release 2 of this standard is currently in ballot by the International Standards Organization Technical Committee 215 on Health Informatics (ISO TC215), the Committee for European Normalization Technical Committee 251 (CEN TC251), the International Health Terminology Standards Development Organisation (IHTSDO), the Clinical Data Interchange Standards Consortium (CDISC) and Health Level Seven (HL7). The commenter suggested that ''linking'' the function and conformance criteria of the internationally-recognized ISO/HL7 10781 standard to the 2014 Edition EHR certification criteria for the purposes of certification would make EHR technology certified under the ONC HIT Certification Program more competitive in international markets.

Response. It is our understanding that the HL7 EHR System Functional Model provides a comprehensive set of EHR *system* functional requirements that in many cases goes beyond the scope of the capabilities required by the 2014 Edition EHR certification criteria. As such, this comment is outside the scope of this current rulemaking. However, we strongly support methods that could be used to increase international interoperability and acceptance of EHR technology certified under the ONC HIT Certification Program. Accordingly, we intend to explore and request that the HITPC and HITSC consider the applicability and usefulness of the HL7 EHR System Functional Model as a basis for future recommendations on certification criteria.

6. Adopting Versions of Standards

Comments. We received comments recommending that we adopt standards at a higher level of abstraction and that we should not be overly prescriptive about the exact version and release of vocabulary and messaging protocols. That is, that we should not adopt a particular version of a content exchange standard for which certification would be required, (e.g., HL7 2.x, where ''x'' could be any version within the version 2 family) and accompany the adopted standards with detailed implementation specifications or guidance outside of rulemaking.

Response. While the commenters' recommendation may provide added flexibility, we are unable to accept the recommendation for multiple reasons. First, it has the potential to create interoperability challenges. Second, there are processes under the Administrative Procedure Act that must be followed for the adoption of substantive requirements. Third, in accordance with Office of the Federal Register regulations related to ''incorporation by reference,'' 1 CFR

[2] *http://www.whitehouse.gov/omb/circulars_a119.*

part 51, which we follow for this final rule, the publications we reference are ''limited to the edition of the publication that is approved'' and do not include ''[f]uture amendments or revisions of the publication.'' Consequently, we do not include regulatory language that refers, for instance, to ''Version 1.X'' when ''X'' remains a variable.

We note, however, that we have taken two steps for certain vocabulary standards designated as minimum standards code sets. First, in this final rule we have adopted updated versions of four vocabulary standards that we proposed for certification in the Proposed Rule. We proposed the use of the January 2012 International Release of SNOMED CT®, but have adopted the July 2012 International Release of SNOMED CT® as well as the March 2012 U.S. Extension to SNOMED CT®. We proposed the use of version 2.38 of LOINC®, but have adopted version 2.40. We proposed the use of the February 2012 monthly version of RxNorm, but have adopted the August 2012 monthly version of RxNorm. We proposed the use of the August 15, 2011 version of CVX code sets, but have adopted the updated through July 11, 2012 version. In all these instances, we have found that the newer versions improve interoperability and EHR technology implementation, support MU, and do not create additional substantive requirements in comparison to the proposed versions of these vocabulary standards. Further, the adoption of these versions establishes the baseline in the CFR with the most recent versions of these vocabulary standards that is possible. Second, we have also established an approach that permits the use of newer versions of these standards than the one adopted in the CFR. We refer readers to section IV.B for a discussion of ''minimum standards'' code sets and our new more flexible approach for their use in certification and upgrading certified Complete EHRs and certified EHR Modules. Readers should also review § 170.555, which specifies the certification processes for ''minimum standards'' code sets.

7. Display of Vocabulary Standards

Comments. Several commenters asked a similarly themed question with respect to the vocabulary standards we proposed to adopt. The question centered on whether EHR technology was required to display a particular vocabulary to a user (for the certification criteria that require recording certain patient information in a vocabulary standard) in order to be certified. Commenters explained that for the problem list certification criterion that SNOMED CT® codes should not be required for display in EHR technology and that an organization should be able to use whichever code set they prefer to display. Others provided similar rationale and said that health care providers are typically unfamiliar with SNOMED CT®. Commenters raised similar questions regarding the display of race and ethnicity as well as smoking status.

Response. We agree with commenters and want to make clear that EHR technology does not have to display an adopted vocabulary to a user to be certified to the certification criterion that includes the vocabulary standard. For a more detailed discussion and example of our intent please review our responses to the problem list certification criterion.

8. Common Data in Certification Criteria

Comments. Several commenters pointed out that we repeat much of the same data in the ''view, download, and transmit to a 3rd party,'' ''clinical summaries,'' and both ''transitions of care'' certification criteria. These commenters suggested that we specify a single definition that included this common data and then reference that definition in the applicable certification criteria. They added that this would cut down on the repetitiveness of the certification criteria, make the certification criteria smaller and, thus, easier to read, and that this approach would be more efficient overall. Commenters recommended that we define a ''Summary Care Record.''

Response. We agree with commenters' suggestions. Further, we note that the data we reference in these certification criteria mirror those specified by CMS for the objectives and measures to which these certification criteria correlate. Because there is a common set of MU data types/elements for which certification would be required across several certification criteria, we have created the term ''Common MU Data Set.'' We define this term by only the data that is common to (i.e., included in all five certification criteria) the ''view, download, and transmit to a 3rd party,'' ''clinical summary,'' ''transitions of care—receive, display, and incorporate transition of care/referral summaries,'' ''transitions of care—create and transmit transition of care/referral summaries,'' and ''data portability'' certification criteria (see Table 2 below). We decline to create a specific definition for ''summary care record'' because the Common MU Data Set definition serves multiple certification criteria that reference different ''summary'' oriented documents. For instance, data referenced in the ''clinical summary'' shares the data in the Common MU Data Set with the ''transitions of care'' certification criteria, but also includes unique data that is specific to a clinical summary. The following data are included in the Common MU Data Set definition and where applicable reference the standard that would have otherwise been assigned if the data were individually included within the certification criteria.

TABLE 2—COMMON MU DATA SET

1. Patient name	2. Sex.
3. Date of birth	4. Race.
5. Ethnicity	6. Preferred language.
7. Smoking status	8. Problems.
9. Medications	10. Medication allergies.
11. Laboratory test(s)	12. Laboratory value(s)/result(s).
13. Vital signs (height, weight, BP, BMI)	14. Care plan field(s), including goals and instructions.
15. Procedures	16. Care team members.

We also believe that further clarity for stakeholders can be provided through the use of more specific descriptions for the different types of ''data summaries'' referenced in certification criteria. These specific descriptions are listed below and are used in the applicable certification criteria and referenced in the preamble discussions of the certification criteria. This revision is intended to make the data referenced in the final rule and the ''data summary'' to which it is assigned more readily apparent to readers. We note that the use of these specific descriptions in the certification criteria are for regulatory clarity purposes only and do not imply any additional meaning.

Certification criterion	Type of summary
Data portability § 170.314(b)(7)	Export Summary.
Transitions of care—receive, display, and incorporate transition of care/referral summaries § 170.314(b)(1).	Transition of care/referral summary.
Transitions of care—create and transmit transition of care/referral summaries § 170.314(b)(2)	

Certification criterion	Type of summary
View, download, and transmit to a 3rd party § 170.314(e)(1)	Ambulatory Summary. Inpatient Summary.
Clinical Summary § 170.314(e)(2)	Clinical Summary.

9. New Certification Criteria

In the Proposed Rule, we described certification criteria that we considered ''new.'' We noted the following factors that we would consider when determining whether a certification criterion is ''new'':

- The certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or
- The certification criterion was previously adopted as ''mandatory'' for a particular setting and subsequently adopted as ''mandatory'' or ''optional'' for a different setting.

Comments. We did not receive comments questioning our description of new certification criteria.

Response. We therefore continue to use this description of new certification criteria to categorize the following certification criteria we have adopted as part of the 2014 Edition EHR certification criteria. The adopted new certification criteria include those certification criteria that we explicitly proposed in the Proposed Rule and two additional certification criteria stemming from proposals related to quality management principles for EHR technology development and data portability for which we solicited comments. We have not adopted the proposed ''non-percentage-based measure use report'' certification criterion.

a. Ambulatory and Inpatient Setting

We have adopted 9 new certification criteria that will be applicable to both the ambulatory and inpatient settings. We also discuss the proposed ''non-percentage-based measure use report'' certification criterion but, as noted above, we have not adopted it as part of the 2014 Edition EHR certification criteria.

- *Electronic Notes*

MU Objective
Record electronic notes in patient records.
2014 Edition EHR Certification Criterion
§ 170.314(a)(9) (Electronic notes).

We proposed a certification criterion that was similar to the one recommended by the HITSC to support the MU objective and measure recommended by the HITPC. CMS did not specifically propose the HITPC recommended MU objective and measure for Stage 2, but requested public comment on whether the objective and measure should be incorporated into MU Stage 2.

We proposed to replace the terms ''modify'' and ''retrieve'' in the recommended criterion with ''change'' and ''access,'' respectively. We proposed that ''search'' in the certification criterion was intended to mean the ability to search free text and data fields of electronic notes. We further proposed that the ability to search would mean the ability to search the notes that any licensed health care professional has included within the EHR technology and the ability to search for information across separate notes rather than just within notes.

Comments. Many commenters stated that we should not adopt an electronic notes certification criterion without CMS establishing a corresponding MU objective and measure. Commenters requested that we define a note for qualifying in the numerator and clarify who could create, edit, and sign a note. Commenters suggested permitting a range of options for capturing notes, such as templates and free text. A few commenters suggested that electronic notes should be recorded in structured data. These commenters thought this would help avoid illegible scanned notes or make searching more efficient and useful (e.g., searching be defined attributes such as physician name). One commenter suggested structured data fields that include: symptomatic (subjective); objective; assessment; and plan. The same commenter suggested specific note structure for patient problem lists.

Commenters expressed general support for the search functionality. They stated that the ability to search notes for relevant keywords will reduce time spent reviewing documentation that is irrelevant to the patient's current medical condition(s). Commenters, however, asked for further clarification on the extent of the search capability EHR technology needed to have in order to meet this certification criterion. Commenters expressed concern that this certification criterion would require a capability to search across notes, especially across providers and patients' charts. Multiple commenters suggested that a reasonable requirement for certification would be to require the capability to search for a free-text string within a particular open note, while other search capabilities should be left as competitive differentiators within the marketplace. These commenters noted that more specific certification requirements could interrupt innovative ways to do effective chart search and information display. Conversely, other commenters suggested requiring additional search functionality, such as searching across notes based on date ranges or indexing of notes in much the same way today's common search engines create background indexes allowing for almost instant retrieval of documents (e.g., Google, Spotlight on the Mac or ''locate'' on Unix-based machines).

Commenters stated that some providers will find it particularly challenging and burdensome to directly document their notes into EHRs. For example, some EPs would need to have their notes dictated or transcribed. Commenters stated that many hospitals scan physician paper notes into EHR technology, particularly in the small hospital setting where the EPs are not normally employed by the hospital.

A commenter suggested that the capabilities included in this certification criterion be expanded to require EHR technology to be able to export electronic notes as CDA Level 2 documents. The commenter stated that this would require the electronic notes to be wrapped with a CDA document header and to identify the document type and section headings with LOINC® codes. The commenter stated that this would not be an onerous requirement because most commercial transcription services can already meet these requirements. The commenter further stated that this requirement would provide hundreds of millions of interoperable clinical documents per year and enrich the clinical content shared during care transitions.

Response. We have adopted an ''electronic notes'' certification criterion for the 2014 Edition EHR certification criteria at § 170.314(a)(9) as proposed. After consideration of public comments, CMS has included an ''electronic notes'' objective and measure in the MU Stage 2 menu set and the adoption of this certification criterion will support that objective and measure. We direct commenters to the Stage 2 final rule for further discussion of the ''electronic

notes'' objective and measure, including description of notes that qualify for the numerator and explanation of who can create, edit, and sign a note.

We did not propose, nor do we believe, that there is a standard and industry-wide accepted format for capturing electronic notes. Therefore, we agree with the commenters that suggested that a range of options be permitted for capturing notes, including templates and free text. We also note that in the Stage 2 final rule scanned notes that are text searchable are acceptable for inclusion in the numerator. This requirement should address the commenters' concern about illegible scanned notes.

We appreciate the support expressed for the search capability included in this certification criterion. After consideration of comments, we have concluded that the search capability that EHR technology must demonstrate to meet this certification criterion should be limited to the ability to search within a note. We believe this will provide EPs, EHs, and CAHs with a search capability that will be useful, but still permit EHR technology developers to design and develop search capabilities that meet specific customer needs. Additionally, as commenters noted, this will permit the market to innovate and offer various search capabilities for EPs, EHs, and CAHs.

While we appreciate the commenter's suggestion that the capabilities included in this certification criterion be expanded to require EHR technology to be able to export electronic notes as CDA Level 2 documents, we decline to require EHR technology to demonstrate this capability as a condition of certification since such a capability would go beyond what we believe it is necessary to require for certification in support of MU.

• *Image Results*

MU Objective
Imaging results and information are accessible through Certified EHR Technology.
2014 Edition EHR Certification Criterion
§ 170.314(a)(12) (Image results).

We proposed to adopt a new ''imaging'' certification criterion as part of the 2014 Edition EHR certification criteria to support an EP's, EH's, and CAH's performance of the proposed new MU objective and measure. In the Proposed Rule, we clarified that the phrase ''immediate electronic access'' was intended to mean that a user should be able to electronically access images and their narrative interpretations directly and without, for example, having to log in to a separate electronic system or repository. We stated that this access could be provided by multiple means, including, but not limited to, ''single sign-on'' and ''secure identity parameter passing.'' We also considered the Digital Imaging and Communications in Medicine (DICOM) standard for this certification criterion, but concluded that the adoption of this or other standards was not necessary to enable users to electronically access images and their narrative interpretations, as required by this certification criterion.

We have categorized and responded to comments under subheadings for the purposes of clarity and readability.

Types of Images

Comments. Commenters requested a clear definition of ''image'' as well as ''narrative interpretation.'' Commenters asked whether both cardiology and pathology images are included or whether images were limited to radiology. A few commenters specifically suggested that images be limited to radiology and MRIs and not include photography or electrocardiograms (ECGs). One commenter suggested the inclusion of ECGs.

Response. It is outside the scope of this rulemaking to define the scope of images and narrative interpretations. We direct commenters to the Stage 2 final rule found elsewhere in this issue of the **Federal Register** for a discussion of the MU objective and measure and responses to these comments.

Internal and External and Storage of Images

Comments. Commenters stated that the requirement to display diagnostic images is ideal; however, the infrastructure to display images from all possible modalities, along with all possible technology solutions within the ambulatory setting, would require huge numbers of costly interfaces to integrate the images into the EHR technology. Commenters further stated that clinical images are often large and stored on external PACS systems. As such, these commenters contended that requiring EHR technology to duplicate image storage and perform at the level of a PACS system would be difficult and unnecessary functionality for EHR technology. Some commenters stated that EHR systems should not be required to store images, since the use of reference pointers is enabled by DICOM Web Access to DICOM Persistent Objects (WADO) standards. Commenters stated that the incorporation of scanned images into EHRs is generally ineffective at improving patient care. These commenters stated that when images are scanned into EHRs, physicians cannot manipulate the data, which may prevent them from truly seeing the images or understanding what the images represent. A few other commenters stated that the storing of images by any means to facilitate access will be costly.

Commenters recommended that the certification capability be limited to directly linking to images stored in the EHR technology or providing a context-sensitive link to an external application, which provides access to images and their associated narrative. Other commenters asserted that current EHR technology does not track whether a PACS link is ''available'' or ''clicked on'' because the user interaction happens largely with the Web-based PACS application. These commenters believed that there might be barriers to EHR technology collecting information about the availability of third party data accessible via a Web link within the EHR to sufficiently meet this requirement. A few commenters suggested that we limit the capability to provide narrative interpretations and recommended that the ability to view images within or through EHR technology be optional.

Response. We have adopted a new ''image results'' certification criterion to support the new MU objective and measure. We clarify that we did not propose nor are we requiring that EHR technology has to be able to store images to meet this certification criterion. EHR technology can meet this certification criterion by demonstrating a capability to directly link to images stored in the EHR system or providing a context-sensitive link to an external application which provides access to images and their associated narrative. By ''context sensitive link'' we mean that the link to the image will ideally include parameters that enable access to the images themselves rather than access to a system—which would require login, patient search, image selection, and (finally) image viewing. However, we agree with commenters that there is insufficient penetration of single sign-on or services-oriented integration capabilities between EHR technology and PACS systems, and that the fluidity with which this access is enabled may not be under the CEHRT's control. We therefore do not explicitly require that this link provide ''immediate access'' as described below. Finally, we emphasize that access to both narrative and imaging data must available to the user.

In cases where there is no narrative data (for example when a radiographic image has not yet been interpreted by a radiologist) there will obviously be no narrative available. Nonetheless, the EHR technology must be capable of retrieving and displaying the narrative information in order to meet this certification criterion.

Comments. A commenter requested clarification on whether the proposed certification criterion pertains only to EPs who send x-rays outside of their facility or whether providers that take x-rays in their own offices required to meet this certification criterion.

Response. This certification criterion applies to EHR technology designed for both the ambulatory and inpatient setting and expresses the capabilities that EHR technology would need to include in order to be certified to this certification criterion.

Clarification of Certification Criterion Text

Comments. A few commenters asked for clarification of ''and/or'' and whether it implies optionality regarding either images or the corresponding narratives. Alternatively, the commenters asked if it means that the EHR technology must be certified for both availability of images and narrative interpretations. Other commenters asked whether the intent of ''electronically indicated to a user the availability of a patient's images'' was to identify imaging results as available in order to circumvent redundant imaging tests. If that is the intent, the commenter recommend that we require, at minimum that information on when the imaging test was completed, results pending, results location and date of completion be provided. Similarly, a commenter requested clarification of whether a ''list'' of past imaging tests completed would helpful.

Response. For clarity, we have removed the ''or'' from the ''and/or'' in the regulation text. EHR technology must be capable of electronically indicating the availability of both images and narrative interpretations. Redundant imaging tests can lead to unnecessary costs. We believe that the capabilities included in this certification criterion can assist in preventing redundant testing. This certification criterion, however, includes those capabilities that are necessary to support an EP, EH, or CAH's attempt to achieve the associated MU objective and measure. Therefore, we decline to include the additional capabilities recommended by the commenters.

Immediate Electronic Access

Comments. Some commenters expressly supported our proposal that users should have ''immediate electronic access'' to images and their narrative interpretations directly and without having to login to a separate electronic system. Many commenters stated that the requirements for ''immediacy'' go beyond the capabilities of the EHR system. Some commenters suggested the term ''immediate'' be removed from the certification criterion. Other commenters requested clarification of what immediate electronic access entailed. A commenter stated that there appeared to be two different functions coupled with the word ''immediate''—taking the image and getting access to the image. Commenters also specifically stated that the requirements for ''immediacy'' via additional sign-on capabilities and other system requirements are beyond the control of the EHR system and, thus, should not be required for certification. One commenter suggested that, in order to ensure immediate access, EHR technology should provide stream-capable hyperlinks to images that can be viewed in a typical web browser without the delay related to use of DICOM file transfer and without the requirement to install additional software beyond the standard web browser itself.

Response. We agree with commenters that ''immediate'' access is vague and would be difficult to implement in EHR technology at this time, particularly with methods such as single sign-on. Therefore, we are removing the term ''immediate'' from the certification criterion.

Applicable Standard

Comments. Some commenters suggested that no standard be adopted for this certification criterion. Conversely, some commenters recommended the inclusion of the DICOM standard as a requirement for EHR certification, as well as certification of DICOM compliance for the storage and transmission of images. Commenters reasoned that the DICOM standards and complementary implementation guides developed by Integrating the Healthcare Enterprise® (IHE) provide satisfactory methods for the formatting of medical imaging and for their access through EHR systems. Some commenters specifically recommended that DICOM Supplement 127: CT Radiation Dose Reporting (Dose SR) should be required for the transmission of patient radiation dose information.

Some commenters suggest that we adopt the Consolidated CDA Diagnostic Imaging Report standard and the DICOM image standard for exchanging images and their interpretations. A few commenters recommended that we at least communicate that we intend to move towards requiring this standard to complement the DICOM image standard for use in exchanging images and their interpretations.

Response. We appreciate commenters' recommendations regarding the DICOM standard, but the recommendations and information provided has not altered our position expressed in the Proposed Rule nor has CMS made revisions to the associated MU objective and measure that would alter our position. As stated in the Proposed Rule, we concluded that the adoption of the DICOM standard (or any other standards) was unnecessary to enable users with electronic access to images and their narrative interpretations, the capability required by this certification criterion and for MU.

- *Family Health History*

MU Objective
Record patient family health history as structured data.
2014 Edition EHR Certification Criterion
§ 170.314(a)(13) (Family health history).

We proposed to adopt at § 170.314(a)(13) a 2014 Edition EHR certification criterion for family health history. The proposed certification criterion required that EHR technology be able to, at minimum, electronically record, change, and access the health history of a patient's first-degree relatives. The Proposed Rule also solicited comment on whether we should adopt specific standards for this certification criterion, including the HL7 Pedigree standard [3] and the use of Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT®) terms for familial conditions. We also noted that the Surgeon General had produced a tool that can capture, save, and manage family health histories using standard vocabularies and can export the data in eXtensible Markup Language (XML) format and sought comments on the maturity and breadth of adoption of this tool and its export format.

Comments. Commenters generally supported the concept of including a certification criterion related to family health history. A commenter noted that our description of the capabilities in this certification criterion was

[3] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=8.*

somewhat ambiguous and thus requested confirmation that we did not mean to imply that this criterion requires the capability to access the patient's first degree relatives' records. Many commenters expressed that the HL7 Pedigree standard was not widely used or sufficiently mature to adopt at the present time. Similarly, many commenters also expressed that if a specific terminology is required for coding familial conditions, then SNOMED CT® would be an appropriate terminology. Commenters requested that the certification criterion permit unstructured/free text entry.

Response. We appreciate commenters' general support for this certification criterion. Equally, CMS received a great deal of support and has included a family health history objective in the MU Stage 2 menu set. Accordingly, we have finalized a certification criterion for family health history.

We clarify that this certification criterion requires EHR technology to demonstrate that it is capable of enabling a user to electronically record, change, and access a patient's family health history. This means that EHR technology must, at minimum, be capable of recording information about a patient's first degree relative in the patient's record and permitting a user to change and access that information as needed. EHR technology would not need to be able to access the records of a patient's first degree relatives.

In support of MU, this certification criterion requires that EHR technology be capable of capturing family health history in structured data. Therefore, the certification criterion we have adopted does not permit unstructured/free text for certification because such entries would not constitute MU of CEHRT. Similar to commenters, we believe that SNOMED CT® is an appropriate terminology, and perhaps the best intermediate step, for coding family health history in structured data if one was not to use the HL7 Pedigree standard. We also understand that some organizations have built family health history CDS interventions using SNOMED CT®.

The HL7 Pedigree standard was originally released in 2007. Release 1 was recently reaffirmed by the American National Standards Institute (ANSI), which is a process that occurs every five years. We have adopted this reaffirmed version as it is the same version (Release 1) of the standard as the version we proposed. An implementation guide for this standard is scheduled to be published shortly after this final rule. Although EHR technology will not be required to conform to the implementation guide for certification, the implementation guide will provide important guidance for use of the HL7 Pedigree standard with EHR technology.

We have finalized that EHR technology may meet this certification criterion by either being able to capture a patient's family health history in SNOMED CT® or in the HL7 Pedigree standard. Since the use of SNOMED CT® is required for meeting several other certification criteria, we do not believe that it will be a challenge to meet this certification criterion. We emphasize, as specified in the § 170.300(b), when ''a certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant.'' Thus, an EHR technology can demonstrate use of SNOMED CT® or the HL7 Pedigree standard to meet this certification criterion.

- *Amendments*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion
§ 170.314(d)(4) (Amendments).

We proposed to adopt a new ''amendments'' certification criterion (§ 170.314(d)(4)) as part of the 2014 Edition EHR certification criteria. We made this proposal based on HITPC and HITSC recommendations which included that a certification criterion should be adopted that provides some of the basic technical tools to support compliance with the HIPAA Privacy Rule. We noted in the Proposed Rule that the proposed certification criterion does not address all of the requirements specified at 45 CFR 164.526 and that EHR technology certification is not a substitute for, or guarantee of, HIPAA Privacy Rule compliance. Finally, we requested comment on whether EHR technology should be required to be capable of appending patient supplied information in both free text and scanned format or only one or these methods to be certified to this proposed certification criteria.

Comments. Many commenters recommended that the proposed certification criterion's reference to ''free text or scanned'' patient supplied information be revised. Many supported both and suggested that both be permitted. Others contended that the certification criterion was over specified and suggested that ONC not specify one or the other because patient-supplied information could take many forms. In general, commenters suggested that EHR technologies have different ways of appending information and that either of these methods would be sufficient for certification. Another commenter noted that scanning patient amendments could be problematic from a storage perspective. One commenter agreed with the certification criterion but recommended that ONC should have robust standards for how patient information is appended to EHR technology before allowing EHR technology developers to create multiple versions of this workflow. Yet another stated that the ability to append patient supplied information should be no different from the ability to append any other ancillary information (outside reports from other providers). One commenter stated that EHR technology developers should only need to be certified to one method of amendment and not all (i.e., free text, scanned information, or embedded links) in order to meet the certification criterion. Additionally, a commenter noted that amending the patient record should be allowed via the two methods proposed, but that scanned documents should have to adhere to a standard such as PDF or JPG.

Last, a group of commenters took issue with the phrase ''electronic link'' in the certification criterion. They raised concerns that the phrase ''embedding an electronic link'' in the certification criterion could be interpreted in many ways, including some that would create security risks. Commenters suggested removing ''or by embedding an electronic link'' to allow different forms and ways to append patient-supplied information. They also noted that the HIPAA Privacy Rule does not mention electronic links.

Response. In consideration of the comments received, we have modified this proposed certification criterion to make clear the capabilities that EHR technology must include in order to be certified. As we indicated in the Proposed Rule, we proposed this certification criterion at the HITPC's recommendation. Along those lines, we reiterated our agreement with the HITPC's expectation for this certification criterion, that it be ''kept as simple as possible and evolve over time to greater complexity, including potentially greater standardization and automation.'' Our revisions seek to make clear this certification criterion's focus on supporting the instance where a HIPAA covered entity agrees or declines to accept a patient's request for an amendment. Additionally, this certification criterion is meant to be a

starting point from which more comprehensive capabilities and standards can be included, so we disagree with the commenter that suggested we wait until more comprehensive standards are available.

In response to commenter feedback, we have revised the certification criterion to more closely mirror the language in the HIPAA Privacy Rule at 45 CFR § 164.526. In doing so, we no longer specify a particular format (i.e., free text or scanned) and we have revised the language associated with ''electronic link.'' The ''link,'' which is an alternative to appending the patient's record must convey to a user or enable a user to obtain the information associated with an amendment's acceptance or denial. We believe this adjustment to the certification criterion provides EHR technology developers with more flexibility with which to design a capability that can accommodate the outcome this certification criterion expresses.

Comment. A commenter supported this proposed certification criterion and stated that there should be a mechanism to identify and make visible the source of the information to allow evaluation by any recipient that the information came from a reliable and accurate source.

Response. We appreciate this commenter's suggestion. However, it appears to be more specific than we believe necessary at this point for this new certification criterion. We believe that the requirements we have included in the final certification criterion are a sufficient start. We also believe that the certification criterion may, in part, address this commenter's suggestion in that the information appended or linked in the case of an accepted or denied amendment should at least have an indication as to the source of the information (i.e., patient or provider/organization).

Comments. Several commenters sought clarification as to whether patient-supplied information had to be appended to specific data in the patient's health record or attached to a specific instance of a clinical note or document. Another commenter expressed concern regarding the feasibility of being able to append patient supplied information to specific data. The commenter stated that this practice would be inconsistent with common provider policies that require all amendments to documents be classified as separate documents. In this way such information is clearly identified and maintained in a section or folder of the electronic record, and then subject to clinician review for what may be actually incorporated into the record upon acceptance. They indicated that by following this approach the patient requested amendment has its own ''wholeness'' or integrity as a medical record entry. In general, other commenters echoed this statement and suggested that it should be acceptable to have a separate section of the record for patient-supplied information.

Response. The final certification criterion does not require that accepted or denied amendments be appended to specific data in order for compliance to be demonstrated. As indicated above, this criterion is intended to support compliance with the HIPAA Privacy Rule's amendment requirements at 45 CFR 164.526. The Privacy Rule provides some flexibility with how accepted or denied amendments are appended to an individual's protected health information, recognizing that the type and scope of an amendment will vary based on the circumstances. For example, the affected record could include a link to documentation of an accepted or denied amendment, while still allowing, in the case of an accepted amendment, any necessary corrections to be incorporated directly into the record itself.

Comments. A couple of commenters requested clarification regarding the interplay between the terms ''amend'' and ''append'' in the certification criterion. One commenter stated that amendments are documentation meant to clarify health information within a health record whereas addendums are new documentation used to add information to an existing entry, and corrections are changes to information meant to clarify inaccuracies after the original document has been signed or rendered complete. The other commenter stated that we described ''amending'' a patient's record as allowing clinicians to correct errors or update the information within their record and that later we referred to the act of ''appending'' patient supplied information by using free text and/or scanned material. This commenter stated that ''amend'' and ''append'' are distinct concepts and should not be combined into one certification criterion because if we intend to allow these functions of correcting and/or attaching information to the patient's record they should remain separate. The commenter reasoned that amending should not permit any overwriting of the existing documentation and should include a date, time and authentication record of who took the action—while appending data should accurately capture the date, time, and authentication of the appended information.

Response. The terminology used in this certification criterion is meant to mirror the terms used in the HIPAA Privacy Rule at 45 CFR 164.526. Put simply, those rules describe that a patient is permitted to request an amendment to their health information and the corresponding obligations a HIPAA covered entity must follow to either accept or deny the requested amendment. As stated in 45 CFR § 164.526(c)(1), for example, if the amendment is accepted, ''[t]he covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by * * * appending or otherwise providing a link to the location of the amendment.'' Thus, this certification criterion reflects some of the capabilities needed in the event of an accepted or denied amendment.

Comment. A commenter stated that § 170.314(d)(4)(i)(A) conflicts with the description of the term of ''Change'' included in the Proposed Rule and that this criterion needs to be consistent with that definition.

Response. This comment is incorrect. The term ''change'' as described in the Proposed Rule was not included in this certification criterion. Thus, there is no conflict with respect to the clarity of the capabilities specified by this certification criterion and others that include the term ''change.''

Comment. A commenter asked for clarification on the degree of information retained. They stated that too much information makes the data storage requirements burdensome on providers and superfluous data makes it difficult for auditors to detect unauthorized access.

Response. This certification criterion seeks to specify the EHR technology capabilities necessary to support, in part, the requirements specified at 45 CFR § 164.526 and it is not within its scope to address the degree or amount of information retained.

Comment. A commenter recommended that the electronic amendment contain a date/time stamp and reflect the user who took such action when content is amended.

Response. We appreciate this commenter's suggestion, however, we expect that this kind of event would be subject to the audit log requirements we have already specified (and which includes time and date stamp).

Comments. One commenter asked for clarification as to whether this criterion makes a distinction between ''work in progress'' records and ''signed off'' records. They stated, for example, a user may make several changes to the same

data while working within a particular screen of the EHR technology. They suggested that the changes should only be captured when the user saves their changes and signs off on the record.

Response. No, this certification criterion does not make such a distinction because those distinctions are inapplicable to this certification criterion. We believe the commenter misinterpreted the purpose of this certification criterion and its focus on incrementally building in the capacity of EHR technology to make compliance with the HIPAA Privacy Rule more efficient.

Comment. One commenter noted a concern that if this certification criterion is applied to EHR Modules that are not part of the Base EHR definition that it could result in conflicting and overlapping practices and result in incorrect or inconsistent information in a patient record. For example, the commenter noted that it was a downstream business associate (or business associate subcontractor) and an intermediary, and thus does not amend patient information. Further they stated that they provide notice of any requests for amendments to their upstream business associates and covered entities with whom they directly contract. They concluded by stating that requiring an intermediary or developers of certain EHR Modules to have the capability to amend information could present confusion and should be applicable to core functionality of the EHR technology utilized at the provider level.

Response. For some of the reasons expressed by this commenter, we proposed to remove the requirement that EHR Modules also be certified to the privacy and security criteria. We clarify that this certification criterion is not separately applied to any EHR Modules in order for them to be certified. An EHR technology developer needs to include such capability, however, if they seek certification for EHR technology that would meet the Base EHR definition.

Comments. Two commenters recommended that we remove this certification criterion. One agreed that HIT should support workflow for complying with HIPAA privacy regulations, including allowing a user to amend a patient record, but contended that this functionality is typically found in a Medical Record Management system. Thus, they encouraged ONC to remove the certification criterion. However, they stated that if it remained, we should only require scanned documents. The other commenter recommended that we delay this certification criterion's adoption to a later edition of EHR certification criteria because the technical and legal implications of supporting patient amendments to the EHR are complex and evolving.

Response. We have not removed this proposed certification criterion. We agree with the HITPC that starting with a simple certification criterion can set us on a path to include more comprehensive capabilities over time. We acknowledge that the processes involved in supporting patient amendments can sometimes be difficult, which is why we explained in the Proposed Rule and reiterated in the above responses that this certification criterion can only help support (and potentially make more efficient) a HIPAA covered entity's compliance with the HIPAA Privacy Rule.

Comments. Several commenters supported the proposed certification criterion, but requested joint confirmation from ONC and CMS that EPs, EHs, and CAHs do not have to demonstrate use of this capability in order to meet meaningful use. Other commenters urged us to acknowledge that this functionality has importance beyond a privacy and security context.

Response. This certification criterion expresses capabilities that EHR technology would need to include in order to meet this certification criterion. Given that this certification criterion is included as part of the Base EHR definition, EPs, EHs, and CAHs, will need to have EHR technology certified to this certification criterion in order to have EHR technology that meets both the Base EHR and CEHRT definitions. We have consulted with CMS and clarify that since there is not a meaningful use objective expressly requiring the use of this capability to satisfy an associated measure that EPs, EHs, and CAHs do not need to demonstrate use of this capability in order to meet any meaningful use stage. However, we encourage EPs, EHs, and CAHs to consider if this capability could make compliance with the requirements of the HIPAA Privacy Rule, particularly, 45 CFR § 164.526, more efficient.

• *View, Download, and Transmit to 3rd Party*

MU Objective
EPs:
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.
EHs and CAHs:
Provide patients the ability to view online, download, and transmit information about a hospital admission.
2014 Edition EHR Certification Criterion
§ 170.314(e)(1) (View, download, and transmit to 3rd party).

We proposed a new criterion at § 170.314(e)(1) to subsume the certification criteria previously adopted at §§ 170.304(f), 170.304(g), 170.306(d), and 170.306(e). This proposal was based on the HITPC issued MU recommendation that patients (or their authorized representative(s)) be able to view and download their health information online (i.e., Internet/web-based). The HITPC recommended that this MU objective should replace or subsume the objectives for providing patients with timely electronic access to their health information and providing patients with an electronic copy of their health information and hospital discharge instructions upon request. Consistent with these recommendations, the HITSC recommended a certification criterion that framed the capabilities EHR technology would need to include to support this new objective and that, for the 2014 Edition EHR certification criterion, the criterion should replace the certification criteria previously adopted at §§ 170.304(f), 170.304(g), 170.306(d), and 170.306(e).

In addition to the view and download capabilities recommended by the HITSC, we proposed to include a third specific capability in this certification criterion—the ability to transmit an ambulatory and inpatient summary to a third party. Coupled with this addition, we proposed that EHR technology would need to be capable of transmitting an ambulatory and inpatient summary according to the two specifications—developed under the Direct Project—which we proposed for adoption: (1) Applicability Statement for Secure Health Transport [4] and (2) Cross-Enterprise Document Reliable Interchange (XDR) and Cross-Enterprise Document Media Interchange (XDM) for Direct Messaging.[5] We indicated that these transport standards were ideal for this purpose and would make it possible for patients to transmit a copy of their ambulatory or inpatient summary to the destination of their choice. Additionally, because we proposed requiring the capability to perform transmissions in accordance with these transport standards (which provide for encryption and integrity protection) in

[4] *http://wiki.directproject.org/Applicability+Statement+for+Secure+Health+Transport.*

[5] *http://wiki.directproject.org/XDR+and+XDM+for+Direct+Messaging.*

this criterion and in the ''transitions of care—create and transmit transition of care/referral summaries'' certification criterion, we determined that it would not be necessary to include in the 2014 Edition EHR certification criteria the ''encrypting when exchanging'' certification criterion adopted in the 2011 Edition EHR certification criteria (§ 170.302(v)). We stated our belief that to include the 2011 Edition EHR certification criterion would be redundant and that our proposed approach more explicitly tied security to a particular transmission.

At the recommendation of the HITSC, the proposed certification criterion required that EHR technology certified to this criterion include a ''patient accessible log'' to track the use of the view, download, and transmit capabilities included in this certification criterion and make that information available to the patient. We required this specific capability within this certification criterion because we believed that it was highly likely numerous EHR Modules could be certified to this criterion without also being certified to the auditable events and tamper resistance certification criterion we proposed to adopt at § 170.314(d)(2) (due to the proposed policy change we specified in section IV.C.1 of the proposed rule related to EHR Modules and privacy and security). Thus, this explicit proposal was meant to guarantee that an EHR Module certified to this criterion would include the capability to track who has viewed, downloaded, or transmitted to a third party electronic health information and that patients would have access to this information. That being said, we noted that we did not intend for this portion of the certification criterion to impose a redundant requirement on EHR technology developers who present a Complete EHR or EHR Module for certification to both this certification criterion and the auditable events and tamper resistance certification criterion. Accordingly, we provided in paragraph (e)(1)(ii)(B) of § 170.314 that EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of § 170.314 if it is also certified to the certification criterion proposed for adoption at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) of § 170.314 is accessible to the patient. In other words, we clarified that an EHR technology certified to § 170.314(d)(2) would not need to also include the ''patient accessible log'' capability specified in paragraph (e)(1)(ii)(A) of § 170.314 because it would be capable of logging such events and providing the information to the patient.

We also proposed that the ''patient accessible log'' capability would need to record the date and time each action occurs using a system clock that has been synchronized following either Request for Comments (RFC) 1305 Network Time Protocol (NTP) v3 or RFC 5905 Network Time Protocol Version 4: Protocol and Algorithms Specification (NTPv4).

We proposed to require EHR technology to be capable of enabling images formatted according to the Digital Imaging and Communications in Medicine (DICOM) standard [6] to be downloaded and transmitted to a third party. We stated our belief that this specific capability has the potential to empower patients to play a greater role in their own care coordination and could help assist in reducing the amount of redundant and duplicative imaging-oriented tests performed.

Consistent with our belief that all patients should have an equal opportunity to access their electronic health information without barriers or diminished functionality or quality, we proposed that the viewing capability must meet Level AA conformance with the most recent set of the Web Content Accessibility Guidelines (WCAG). We explained that the most recent set of guidelines (WCAG 2.0) were published in 2008 and are organized under 4 central principles with testable ''success criteria'': Perceivable, Operable, Understandable, and Robust.[7] We further explained that each guideline offers 3 levels of conformance: A, AA, and AAA. We proposed compliance with Level AA because it provides a stronger level of accessibility and addresses areas of importance to the disabled community that are not included in Level A. In addition to WCAG 2.0 Level AA conformance, we requested public comment on whether commenters believed additional standards were needed for certification to ensure accessibility for the viewing capability, such as the User Agent Accessibility Guidelines (UAAG).[8]

We proposed to require that EHR technology be capable of providing the information that CMS proposed be required in an ambulatory or inpatient summary that is provided to patients or their authorized representatives. This proposal was based on the HITSC's recommendation that we move to one standard for capturing this information and our belief that moving to one standard would lead to increased interoperability and spur innovation. We explained that we believed the Consolidated CDA was the most appropriate standard to achieve this goal because it was designed to be simpler and more straightforward to implement and, in relation to this rulemaking, its template structure can accommodate the formatting of an ambulatory or inpatient summary that includes all of the data elements that CMS proposed be available to be populated in an ambulatory or inpatient summary.

In certain instances in § 170.314(e)(1), we proposed to require that the capability be demonstrated in accordance with the specified vocabulary standard—which were previously adopted or proposed for adoption in the Proposed Rule consistent with the recommendations of the HITSC. With the exception of four standards (LOINC®, ICD–10–CM, ICD–10–PCS, and CPT/HCPCS), the vocabulary standards included in the certification criterion were discussed elsewhere in the Proposed Rule in connection with the certification criteria where the vocabulary standard is central to the required data or serves a primary purpose (e.g., RxNorm for e-prescribing).

For encounter diagnoses and procedures, we proposed the use of ICD–10 (ICD–10–CM and ICD–10–PCS, respectively). We requested comment, however, on whether we should be more flexible with this proposed requirement based on any potential extension of the ICD–10 compliance deadline or possible delayed enforcement approach. More specifically, we noted our interest in whether commenters believed it would be more appropriate to require EHR technology to be certified to a subset of ICD–10; either ICD–9 or ICD–10; or to both ICD–9 and ICD–10 for encounter diagnoses and procedures. We also asked that commenters consider these options when reviewing and commenting on the other proposed certification criteria that include these standards (i.e., § 170.314(a)(3), (b)(2), and (e)(2)). For procedures, we proposed to continue to permit a choice for EHR technology certification, either ICD–10–PCS or the combination of Health Care Financing Administration Common Procedure Coding System (HCPCS) and Current Procedural Terminology, Fourth Edition (CPT–4). For outbound messages including laboratory tests, we stated that EHR technology must be capable of transmitting the tests performed in LOINC® 2.38 to meet this

[6] *ftp://medical.nema.org/medical/dicom/2011/.*

[7] *http://www.w3.org/TR/WCAG20/.*

[8] *http://www.w3.org/WAI/intro/uaag.php.*

certification criterion and for all other proposed certification criteria that include the capability to transmit laboratory tests in the LOINC® 2.38 standard. We proposed to adopt the ''view, download, and transmit to 3rd party'' certification criterion at § 170.314(e)(1) and the ICD–10–PCS and ICD–10–CM standards for procedures and encounter diagnoses at § 170.207(b)(3) and (m), respectively.

We received a significant amount of comments on the proposed view, download, and transmit to a 3rd party certification criterion. To make clear the policy expressed in our responses to comments, we have used subheadings under which specific comment themes will be discussed. In response to comments, we have made several revisions to the proposed certification criterion. Those revisions are explicitly noted in the applicable response.

View

Comments. Many commenters raised questions and concerns about the data we specified EHR technology would need to be capable of making viewable to a patient or their authorized representative. Some contended that the data exceeded those required for this use case and questioned the value of such data. Others pointed out that we did not have a consistent list of data between the ''view'' and ''download'' paragraphs. Commenters specifically called out ''encounter diagnoses'' as being inconsistently applied and raised concerns about our proposal to refer to ICD–10–CM.

With respect to the vocabularies we proposed for procedures several commenters disagreed with our proposal to permit EHR technology to be certified to represent procedures in ICD–10–PCS. Overall, commenters suggested in one form or another that SNOMED CT® should be the sole clinical vocabulary for documentation because it would help better meet the information objectives for MU. They further stated that SNOMED CT® is most appropriate when data is to be represented for clinical purposes and clinical accuracy. Commenters also contended that ICD–10–PCS was an inappropriate standard to reference for the purposes of clinical data exchange and was best suited for billing diagnosis and billing purposes. Among those comments at least one commenter stated that SNOMED CT® should be an alternative vocabulary standard included in the final rule. Another commenter stated that permitting the use of ICD–10–PCS to represent procedures in a Consolidated CDA formatted document would unnecessarily limit the usefulness of the Consolidated CDA document. This commenter stated that SNOMED CT® was the appropriate reference terminology to use to encode procedures. Similarly, other commenters recommended we replace ICD–10–PCS with SNOMED CT® because they believed that ICD–10–PCS would be inappropriate to use to represent procedures. They contended that procedures need to address counseling, education, and specific interventions that are not managed with a billing vocabulary. Last, one commenter stated that we should adopt the American Dental Association's Current Dental Terminology (CDT) as a vocabulary to represent procedures. They reasoned that CDT is a named HIPAA standard for use in electronic administrative transactions for dental claims and that this is the standard vocabulary dentists use to represent procedures.

Response. The data that is specified in this certification criterion was proposed to directly mirror the data that CMS proposed should be available for patients to view, download, and transmit to a 3rd party. Thus, we disagree that the data exceeds what is required for this use case. We have worked with CMS to align the data specified in this certification criterion. In that respect if there were any discrepancies we have corrected them. Additionally, as discussed earlier in this preamble we have revised this certification criterion to refer to the Common MU Data Set, which has significantly reduced the certification criterion's overall size and complexity. Further, we have removed ''encounter diagnoses'' from this certification criterion because it is no longer data that is minimally necessary to support what CMS has finalized for the objective and measure this certification criterion is designed to support. ''Encounter diagnoses'' is referenced by the transitions of care certification criterion (§ 170.314(b)(2)) and the data portability certification criterion (§ 170.314(b)(7)). Since the data portability certification criterion mirrors a portion of the transitions of care certification criterion, we have chosen to provide our response to comments on encounter diagnoses when we discuss the transitions of care certification criterion.

In consideration of the comments we received in response to our questions about ICD–10–PCS, we agree with those commenters that argued SNOMED CT® is a more appropriate vocabulary to reference in this case. As commenters noted, SNOMED CT® is more appropriate for clinical purposes and provides greater clinical accuracy. Thus, this final rule requires that in order for EHR technology to be certified to a certification criterion that references ''procedures'' data, it must demonstrate compliance with the use of SNOMED CT® or CPT/HCPCS (the latter is already adopted as part of the 2011 Edition EHR certification criteria and was carried forward in the Proposed Rule). However, in recognition that it may be beneficial for inpatient EHR technology developers to demonstrate compliance with, and support for the use of, ICD–10–PCS to represent procedures in the various certification criteria that reference procedures, we have adopted ICD–10–PCS as an ''optional'' vocabulary standard to which EHR technology developers can seek certification for their EHR technology.

In consideration of the comment suggesting that we include CDT as an alternative vocabulary for dentists, we have done so. However, we have adopted this vocabulary as ''optional'' and in addition to (not in lieu of) one of the primary vocabularies necessary for representing procedures data. Therefore, in the event that an EHR technology developer seeks to get its EHR technology certified to CDT, it will have to also be certified to one of the mandatory standards we have adopted for representing procedures, either SNOMED CT® or CPT/HCPCS.

Comments. Commenters recommended that we delineate which data for view is optional as which data is required.

Response. We decline to make this change. In order to be certified, EHR technology must be capable of permitting a patient or their authorized representative access to all of the data specified by the certification criterion. What information is actually made available by an EP, EH, or CAH and how it is displayed to a patient or their authorized representative should be determined by the EP, EH or CAH.

Comments. Some commenters asked that we clarify that the term ''gender'' as proposed was really intended to mean ''sex'' given the wide range of characteristics that could be encompassed by the term gender.

Response. We agree. Both ONC and CMS have included the term ''sex'' in our final rules.

Comments. A commenter advocated that the substitution of patient friendly terms for diagnoses should be permitted.

Response. We agree. We clarify and have modified the regulation text to explicitly indicate that for view (and download) that where certain coded data exists, the English language

descriptions and not the codes should be viewable to a patient or their authorized representative.

Comments. Commenters recommended that we include the additional flexibility of being able to import (save ''as is'') and view CCD/C32 and CCR documents in order to provide a transition between Stages 1 and 2. They stated that as a patient if they viewed an old CCD it should still count towards the MU numerator.

Response. We did not accept this recommendation and have not included this type of capability in the certification criterion. In large part, these comments are out of scope for this rulemaking and focus on measurement, which is relevant to the MU objective and measure with which this certification criterion correlates. That being said, the certification criterion does not specify how data is made viewable. Taking this approach is not necessarily precluded by the certification criterion and may somehow be able to address the view capability. However, we are uncertain, without additional details, whether the use of these older standard document formats would in practicality meet the numerator and denominator requirements for the MU measure or the new data required to be made viewable.

Comment. A commenter requested that we provide detailed requirements to EHR technology developers on how to address potential language barriers in their products (especially with regard to the use of the patient portal). They stated that a language barrier would negatively impact providers' abilities to engage patients and get them to use the view, download, and transmit capabilities. They contended that it would be inconsistent to require patient engagement through the use of a patient portal and not provide common standards for multi-lingual or predominantly non-English speaking communities where providers might exclusively practice.

Response. While we appreciate this commenter's suggestion and believe in the importance of multi-lingual accommodations, we believe this suggestion is a significant departure from the certification criterion proposed and would require additional study to determine how to appropriately frame it as a certification requirement for EHR technology. Thus, we have not changed the certification criterion in response to this comment.

Comments. A commenter recommended that this certification criterion should include more specific capabilities than we proposed such as, accommodate patient generated data to ''upload'' into the EHR; include linkages to patient specific education materials; and be based upon a standing patient preference.

Response. We did not accept this recommendation. We believe the certification criterion is properly scoped to support its correlated MU objective and measure and do not seek to introduce additional burden that could be value-added functionality outside the scope of certification that EHR technology developers can include for competitive purposes.

Accessibility

Comments. Commenters generally supported the underlying rationale behind the proposal, with some endorsing the requirement as proposed. Other commenters contended that achieving WCAG Level AA compliance in the time available would be extremely difficult for EHR developers to achieve. They stated that it is very complex to achieve compliance in a real world scenario and that Level AA conformance imposes a burden too great at this point in time. Further, they stated that the requirements for interfacing to independent accessibility tools (also required by WCAG 2.0), such as those that read screen text aloud can be impossible to achieve for ''snappy'' and ''intelligent'' JavaScript-dependent applications. One commenter noted that as of April 2012, two well-known news sites reported 76 and 104 known problems, respectively. Some commenters suggested removing this requirement altogether while others suggested that we take a more incremental approach and start with Level A conformance which could set the stage for a predictable progression to Level AA at a later date. Commenters also requested that we clarify that the WCAG standard would apply only to patient viewable information as intended by this certification criterion.

Response. We appreciate commenters support for this proposal. As we noted in the proposed rule, we believe that all patients should have an equal opportunity to access their electronic health information without barriers or diminished functionality or quality. We recognize that this was a new requirement proposed for the 2014 Edition EHR certification criteria and in considering the burden concerns identified by commenters and need for greater experience with WCAG generally, we have decided to require Level A conformance instead of Level AA. As some commenters noted starting at Level A will provide a baseline from an accessibility perspective and one on which we can build in future rulemakings. Accordingly, we would like to express our intention to propose requiring Level AA in our next rulemaking cycle and encourage EHR technology developers to take the steps necessary to be on a path towards Level AA conformance. We also clarify, as requested, that the WCAG standards apply to the information that is viewable to the patient or their authorized representative through the capabilities EHR technology includes that would enable them to electronically view, download, and transmit their health information to a 3rd party.

Comments. Comments stated that most patients want functions and content provided in a more visually appealing manner than the standard allows. Commenters requested that we clarify for certification whether an EHR technology developer would need to show how the product can be configured for WCAG 2.0 requirements by an implementer or whether the EHR technology must be ''preconfigured'' to those requirements (e.g. preset for font, contrast, color settings, etc). They stated, for example, that an EHR technology developer might have a configuration choice for accessibility that a consumer could opt for using that would include setting the contrast, font, color scheme, etc. to be conformant to accessibility requirements but allow other users to be able to select other settings as a matter of choice. They suggested that for certification it should be sufficient for an EHR technology developer to show how the settings for accessibility can be configured, but not predefined or preset.

Response. In order to demonstrate conformance with the certification criterion, EHR technology will need to meet WCAG Level A. So long as the EP, EH, or CAH (as the customer) can appropriately configure the EHR technology for the patient, then that is sufficient. The certification criterion does not specify that certain design elements be predefined or preset.

Comment. A commenter suggested that we consider if there are third parties that can provide supportive independent evidence of conformance to the WCAG standards or if any self-attestation evidence can be provided for review by the NVLAP-accredited testing laboratory so that if a vendor has pursued such third party review, it does not have to do so in repetition for the sake of 2014 certification.

Response. While we believe that such documentation could expedite the review by a NVLAP-accredited testing laboratory, the EHR technology would still need to be independently assessed by the testing laboratory for

conformance following test procedures approved by the National Coordinator.

Comments. Several commenters, in response to our request for comment on the UAAG standard, did not support its adoption as part of this certification criterion because they contended that it does not apply to Web sites like patient portals. Rather, they stated that it applies only to web browsers.

Response. We have not included or adopted the UAAG standards at this time and appreciate commenters' detailed feedback.

Download

Comments. A couple of commenters stated their belief that in order to meet the ''human readable'' aspect of this certification criterion that an HTML view of the XML file for the Consolidated CDA should be adequate for both viewing and downloading.

Response. As we have previously stated in the S&CC July 2010 final rule (75 FR 44598) in response to questions about the meaning of human readable, the use of a style sheet associated with a document formatted according to the Consolidated CDA would be permitted.

Comments. Commenters asked that we specifically clarify that for the ''download and transmit'' requirements, the data itself must be downloaded and transmitted and not merely a link to the data is what is downloaded and transmitted.

Response. Yes, the data itself must be downloaded and transmitted. A hyperlink to the data would not be sufficient for EHR technology to demonstrate compliance with this certification criterion.

Comments. Many commenters supported the proposed adoption of the Consolidated CDA standard and our proposal to move to this as the single standard. Some opposed this proposal altogether, while others suggested that the previously adopted CCD standard as well as the CCR standard should continue to be permitted because the Consolidated CDA was immature.

Several commenters requested clarification related to the aspects of the Consolidated CDA that are required for certification. More specifically, they stated that the Consolidated CDA is an implementation guide for nine different document types (eight structured and one unstructured), and that it would not only be inappropriate to require the use of all of these document types for all environments but would in fact not make sense for elements like a discharge summary for an EP). Many recommended that the certification requirement be that the EHR technology should demonstrate the ability to generate at least one of the available CCDA document types and that providers will be able to use the document type most appropriate to the clinical situation.

A couple of commenters stated that we should explicitly prohibit the use of the unstructured document template because not doing so would allow EHR technology developers to bypass using structured and coded data.

Last, a couple of commenters noted that each time a ''care summary'' is specified in the Proposed Rule that it was described slightly differently. They contended that these differences will cause unnecessary confusion and disruption throughout the care delivery process. Additionally, they noted that none of the data sets specified for the certification criteria that reference the Consolidated CDA precisely matched any existing document-level templates in the Consolidated CDA.

Response. We appreciate commenters support for the Consolidated CDA, and have finalized its adoption in the final rule. We believe that moving to a single standard is absolutely necessary to advance interoperability. The Consolidated CDA represents a significant amount of effort by industry stakeholders and we believe it is the best available standard to require for certification and to meet our policy objectives for interoperability. As noted by some commenters and, what appeared to be unknown to others, the Consolidated CDA is not per se a competing standard with the CCD because it contains within it a document-template that describes how to implement a CCD according to new, harmonized and consolidated implementation guidance (CCD v1.1). So the CCD document-template represented in the Consolidated CDA is an update to the CCD/C32 implementation guidance. That being said, as precisely noted by commenters, none of the 8 specific structured document-level templates in the Consolidated CDA neatly support the data specified by this certification criterion as well as the others in which it is also referenced (clinical summary, transitions of care, and data portability). Accordingly, we clarify that, with respect to the Consolidated CDA, certification will *not* focus on a specific document-level template because none are particularly suited to support MU's policy objectives and the data elements specified across the different certification criteria that reference the Consolidated CDA. Rather, certification will focus on an EHR technology's ability to properly implement the US Realm header and the associated section-level templates necessary to support each certification criterion in which the Consolidated CDA is referenced and for the appropriate data specified in each of those certification criteria. We intend for testing and the test data made available for these certification criteria to enable consistent Consolidated CDA implementations. Further, based on our policy decision to focus testing and certification on section-templates, we have performed additional analysis of the Consolidated CDA. Based on our analysis, we note that absent certain conformance requirements otherwise specified in a particular document-level template, our approach could result in implementation ambiguities. These ambiguities could exist because section-templates when viewed independently of a particular document-template permit the use of narrative text, coded entries optional, or narrative text and required structured data, coded entries required. Thus, we believe it is necessary to clarify for EHR technology developers that in all instances where we have adopted a vocabulary standard in § 170.207 the accompanying section-template implemented must be done so using the section-template with required structured data, coded entries required.

We agree with the comments that suggested we prohibit the use of the unstructured document-template included in the Consolidated CDA. As referenced in the Consolidated CDA, an ''unstructured document is a document which is used when the patient record is captured in an unstructured format that is encapsulated within an image file or as unstructured text in an electronic file such as a word processing or Portable Document Format (PDF) document.'' We believe that permitting this document template to be used as part of the Consolidated CDA or leaving any ambiguity as to whether it can be used to meet this certification criterion would be inconsistent with our policy objectives. Thus, we have indicated in § 170.205(a)(3) where we have adopted the Consolidated CDA that the use of the unstructured document template is not permitted.

We also take this opportunity to identify for stakeholders a modification we believe must be made to this certification criterion in order to align our final rule with clarifications made in CMS's final rule and, ultimately, in order to ensure the CEHRT EHs and CAHs adopted can support their achievement of MU. Further, this modification is only applicable to the inpatient setting only and is designated in the certification criterion as such. In its proposed rule (77 FR, 13730) CMS

proposed that one of the information types, a patient should be able to download would be their ''care transition summary and plan.'' In response to comments, CMS clarified and has listed these two information types as separate kinds of information that must be able to be downloaded. Accordingly, we have included in this certification criterion that for the inpatient setting a patient would need to be able to electronically download transition of care/referral summaries that were created as a result of a transition of care/referral (pursuant to the capability expressed in the certification criterion adopted at paragraph § 170.314(b)(2)). We believe this addition poses limited additional burden since EHR technology would just need to be able to make available for download any transition of care/referral summaries created as a result of a transition of care (so if a patient has had multiple hospitalizations during the EHR reporting period and been transitioned out of the hospital, the EHR technology would need to be capable of making available both inpatient summaries and transition of care/referral summaries that were created as a result of the transitions).

We received comments on our proposal to adopt the Consolidated CDA where it was proposed for other certification criteria. In drafting this comment and response we considered those comments and included them in the comment summary above. Accordingly, our response here to the proposal to adopt the Consolidated CDA is not repeated in the other certification criteria where its adoption was also proposed.

Comments. A couple of commenters stated that we mentioned in the Proposed Rule that there needs to be a confidentiality type included in the CCDA. They noted that it was unclear what that requirement meant in the use case where a patient downloads their information. They requested further clarification and guidance on the indication of this element within this certification criterion.

Response. As we noted in the Proposed Rule, one of the metadata elements required by the US Realm Header is the ConfidentialityCode which should be populated with a value from the value set of BasicConfidentialityKind (this value set includes 3 possible values: ''N'' Normal, ''R'' Restricted, and ''V'' Very Restricted). In this context, we believe that ''N'' would likely be the default value.

Comments. Several commenters stated that we should require EHR technology to include the capability to do a ''Blue Button'' download. Other commenters opposed this idea because all that would be downloaded would be a text file. They contended that such an outcome would be a step backwards from requiring the Consolidated CDA.

Response. The view, download, and transmit capabilities required by this certification criterion are fully aligned with the Blue Button goals of empowering patients to be partners in their health care through access to and use of personal health information. We expect the Blue Button vision to evolve and expand to encompass a variety of technical solutions beyond the traditional download of a text file, including view, download, and transmit capabilities. Along those lines, we strongly encourage every EHR technology developer to associate this certification criterion's download capability related to a human readable file with the increasingly popular ''Blue Button'' phrase and logo. To be clear, we also require for certification that EHR technology be capable of enabling a patient or their authorized representative to be able to download a file formatted according to the Consolidated CDA.

Comments. Commenters noted that the Consolidated CDA had been updated since the Proposed Rule was published and urged us to adopt the most recent version in the final rule.

Response. We agree with commenters and have adopted the HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Draft Standard for Trial Use (DSTU) Release 1.1 (US Realm) Draft Standard for Trial Use, July 2012. This version of the Consolidated CDA constitutes the most recent balloted version—a process which has been underway since the Proposed Rule was published. It corrects errors in the prior version, and was modified to more fully and closely support capturing the MU data that CMS requires for EPs, EHs, and CAHs to meet certain MU objectives and measures related to transitions of care, clinical summaries, and providing patients with the ability to view, download and transmit their health information. As noted by HL7 in its documentation, this DSTU version of the standard will be open for comment for 24 months and following this evaluation period, it will be revised as necessary and then submitted to ANSI for approval as an American National Standard (normative standard). Further, HL7 specifies that implementation of this DSTU version will be valid during the ANSI approval process and ''for up to six months after publication'' of the normative standard. Given the state at which this DSTU version of the standard is and the fact that this version alone is subject to the evaluation period, we believe that it is the best possible choice for this final rule, especially in place of the draft version we referenced in the Proposed Rule.

Comments. A few commenters stated that this certification criterion did not expressly include privacy and security requirements. They suggested that we should require EHR technology to be able to ensure that a patient's online experience is secure. They recommended that we specify requirements for authentication such as OAuth as well as a specific level of assurance (NIST level 3). They also recommended that we require EHR technology to be certified for its ability to establish a secure channel for view and download.

Response. We are convinced by commenters that it is important and necessary to add a more explicit requirement for security in this certification criterion. In that respect, we have revised our proposed criterion to accept commenters' suggestions in part. As suggested, we have included a requirement that EHR technology must be able to establish a secure channel through which a patient can access the capabilities to view, download, and transmit their electronic health information. We agree that certification can provide some assurance that EHR technology can properly establish for a secure channel through which health information can be viewed, downloaded, and transmitted. This secure channel requirement mirrors that portion of the secure messaging certification criterion. Thus, it is possible for an EHR technology to be certified to both this certification criterion and the secure messaging certification criterion, depending on how it is designed.

We continue to decline to change the certification criterion in response to commenters' recommendations that we prescribe a particular form or ''level of assurance'' for authentication. It is not that we disagree that some form of authentication will be necessary when EHR technology certified to this certification criterion is implemented. Rather, as some comments suggest, there is significant innovation taking place with respect to authentication. Thus, we believe that requiring a particular form in this certification criterion would be overly prescriptive and have little practical effect on the eventual authentication approach EPs, EHs, or CAHs implement.

Comment. A commenter noted that the Consolidated CDA stated that vital signs are an optional section which may be included in CCDs, while the Proposed Rule stated that this section is required. They contended that if such discrepancies are allowed to persist, EHR technology developers will inevitably make mistakes on what they choose to include and marked heterogeneity will persist.

Response. We seek to make clear for this commenter (and this response is generally applicable to any instance where we have adopted certification criteria that reference standards and required data) that this final rule and its requirements take precedence (i.e., override) any ''optional'' requirements in a standard or implementation specification if they are deemed required as part of a certification criterion. For example, if sections or certain data in an implementation guide are designated ''optional,'' but a certification criterion requires compliance with such sections or data, EHR technology must be designed to comply or accommodate those sections or data in order to meet the certification criterion.

Transmit

Comments. Many commenters asked that we clarify why a SOAP-based transport standard was not proposed as part of this certification criterion when it was for the transitions of care certification criterion. Commenters contended that this was an inconsistency and asked that ONC and CMS reconcile the two. They also referenced CMS's proposed rule and preamble that stated that transmission could occur via any means of electronic transmission according to any transport standards for the view, download, and transmit to a third party objective. Other commenters stated that other transport standards should be permitted for use, such as those for query and response. Last, commenters asked questions about workflow and how transmission should be implemented so that a patient's information can be transmitted to a 3rd party.

Response. There was no inconsistency between the ONC and CMS proposed rules. The proposed transport standard(s) for each certification criterion were purposefully chosen and proposed to specify the capabilities EHR technology would need to include in order to demonstrate compliance with each certification criterion. Commenters have confused *two very distinct concepts:* (1) What is required for EHR technology to demonstrate compliance with a certification criterion; and (2) how EHR technology, once certified, must be used to demonstrate meaningful use. We seek to make this distinction clear to prevent any further confusion.

The certification criteria adopted in this final rule apply to EHR technology and only EHR technology. The final rule specifies the technical capabilities that EHR technology must include and other requirements that must be met in order for EHR technology to be certified. This rule does *not* specify in any way how EHR technology, once certified, must be used in order to achieve meaningful use. That policy is expressed in CMS's rules and is identified for each MU objective and associated measure. In this scenario with the view, download, and transmit to a 3rd party and transitions of care objectives and measures, CMS purposefully proposed two different policies.

For view, download, and transmit to a 3rd party CMS expressly indicated that other transport standards beyond those required for certification could be used by EPs, EHs, and CAHs. However, for transitions of care, CMS expressly indicated that only the transport standards permitted for certification would count in an EP, EH, or CAH's numerator for the measure. Thus, for the transitions of care certification criterion, we included the SOAP-based transport standard as an option for certification to expand the potential approaches EPs, EHs, and CAHs could take to also include electronically transmitted transition of care/referral summaries according to that standard in the transitions of care measure's numerator. In other words, had we not proposed the SOAP-based transport standard as an option in the transitions of care certification criterion, EPs, EHs, and CAHs would have been limited to meeting that MU objective and measure through only the use of the Applicability Statement for Secure Health Transport specification (the primary Direct Project specification). In the case of view, download, and transmit to a 3rd party, we proposed the adoption of the Applicability Statement for Secure Health Transport specification because we believe it is necessary for EHR technology certified to this certification criterion to include at least the capability to use that transport standard, even though CMS permits EPs, EHs, and CAHs to use alternative transport standards. We note that consistent with the changes we have made in the transitions of care certification criterion, we are requiring certification only to the Applicability Statement for Secure Health Transport standard and not also the second Direct Project specification (XDR and XDM for Direct Messaging). Additionally, the Applicability Statement for Secure Health Transport has been updated to Version 1.1 (July 10, 2012). We have adopted this version of the specification because it improves EHR technology implementation and the testing of the specification's requirements and, consequently, makes the version of the specification we proposed outdated. Version 1.1 was established by the stakeholder community during this final rule's drafting. Version 1.1 of the specification provides clearer instruction for implementation through additional guidance on how certificates can be discovered in a consistent manner. If we had adopted the proposed version, EHR technology developers would have encountered difficulty with consistently implementing EHR technology to the specification and testing of the specification's requirements would have been hindered. Last, we do not believe that it is within this rule's scope to specifically describe a particular workflow or how transmission should be implemented. Many commenters raised certification concerns related to the Applicability Statement for Secure Health Transport specification when they commented on the transitions of care certification criterion. Thus, we do not repeat those concerns and our responses and instead address them once in the transitions of care certification criteria comment and responses.

Comments. Commenters stated that the reference to the Applicability Statement for Secure Health Transport specification was the right direction to take for provider-to-provider (or clinician or organization) transmissions but that it was unclear whether this specification was also appropriate for a patient-focused certification criterion. They requested that the ''transmit to third party'' via this standard should be clarified to express that the intended transmission was to another provider or a personal health record (PHR). They contended that the standard should not be required for transmission to other individuals who are not providers (e.g., friends, relatives, etc.). Additionally, they stated that in this latter case the word ''transmission'' may not necessarily mean it was transmitted electronically (or in a manner that can be tracked) because the information could be loaded onto a USB drive, DVD, or even printed in being transferred to a new physician by a patient.

Response. We expect that if the Applicability Statement for Secure Health Transport specification is used to complete a transmission to a 3rd party that the receiving party would be

another health care-oriented entity, like a PHR company the patient is using and that it would not be a patient's friend or relative. Furthermore, for the purposes of this certification criterion, the more generic interpretation of the word ''transmission'' stated by the commenter would not be within the scope of this certification criterion as we do not consider transferring data to electronic media like a USB drive or DVD to constitute an ''electronic transmission'' for the purposes of certification.

Comments. Some commenters agreed that patients should be permitted to transmit their health information to another entity, but stated that we should not burden the health care provider to be the party that transmits this information on their behalf. They contended that health care providers should not be a relaying entity on behalf of their patients.

Response. For clarity, we have revised this certification criterion to state that EHR technology must provide patients (and their authorized representatives) with an online means to view, download, and transmit to a 3rd party the data required by the certification criterion. In this sense, it is the EHR technology that an EP, EH, or CAH has that is performing this function, not the EP, EH, or CAH. Thus, we believe that the burden identified by commenters is misplaced.

Comments. A commenter recommended that we consider requiring the transmittal of a provider's National Provider Identification (NPI) number when an NPI has been assigned. They reasoned that including the NPI would allow receiving systems to more easily cross reference provider information that might already exist in the receiving system database.

Response. We decline to change the certification criterion based on this suggestion. We note that the US Realm Header for the Consolidated CDA does require that at least one ''author'' be identified and further that the ''assigned Author'' shall contain at least one ''id'' which the standard recommends with a ''should'' as being the NPI.

Download and Transmission of Images

Comments. Commenters generally supported the principle of providing patients with access to images, however, only a few commenters outright supported our proposal. One commenter that supported our proposal suggested that images also be included in the ''view'' part of the certification criterion and stated that diagnostic quality is unnecessary for patient viewing. They encouraged us not to suggest a standard for image viewing by patients. Another commenter asked if we intended for images to be available for viewing in a basic distribution viewer or if small images embedded in the report or images viewed without tools in a browser would meet the certification criterion's intent. They suggested that we require a basic distribution viewer to be part of the ''view'' portion of the certification criterion. One commenter stated that if we did not specify DICOM as a requirement for certification, that we should at least make available the option for EHR technology to be certified to the standard for the purposes of image downloads.

Several commenters strongly opposed or requested that we remove the capability and proposed standard. These commenters stated that including images for download and transmission by a patient would be a challenging requirement. They also contended that this capability exceeded the requirements in CMS's proposed rule. Additionally, these commenters stated that images are typically stored in a system separate from EHR technology (i.e., a PACS system) and that this requirement would add significant complexity and burden to the certification criterion. They followed this comment by stating that the industry norm is for CDs with pertinent images to be given to a patient with an image reader that allows for viewing. A similar point was made by other commenters who stated that requiring DICOM for the transmission would force the recipient of the images to have a DICOM compliant viewer and to import the images into that viewer before they could be viewed. Many commenters noted that an image's average file size would present significant storage and cost challenges for online downloading and transmitting. The JPEG file format was recommended as a potential solution since patients did not necessarily need diagnostic quality images.

Response. In consideration of the comments received and the complexity and potential burden identified by commenters, we have decided to remove the requirement for images to be available for download and transmission to a third party. We believe further industry dialogue needs to occur with respect to images and our policy goal of enabling patients to have ready, online access to their images. We expect to include this topic on the HITSC's agenda for the next edition of EHR certification criteria we would adopt through rulemaking and intend to propose a requirement for online image access in a future edition of this certification criterion.

Comments. We received the following additional comments that did not fall within the general scope of the comments summarized above. One commenter proposed that a secure hyperlink to the image, supplied by the radiologist and conveyed via the Direct Project standard, become the method of making DICOM images and radiology reports available to patients and ordering providers. A commenter suggested that for image download a patient should be able to identify the location of a study to be referred to another provider as acceptable for the certification criterion. Last, a separate commenter asked that we specify for the ''download and transmit'' requirements, the IHE Portable Data for Imaging (PDI) profile.

Response. We appreciate commenters' feedback. Given our decision to remove the requirement for image downloading and transmission to a third party, we will take this feedback into consideration for our future work with the HITSC as well as our next rulemaking.

Patient Accessible Log

Comments. Several commenters opposed this proposed specific capability in the certification criterion because they thought it was a means to implement the HHS Office for Civil Rights (OCR) HIPAA Privacy Rule accounting of disclosures proposal (76 FR 31426) for patients to be able to get an ''access report.''

Response. These commenters are mistaken. This aspect of the certification criterion was not intended to implement the Department's proposal to give individuals a right to receive an ''access report.'' However, given this confusion, we have decided to change the paragraph heading for this part of the certification criterion to state ''activity history log.'' The purpose of this paragraph in the certification criterion is to simply require that EHR technology be able to monitor when a patient or their authorized representative(s) views, downloads, or transmits their health information to a third party. Those are the actions to which this paragraph referred in the proposed certification criterion. Put simply, this activity log is meant to assist a patient track the history of their actions or those of their authorized representatives.

Comments. Many commenters stated that the Proposed Rule did not clarify or offer a statement regarding how far back in time a patient accessible log should be able to retrieve log event data. They also sought clarification on who a user could be and what would be sufficient data to include in the log.

Response. The time period for which the activity history log should be available is a policy determination that should be made by the organization who implements EHR technology certified to this certification criterion. Thus, we decline to specify a particular retention period in this certification criterion. What is necessary for certification is that an EHR technology can demonstrate that it can properly create such a log. As noted in our response directly above, we intend for ''user'' in this context to be the patient and any authorized representative(s) to whom they have provided access to view, download, and/or transmit their health information to a third party.

Comments. Several commenters supported the ''credit'' we sought to provide if EHR technology leveraged its general auditing capabilities to fulfill the requirements specified by this capability. However, they asked that we clarify that our proposal did not imply electronic or immediate access to the general audit trail via either the Complete EHR or portal. Some commenters explicitly stated that they would oppose any requirement for immediate electronic access to the general EHR technology audit log online. They also requested confirmation that the access does not need to be provided online. Rather, they suggested that EHR technology could produce a printed document for a patient to review, upon request. They also requested clarification that the log could provide summary information, (e.g., that a patient summary was sent to a third party) and not be required to list all the information contained in the summary document that was transmitted.

Response. This certification criterion does not require an EP, EH, or CAH's general EHR technology security audit log to be made available to patients online. However, the activity history log must be available online and readily accessible. We hope that the past two responses have helped clarify many scope-oriented points for these commenters because it was our proposal and our continued belief that the activity history log should be online and readily available for a patient (or their authorized representative) to review ''on demand.'' Given the clarifications and the limited burden we believe is associated with tracking when a ''view,'' ''download,'' and ''transmission'' has occurred and by whom and when, we do not believe that this should be a significantly challenging capability to include. Accordingly, we have finalized this portion of the proposed certification criterion by changing the paragraph heading and making clear that the actions that need to be tracked are simply ''views,'' ''downloads,'' and/or ''transmissions'' that have occurred and by whom and when.

Comments. Commenters expressed support for our proposed ''synchronized clocks'' standard and our proposal to permit either NTPv3 or NTPv4. They noted that the use of these synchronization technologies is very common and supported in all major operating systems. Along those lines, they stated that it was unclear why this would be a requirement for EHR technology certification because it is unlikely that the EHR technology itself will be directly implementing this type of synchronization and more likely that it will be relying on the lower level systems' clock functionality (e.g., the operating system within which the EHR technology runs). One commenter stated that it is important to avoid a requirement that would make the operating system (that provides the standard clock) part of what is needed for EHR certification as this would impose artificial limits on what operating systems can be used without certifying multiple permutations. This commenter contended that because the ability to use an operating system clock is common, it was unnecessary for this standard to be required for certification. They requested that if we did include it for certification, that we acknowledge that: the operating system keeps the time, the EHR technology gets the system clock, and that a particular operating system is not required to be part of EHR technology for certification.

Response. We thank commenters for supporting this proposal. As we indicated in the Proposed Rule, our responses here also apply to comments received on other certification criteria that also referenced the ''synchronized clocks'' standard. We acknowledged in the Proposed Rule and here again our understanding and expectation that EHR technology will likely obtain a system time from a system clock that has been synchronized following the NTPv3 or NTPv4 standard. We expressly worded the standard to acknowledge this likely scenario by stating ''[t]he date and time recorded *utilize* a system clock that has been synchronized * * *.'' (Emphasis added.) We do not intend for this specific capability to create a binding relationship between EHR technology and a particular operating system. For certification, EHR technology must be able to demonstrate, as the standard states, that it can utilize a system clock that has been synchronized following NTPv3 or NTPv4. Accordingly, we have retained this proposal and finalized it for the certification criteria to which it pertains.

- *Automated Numerator Recording*

MU Objective
N/A
2014 Edition EHR Certification Criterion
§ 170.314(g)(1) (Automated numerator recording).

To complement the ''automated measure calculation'' certification criterion adopted at § 170.314(g)(2), we proposed to adopt a 2014 Edition EHR certification criterion that would apply solely to EHR Modules that include capabilities to support an MU objective with a percentage-based measure. We stated that the focus of this new certification criterion would be on the EHR Module's capability to automatically record the numerator for those measures. We proposed to adopt this new certification criterion at § 170.314(g)(1).

We clarified that, while a Complete EHR would need to be capable of meeting the ''automated measure calculation'' which requires the capability to accurately calculate MU denominators, we did not believe that it would be practicable for an EHR Module to do the same because, in most cases, an EHR Module would likely be unable to record or have access to an accurate denominator. We did, however, believe that EHR Modules presented for certification to certification criteria that include capabilities for supporting an MU objective with a percentage-based measure should at least be able to readily and accurately record the numerator for those capabilities.

Comments. Many commenters supported our proposal in concept and as written. Some of these commenters stated that this certification criterion was a welcome improvement and would ease the reporting burden for small providers and hospitals. Other commenters contended that our proposal had a logical flaw and requested that we clarify how an EHR Module would be able to accurately capture the appropriate numerator because the numerator is often a subset of the patients or actions that qualify to be in the denominator. As such, some commenters echoed what we had stated in the Proposed Rule (that it may be difficult for an EHR Module to know the true denominator) and expressed concern that this requirement could not be implemented without additional burden. Some commenters suggested that we remove this certification criterion altogether, while others requested that modify this certification

criterion to fix the logic challenge and asked that we clarify the expected testing and certification process for this certification criterion if it were to remain in the final rule.

Response. We appreciate commenters support for this certification criterion. We have adopted a revised version of the certification criterion. We acknowledge that this certification criterion requires additional explanation and clarity related to our intended outcome. We agree with commenters that, unless clarified, this proposed certification criterion could pose logic problems for EHR technology developers and, correspondingly, that the conditions we expected to be met in our proposal would be difficult to achieve. Especially in circumstances where the EHR Module has no basis on which to determine the patients or actions that would be part of the denominator specified for a given MU measure.

In response, we offer the following clarifications. We proposed this certification criterion in order to make it easier and more efficient for EPs, EHs, and CAHs who pursue an EHR Module approach to meet the CEHRT definition to determine their EHR MU measure percentages. As we acknowledged in the Proposed Rule, this certification criterion could only help so much because of the potential that an EHR Module would not necessarily have the ability to determine the appropriate denominator for a given measure. We agree with commenters that this limitation can extend to the numerator in cases where the numerator is a subset of the denominator. To address this logic issue, we have modified the certification criterion to focus on what we believe an EHR Module will be able to determine without any specific dependency on an MU measure's denominator. This certification criterion now focuses on an EHR Module's ability to correctly identify the patients or actions that would meet the numerator's requirements generally and without the denominator's limitations applied. Thus, we clarify that for the purposes of testing and certification, an EHR Module would not need to be able to precisely identify the MU numerator after all of the denominator's filtering had been applied. Instead, it will need to be able to identify the patients or actions that would generally meet the numerator and the minimum denominator criteria that would be necessary to match the information provided by the EHR Module to the full denominator criteria from other data sources. We have revised the certification criterion to make this point clear. Additionally, to reflect that in order for this information to be useful to an EP, EH, or CAH to determine the true numerator, the EHR Module (similar to the automated measure calculation certification criterion) would need to be able to produce a file/report that identifies those patients or actions that would meet the numerator. We provide the following examples to illustrate the capability that an EHR Module would need to include. We note that depending on the certification criterion or criteria to which the EHR Module is presented for certification that the potential approach to determine the overall number of patients or actions may be different. We intend to provide guidance as necessary with more examples for each MU objective and measure that this certification criterion would need to support. Ultimately, we believe this information will also help EHR technology developers better understand the numerators and denominators associated with the MU measures.

- *Example 1:* An EHR Module presented for certification that includes CPOE and seeks to be certified to certification criterion at 170.314(a)(1). To meet the automated numerator calculation certification criterion, the EHR Module would need to be able to correctly identify a simple number, the number of orders created using the EHR Module. An EP, EH, or CAH would then need to take this output from the EHR Module and compare it to the total number of orders made (inclusive of those where the EHR Module was not used).
- *Example 2:* An EHR Module presented for certification that includes e-prescribing capabilities and seeks to be certified to certification criteria at 170.314(a)(10) (drug formulary check) and 170.314(b)(3) (electronic prescribing). To meet the automated numerator calculation certification criterion, the EHR Module would need to be able to correctly identify a slightly more complicated number, number of permissible prescriptions for which the existence of a drug formulary was queried and a prescription subsequently electronically transmitted. Given this overall number, an EP, EH, or CAH would then need to take this output from the EHR Module and compare it to the total number of permissible prescriptions written for drugs requiring a prescription, which would need to be obtained from somewhere else.
- *Example 3:* An EHR Module presented for certification that includes the ability to record patient demographics and seeks to be certified to certification criterion at 170.314(a)(3). To meet the automated numerator calculation certification criterion, the EHR Module would need to be able to correctly generate a list of patients that identifies each and every patient in the EHR Module who have all of the demographic elements recorded as structured data (or that the patient declined or not collectable under state or local law). An EP, EH, or CAH would then need to take this output from the EHR Module and compare it to the data source they would use to identify unique patients seen during the EHR reporting period (the denominator limitations for this MU measure).
- *Example 4:* An EHR Module presented for certification that includes the ability to provide patients (and their authorized representatives) with an online means to view, download, and transmit to a 3rd party electronic health information and seeks to be certified to certification criterion at 170.314(e)(1). To meet the automated numerator calculation certification criterion, the EHR Module would need to be able to correctly generate a slightly different list of patients that identifies each and every patient in the EHR Module who have taken one of those three actions. An EP, EH, or CAH would then need to take this output from the EHR Module and compare it to the data source they would use to identify unique patients seen during the EHR reporting period (the denominator limitations for this MU measure).

As illustrated by these examples, many MU measures share similar denominators. Thus, we expect that once an EP, EH, or CAH identifies the source they will use as the basis for a denominator (i.e., number of unique patients seen during the EHR reporting period) that it should be relatively straight forward given the information an EHR Module would be required to produce for the EP, EH, or CAH to determine the true numerator.

Comment. A commenter acknowledged that this proposed certification criterion would be applicable to EHR Modules and requested that we clarify whether this policy applied to EHR technology developers who follow an incremental EHR Module certification approach on the way to designing EHR technology that could satisfy the Complete EHR definition. They stated that if our answer was yes, that it would be overwork for such EHR technology developers and requested an exemption for this scenario.

Response. This requirement is broadly applicable to every EHR Module presented for certification and we decline to provide any exemption. While an EHR technology developer may pursue this approach, we do not believe that it would be prudent to offer such an exemption because it is equally likely that the EHR technology developer could decide to stop before it could seek certification for enough EHR Modules that would cumulatively satisfy the Complete EHR definition. If that were to occur, EPs, EHs, and CAHs that had adopted these EHR Modules would be at a disadvantage. Given the revised CEHRT definition and the fact that EPs, EHs, and CAHs do not

necessarily need to have the same quantity of EHR technology certified to the 2014 Edition EHR certification criteria as they would have under our prior CEHRT definition, we believe that this could reduce the potential burden assumed by this commenter and, depending on its customer base, reduce the need to seek Complete EHR certification in the first place.

Comment. A commenter asked that we confirm whether it would be permissible for an EHR Module presented for testing and certification get certified to the automated measure calculation certification criterion instead of the automated numerator certification criterion.

Response. Yes, this approach is permitted and encouraged in instances where EHR technology developers have developed a sufficiently large EHR Module such that it could meet the automated measure calculation certification criterion for all of the capabilities it includes and that correlate to percentage-based MU measures. We clarify that this approach would satisfy the EHR Module certification requirement specified in § 170.550(f)(1). Where possible, we encourage EHR technology developers to follow this approach in order to provide EPs, EHs, and CAHs with the most efficient means of identifying the numerators and denominators for an MU EHR reporting period. We also note that it is also permitted and encouraged for EHR technology developer to seek certification for a combination of automated numerator and measure calculation certification criteria where the EHR Module may have a reliable and known denominator that can be used as the basis for calculating certain percentage-based MU measures.

• *Non-Percentage-Based Measure Use Report (not adopted)*

MU Objective
N/A
2014 Edition EHR Certification Criterion
N/A

In the Proposed Rule, we proposed to adopt a certification criterion at § 170.314(g)(3) that would have applied to any EHR technology presented for certification that included capabilities associated with MU objectives and measures that were not percentage based. We noted that this certification criterion would focus on a Complete EHR's or EHR Module's capability to record that a user had certain EHR technology capabilities enabled during an EHR reporting period and had used those capabilities to demonstrate MU. Further, we stated that in consultation with CMS, we believed that EPs, EHs, and CAHs would benefit from this type of capability being required as a condition of certification and that such a capability could provide EPs, EHs, and CAHs with valuable evidence in the event of a MU audit. We proposed that any EHR technology presented for certification to any one of the following certification criteria would need to be certified to this certification criterion.

170.314(a)(2)	Drug-drug, drug-allergy interaction checks.
170.314(a)(8)	Clinical decision support.
170.314(a)(10)	Drug-formulary checks.
170.314(a)(14)	Patient lists.
170.314(a)(17)	Electronic medication administration record.
170.314(f)(2)	Transmission to immunization registries.
170.314(f)(4)	Transmission to public health agencies (surveillance).
170.314(f)(6)	Transmission of reportable laboratory tests and values/results.
170.314(f)(8)	Transmission to cancer registries.

Comments. Several commenters opposed this proposed certification criterion and suggested that it was unduly burdensome. Many indicated that we had significantly underestimated the complexity involved with accurately capturing this information. Commenters cited several examples and noted that this proposed certification criterion required different analysis far beyond just ''yes/no'' settings for many of the certification criteria listed above. They noted that the use of eMAR is not an on/off step and questioned how we expected enabling ''ongoing submission'' for public health reporting to be recorded. Commenters stated that requiring this certification criterion would take away from the EHR technology development time necessary to address the certification criteria that were necessary to support MU objectives and associated measures. Last, commenters indicated that the fact the capability was active should be sufficient for MU, as well as attestation, because there is not a separate requirement in MU associated with the frequency each particular capability is used.

Response. In response to commenters' feedback we have not included this proposed certification criterion in the final rule. We acknowledge some of the complexities raised by commenters and that additional aspects as well as specificity would be necessary for a more effective certification criterion. However, we continue to believe in the spirit and direction of this certification criterion so that ultimately EPs, EHs, and CAHs could be in a position to electronically report even the non-percentage based MU objectives and measures. In light of the questions raised by stakeholders we intend to engage the HITSC and HITPC on how to best reach this goal.

• *Safety-Enhanced Design and Quality Management System*

MU Objective
N/A
2014 Edition EHR Certification Criterion
§ 170.314(g)(3) (Safety-enhanced design).
§ 170.314(g)(4) (Quality management system).

Safety-enhanced Design

In the Proposed Rule, we provided an overview of the ISO definition of usability as ''[t]he extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.'' [9] We outlined that EHR technology certification could introduce some improvements in usability, which we believed would enhance both the safety and efficiency of CEHRT. In the Proposed Rule, we also reviewed the November 2011 Institute of Medicine (IOM) report titled, ''Health IT and Patient Safety: Building Safe Systems for Better Care,'' in which the usability of EHR technology and quality management was often referenced. The IOM noted that ''[w]hile many vendors already have some types of quality management principles and processes in place, not all vendors do and to what standard they are held is unknown.'' The IOM recommended that ''[t]he Secretary of HHS should specify the quality and risk management process

[9] ISO 9241–11.

requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability.''

We proposed that a significant first step toward improving overall usability would be to focus on the process of user-centered design (UCD). While valid and reliable usability measurements exist, including those specified in NISTIR 7804 ''Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records,'' [10] we expressed that it would be inappropriate for ONC to seek to measure EHR technology in this way. Recognizing that EHR technologies exist and are in use today, we prioritized eight certification criteria [11] and associated capabilities to which the proposed certification criterion would require UCD to have been applied. We chose these eight because we believed they pose the greatest risk for patient harm and therefore the greatest opportunity for error prevention. As proposed, this approach was designed to limit this certification criterion's potential burden.

We proposed that the methods for how an EHR technology developer could employ UCD are well defined in documents and requirements such as ISO 9241–11, ISO 13407, ISO 16982, and NISTIR 7741. We proposed that it would be best to enable EHR technology developers to choose their UCD approach and not to prescribe specific UCD processes that would be required to meet this certification criterion. Thus, the use of any one of these processes to apply UCD would meet this certification criterion. We acknowledged and expected that EHR technology developers who have already followed UCD in previous development efforts for the identified certification criteria would be performing a retrospective analysis. However, if UCD had not been previously applied to capabilities associated with the certification criteria, the EHR technology would ultimately need to have such UCD processes applied before it would be able to be certified. We proposed that testing [12] to this certification criterion would entail EHR technology developers documenting that their UCD incorporates all of the data elements defined in the Customized Common Industry Format Template for EHR Usability Testing (NISTIR 7742). We noted that with respect to demonstrating compliance with this certification criterion that this information would need to be available to an ONC–ACB for review, but that the form and format for how the data would be presented for testing would not necessarily need to be according to NISTIR 7742 (i.e., an EHR technology developer could capture information specified in NISTIR 7742 without having to use the template). Finally, we indicated that this documentation would become a component of the publicly available testing results on which a certification is based.

Comments. A majority of commenters strongly urged ONC to include this proposed certification criterion in the final rule. We note, however, that of all of the proposed certification criteria, this one appeared to be the most polarizing. Provider organizations, hospitals, and consumer advocates supported its inclusion in certification and most (but not all) EHR technology developers expressed some form of opposition—with concern about the public availability of user-centered design testing results.

Many commenters expressed support for our proposal adding, in many cases, arguments about the critically important role that usability plays in the aspect of the safety and reliability of EHR systems, noting that if usability is not carefully analyzed it can cause design induced errors. Other commenters were clear that they felt the results of UCD and quality systems testing should not be made publicly available, and that doing so would open the door for EHR developers' intellectual property to be misappropriated. Some commenters were simply opposed to this criterion, citing an unnecessary burden on the industry.

Many commenters supported our proposal to not specify certain standards or requirements for UCD processes. Commenters also agreed with our proposal to require that the documentation for how UCD was applied in the software development process would be publicly available. These commenters noted that this transparency would foster EHR technology developer competition to make UCD a competitive advantage, thus spurring innovation, improving clinician adoption, and enhancing patient safety. These commenters also suggested that the proposed certification criterion would not compromise innovation nor require the release of intellectual property. Most commenters agreed with the decision not to include NISTIR 7804, and asked for clarification regarding the proposed CIF template (NISTIR 7742) and which specific elements are required. One commenter asked for clarification of the testing methods, and whether self-attestation would be sufficient for consumers and purchasers of Certified EHR Technology.

Many commenters quoted an AHRQ report as follows, ''Usability studies are often difficult to generalize or transfer across settings, in part because medication management health IT (MMIT) effectiveness is linked strongly to the culture, institutional leadership, and other situation specific factors. Therefore, applicability of findings related to usability is problematic in MMIT applications.'' [13] Along those lines, they suggested a slight alternative to what we proposed by suggesting that EHR technology developers attest to and document their current processes for incorporating UCD practices into their software design, as well as any UCD approaches used for currently certified products, but not be required to have the findings published publicly. These commenters also suggested that summative testing, as used in the referenced NIST template, can catch the most basic usability errors, but is unlikely to have a significant impact on patient safety relative to cost. These commenters advised that we broaden the criteria to include other, formative UCD techniques instead of just summative testing as valid for certification. Finally, these same commenters expressed strong objections to the requirement for retrospective UCD analysis and application. Many commenters were supportive of our identification of several applicable UCD standards, but requested some changes including the replacement of ISO 13407 with ISO 9241–11, and the addition of ISO/IEC 62366 and ISO 9241–210.

One commenter asked for clarification on what was meant by ''retrospective analysis'' and whether it means summative testing or simply asserting and providing evidence that a UCD process was followed. Many commenters agreed that EHR technology developers should be able to choose the UCD approach that best supports their design principles and products, adding that this would help minimize the burden of testing and will raise

[10] *http://www.nist.gov/healthcare/usability.*

[11] § 170.314(a)(1) (CPOE); § 170.314(a)(2) (Drug-drug, drug-allergy interaction checks); § 170.314(a)(6) (Medication list); § 170.314(a)(7) (Medication allergy list); § 170.314(a)(8) (Clinical decision support); § 170.314(a)(16) (Electronic medication administration record); § 170.314(b)(3) (Electronic prescribing); and § 170.314(b)(4) (Clinical information reconciliation).

[12] The National Voluntary Laboratory Accreditation Program, as administered by NIST, is responsible for accrediting testing laboratories (who perform EHR technology testing) under the permanent certification program (''ONC HIT Certification Program'') (76 FR 1278).

[13] *http://www.ahrq.gov/clinic/epcsums/medmgtsum.htm.*

awareness on the importance of usability from end-users. One commenter noted that usability is a quality of interactive software that can be objectively defined and evaluated. This commenter suggested that we adopt the following standards for EHR technology certification: Standard 13407, UCD/NISTIR 7804, ISO Standard 25062, and Common Industry Format for Summative Usability Tests NISTIR 7742. This commenter noted that some EHR technology developers have published objections that the scope of this type of testing would be unrealistic for an EHR that would be used in a wide variety of conditions, but also noted that by limiting the scope to eight high priority certification criteria identified in the Proposed Rule mitigates any such concerns.

One commenter expressed disagreement with the component of the proposal that would require all testing elements to be made public and strongly argued that this part be removed from the final rule. This commenter stated that this equates to the public disclosure of trade secrets and other proprietary information may force EHR technology developers that are publicly-traded to violate their obligations to shareholders, as defined in regulations enforced by the Securities and Exchange Commission (SEC) that govern the disclosure of both financial and non-financial information.

One commenter expressed the opinion that UCD is subjective, while several others request clarification regarding this proposal and ask if this certification criterion will allow each EHR technology developer to implement the UCD approach which best suits their development methodology.

Response. We thank commenters for the detailed and thoughtful responses. We agree with those commenters who saw this proposed certification criterion as an important way to improve both EHR technology design and safety. Therefore, we have adopted this certification criterion as proposed. We disagree with commenters who argued that this certification criterion represented an unnecessary burden. However, in response to those comments, we have issued several clarifications to better explain the certification criterion's intent and the requirements that are necessary to demonstrate compliance with this certification criterion.

To demonstrate compliance with this certification criterion, UCD must have been applied to each capability of an EHR technology that is associated with the eight certification criteria named in this certification criterion. We clarify that the application of UCD is limited to only those eight certification criteria specified in this certification criterion and for which certification is sought. For example, if an EHR Module is presented for certification and includes capabilities to which this certification criterion would apply, but for which certification is not sought, then those other capabilities for which certification is not sought would not have to have had UCD applied because they would be beyond the scope of the EHR Module's certification.

We clarify that what we meant by ''retrospective analysis'' is that an EHR technology developer would not necessarily have to initiate new UCD analysis to meet this certification criterion if they had already completed UCD for the capability in the past. In other words, if an EHR technology had never applied UCD to the capabilities to which this certification criterion applies then UCD would need to be completed before that EHR technology could be certified. However, if UCD had been applied to an EHR technology for the capabilities relevant to this certification criterion, UCD would not need to be redone and an EHR technology developer could provide the required information specified by NISTIR 7742 that reflects the UCD that they had previously completed. We make this clarification to acknowledge that many EHR technologies are designed to follow standard UCD processes and we did not intend to disregard that prior work. We also believe this clarification will help assuage commenters' concerns about the potential burden posed by this certification criterion.

The method(s) that could be employed for UCD (e.g., ISO 9241–11, ISO 13407, ISO 16982, and NISTIR 7741) and that were listed in the Proposed Rule are examples of resources that EHR technology developers may choose to review in order to select a UCD. We agree that ISO/IEC 62366 and ISO 9241–210 are also acceptable alternatives. Any UCD process selected by an EHR technology developer is appropriate, and it need not be listed in the examples we provided in order to be acceptable. We do, however, strongly advise EHR technology 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. In the event that an EHR technology developer selects a UCD process that is not an industry standard (i.e., not developed by a voluntary consensus standards organization (VCSO)), 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. Submission of the information specified in the NISTIR 7742 template will need to be submitted for each and every one of the applicable eight certification criteria specified in this certification criterion and for which certification is sought. This information will become part of the EHR technology's test report that is required to be made publicly available.

The following information/sections in NISTIR 7742 are required for submission:

- Name and version of the product
- Date and location of the test
- Test environment
- Description of the intended users
- Total number of participants
- Description of participants: their experience and demographic characteristics
- Description of the user tasks that were tested
- List of the specific metrics captured during the testing for effectiveness, efficiency and satisfaction
- Data scoring
- Results of the test and data analysis
- Major test findings
- Identified area(s) of improvement(s)

There are illustrative tables on pages 11 and 20 of the NIST 7742 document that may not need to be populated, depending on the tasks tested. We clarify that all of the sections specified above must to be completed, including ''major findings'' and ''areas for improvement.'' We note that EHR technology developers can perform many iterations of summative user testing. Thus, the submission that is ultimately provided for testing and certification may be the expression of a final iteration in which few areas for improvement would be identified. We do not expect EHR technology developers to include trade secrets or proprietary information in these reports. We disagree that UCD is subjective, and have offered several examples of industry standard UCD processes above. Regarding one commenter's concern that the publication of usability testing may violate SEC regulations regarding public disclosure, this commenter provided no additional detail as to why this would pose a conflict with SEC regulations, nor did it cite a particular SEC regulatory provision that they believed was in conflict with the proposed certification criterion. We are unaware of any provision that would result in EHR technology developers violating any SEC regulations.

Comments. One commenter expressed support for the certification criterion, but disagreed with the assumption that user interface (UI) validation testing must be performed by end-users. This commenter's experience was that UI validation tests performed by internal design experts are more effective than the same testing performed by end-users. This commenter reported that engineering a UI to the needs of a user who is encountering that interface for the very first time, invariably results in an interface designed to accommodate the novice, at the expense of denying power and efficiency to the same user who will quickly gain familiarity with a well designed interface.

Response. The NISTIR 7742 includes several sections: Executive Summary, Introduction, Method, Results, and Appendices. In each of these sections, there are required data elements—and some of these elements call for the expression of the number of study participants, their level of experience with EHR technology, and other pertinent details. Regarding comments about the participants of usability testing, many UCD processes incorporate involvement of end-users in formative and summative testing. The cohort of users who are selected as participants will of course vary with the product and its intended users.

Comments. One commenter supported this criterion, but expressed concern that testing in a lab setting would be insufficient and would need to be augmented by field testing as well, advocating for provisional certification for this certification criterion until it had been implemented and tested in the field.

Many commenters expressed support for this criterion, stating agreement that EHR technology developers should conduct usability testing. One commenter suggested that usability testing be conducted and mandated by a third party such as a Sharp C grant recipient, and strongly recommending standardization of EHR data output to make the transfer of data more seamless, less administratively burdensome, and less costly.

One commenter suggested that ensuring usability is the key to successful physician adoption of EHRs, yet expressed concern that our proposals as drafted gave no consideration as to the clinician decision-making process or practice workflow.

One commenter expressed concern that the adoption of a particular methodology does not guarantee that software will improve. Other commenters suggested that the testers would need to be selected who are professionals already familiar with more than one EHR technology and are in the same specialty as the target market of the EHR technology developer.

One commenter contended that the NISTIR 7804 would be appropriate, and advocated for its inclusion as a certification requirement.

Many commenters suggested that we enhance our usability testing requirements beyond what was described in our proposed rule such as: (1) Requiring the collection of data based on an EHR user (physician) satisfaction survey that can be included in the attestation phase of the MU program; (2) collecting and disseminating survey results on usability experiences based on practice size, specialty type, and geographic location, and incorporation of this feedback into future certification processes; (3) including usability and patient safety criteria into the certification process as discussed in the IOM report; (4) promoting innovation in EHR technology design that not only addresses patient safety and usability, but can be more seamlessly integrated into smaller practices that do not have the luxury of resources to completely redesign the way they work to accommodate the EHR; (5) seeking industry feedback—including physician feedback—on what constitutes an appropriate level of risk as it relates to patient safety; and (6) applying the principles in the NISTIR 7804 to the entire EHR certification process.

Response. We thank these commenters for their thorough and thoughtful feedback. Although the implementation of suggestions 1 through 5 may provide a better understanding of EHR usability today and chart a path toward improved usability in the future, they fall outside the scope of this certification criterion. We have not included NISTIR 7804 in the 2014 Edition EHR certification criteria, but may consider it for future editions of certification criteria. We do believe that UCD will—by definition—consider the clinical decision-making process and disagree with the commenter that it does not. Finally, we agree that both formative and summative testing are valuable, and we agree that testing in a lab setting and testing in the field are also important. This certification criterion is a first step toward formal usability testing becoming part of the culture of EHR technology development. We therefore clarify that, at a minimum, only lab-based summative testing is necessary to be performed in order to demonstrate compliance with this certification criterion. Nothing precludes field-testing and formative testing from also being performed and we encourage EHR technology developers to do so.

Quality Management System

In the Proposed Rule we noted that the IOM had also recommended that we ''[establish] quality management principles and processes in health IT.'' We stated that, working with other Federal agencies, we intended to publish a quality management document that would be customized for the EHR technology development lifecycle and express similar principles to those included in ISO 9001, IEC 62304, ISO 13485, ISO 9001, and 21 CFR part 820. We anticipated that this document would provide specific guidance to EHR technology developers on best practices in software design processes in a way that mirrors established quality management systems, but would be customized for EHR technology development We stated that we understood that some EHR technology developers already have processes like these in place, but did not believe, especially in light of the IOM recommendation, that the EHR technology industry as a whole consistently follows such processes. We indicated our expectation to publish the quality management document around the same time as the Proposed Rule would be available for public comment. We indicated that we were considering including an additional certification criterion in the final rule that would require an EHR technology developer to document how their EHR technology development processes either aligned with, or deviated from, the quality management principles and processes that would be expressed in the document. We emphasized that this certification criterion would not require EHR technology developers to comply with all of the document's quality management principles and processes in order to be certified. Rather, to satisfy the certification criterion, EHR technology developers would need to review their current processes and document how they do or do not meet the principles and processes specified in the document (and where they do not, what alternative processes they use, if any). We stated our expectation that this documentation would be submitted as part of testing and would become a component of the publicly available testing results on which a certification is based.

We explained that we were considering adopting this additional certification criterion as part of the 2014 Edition EHR certification criteria for

three reasons. First, all EHR technology developers that seek certification of their EHR technology would become familiar with quality management processes. Second, the public disclosure of the quality management processes used by EHR technology developers would provide transparency to purchasers and stakeholders, which could inform and improve the development and certification of EHR technology. Last, EHR technology developers' compliance with the certification criterion would establish a foundation for the adoption of a more rigorous certification criterion for quality management processes in the future without placing an immediate significant burden on EHR technology developers. We requested public comment on this additional certification criterion and the feasibility of requiring EHR technology developers to document their current processes.

Comments. Most comments supported our proposal to adopt a certification criterion for quality management practices. Several commenters expressed concern that the quality management systems document referenced in our proposal was not available for review during the public comment period as we had proposed. Many commenters expressed concern that public availability of the documentation produced for this certification criterion might reveal proprietary and confidential software information.

Other commenters expressed support for having quality management systems in place and the general approach proposed of describing the nature of each EHR technology developer's quality processes. These commenters also expressed that the proposal is preferable to a specific requirement for EHR technology developers to adopt a particular quality management system.

One commenter observed that due to the recent FDA rule for Medical Device Data Systems (MDDS), they are actively implementing these quality principles across their enterprise development projects and believe that the use of quality management systems will help to: Improve traceability of clinician requirements to EHR system features, keeping requirements at the forefront; improve consistency of development and commissioning activities and thus increase the ability to predict when EHR system updates will become available to the clinicians; and lower the overall cost of quality by minimizing a whole range of failure costs. This commenter also noted additional advantages of quality management systems including: The opportunity to clarify roles and responsibilities in the development organization allowing more precise definition of scope, schedule, and resources needed to develop its clinical systems; improved visibility into the development project progress, providing greater predictability of when resources assigned to projects will be available for other strategic priorities; highlight needs for communication and safety/risk discussions on critical issues; and creation of ownership of quality at all levels of the organization.

One commenter did not support the requirement to provide a gap analysis as part of the certification, due to the fact that this commenter's EHR technology is comprised of many disparate self-developed modules spanning multiple years of development and use, multiple teams and multiple technologies where consistent processes were not performed. This commenter also expressed concern that the publication of this analysis is irrelevant to organizations that develop their EHR technology and do not sell it to others. Finally, this commenter stated that they are already familiar with quality management systems and are actively tightening up their software development lifecycle processes and other QMS related activities to become compliant with the FDA MDDS rule.

One commenter stated that they are actively implementing a quality management system, and that disclosing where [they] are in this process to an agency that currently does not have jurisdiction in this area would add no value. Several commenters expressed that they would not support any requirement that did not align with international standards such as ISO–62304, ISO–14971, ISO–13485, or with FDA's quality system regulation in 21 CFR part 820.

Some commenters noted that the work required to meet this requirement will be very time consuming and costly to provide a formal assessment on each of the legacy development processes that have been employed, and that the review for certification should focus on new development rather than historical development. They stated that certification bodies could perform a spot check quality management systems audit on new processes instead of requiring EHR technology developers to retrospectively define old processes. The commenter expressed that this would be far less burdensome and would allow EHR technology developers to appropriately focus efforts on future development efforts, not past work.

Several commenters agreed that it is important for EHR technology developers to follow rigorous quality management systems and welcomed the inclusion of a quality management systems certification criterion. These commenters suggested that optimal quality management systems for EHR technology should expressly permit modern ''Agile'' development processes, as Agile processes can efficiently yield higher quality software than traditional methods. A commenter also noted that some of the existing quality management regimes referenced (ISO 9001, IEC 62304, ISO 13485, and 21 CFR part 820) predate the development of Agile software development methodologies and were written assuming an old-fashioned stage-gate ''waterfall'' software development process. The commenter stated, for example, that while medical device [14] manufacturers have begun to successfully embrace Agile there has been some confusion about whether Agile processes are even allowed under 21 CFR part 820. This commenter argued that a modern quality management system for EHR technology should expressly permit Agile software development, and should set high-level requirements for software development process and work-product, without unnecessarily constraining the order in which particular process steps are followed. Comments indicated that a quality management system certification criterion should cover the processes associated with custom software development. They stated that unlike other medical devices covered by the quality management systems mentioned (IEC 62304, ISO 13485, and 21 CFR part 820), EHR technology implementations often involve a substantial amount of custom, site-specific, software (including templates, interfaces, and custom code).

One commenter expressed agreement with IOM that it would be useful to establish ''quality management principles and processes in health IT.'' This commenter supported the proposed gradual introduction of a generic quality management system certification criterion with key requirements called out. They suggested that a gradual introduction would support those EHR technology developers who already have quality

[14] We note for readers that we interpreted the term ''medical device'' used in this comment summary by commenters to refer to those devices that fall under the meaning of 'device' in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 321(h). Generally, speaking when the term ''device'' is used throughout this rule it is used in the general sense of the word and not limited to the meaning assigned to ''device'' in section 201(h) of the FD&C Act.

management systems in place without requiring them to rip and replace to conform to a ''standard'' quality management system that may not offer any significant improvement over what they already have in place. These commenters also stated that it is important for EHR technology developers who are currently following one of the existing ISO or FDA standard processes not be disadvantaged by new MU equivalencies.

Response. We appreciate the very thorough and thoughtful comments on our proposal to adopt a quality management system (QMS) oriented certification criterion. We share the sentiments expressed by commenters that selecting and implementing an optimal quality management system (QMS) for EHR technology development can be complex. 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. We appreciate the detailed comments that offered guidance regarding the optimal components of an ideal QMS for EHR technology and we agree with many of these suggestions. Because we were unable to publish the quality management document referenced in the Proposed Rule we recognize that there was an insufficient opportunity to comment on this document and have not included an explicit requirement to use this document.

We agree with the many commenters who described the advantages of an incremental implementation of QMS requirements for EHR technology. Additionally, we support the position of the commenters that stated this requirement should strive not to burden EHR technology developers with the task of documenting previous development processes. We disagree with the commenter who believed that this requirement was beyond our authority. The Secretary has the statutory authority to adopt standards, implementation specifications, and certification criteria for HIT and the National Coordinator has the statutory authority to establish a certification program for the certification of HIT to certification criteria adopted by the Secretary. Additionally, we disagree with the commenter with internally developed EHR technology that objected to our proposed gap analysis because we believe that the purchasers of EHR technology are not the only stakeholders who would take interest in the transparency provided by the submission of this information. Patients, employees, business partners, and shareholders of such organizations would be other such interested parties.

In consideration of comments received for and against this proposal, we have decided to adopt a certification criterion in this final rule at § 170.314(g)(4) that will generally focus on QMS and, as suggested by many commenters, is meant to be a first step that can be built on in an incremental fashion. All EHR technology certified to the 2014 Edition EHR certification criteria would need to be certified to this certification criterion, and we have taken steps to ensure that EHR Modules are certified to this certification criterion by revising § 170.550 as discussed in more detail under section IV.C.2 of this preamble.

We have adopted a certification criterion that accounts for the fact that we did not publish the quality management document as we had proposed. The certification criterion we have adopted is more general and provides more flexibility. The certification criterion expresses that for each capability an EHR technology includes and for which that capability's certification is sought, the use of a QMS in the development, testing, implementation and maintenance of that capability must be identified. Unlike our proposal, any QMS may be used to meet this certification criterion and even an indication that no QMS was used for particular capabilities for which certification is requested is permitted. The commenter who stated that they are implementing the FDA's Quality System (QS) regulations (for example, under the MDDS rule) would—by definition—be meeting this certification criterion so long as they cite their compliance with FDA's QS regulations for certification. Given this flexibility, we cannot foresee any reason why this certification criterion cannot be satisfied nor do we believe that it will be a significant burden to indicate the QMS used (or not used) in the development of capabilities for which certification is sought.

We understand that some EHR technology developers have several teams who work on different functional components of EHR technology. In the case where the whole development organization uses the same QMS (or not at all) across all teams, then this certification criterion may be met with one report. Where there is variability across teams, the EHR technology developer will need to indicate the individual QMS' followed for the applicable certification criteria for which the EHR technology is submitted for certification.

We encourage EHR technology developers to choose an established QMS, but developers are not required to do so, and may use either a modified version of an established QMS, or an entirely ''home grown'' QMS. We also clarify that we have no expectation that there will be detailed documentation of historical QMS or their absence. As specified above, we believe that the documentation of the current status of QMS in an EHR technology development organization is sufficient.

EHR Technology Safety Reporting

We also considered adopting a certification criterion (as mandatory or optional) that would require EHR technology to enable a user to generate a file in accordance with the data required by the Agency for Healthcare Research and Quality (AHRQ) Common Format,[15] including the ''Device or Medical/Surgical Supply, including HIT v1.1a.'' We requested public comment on whether we should adopt such a certification criterion and what, if any, challenges EHR technology developers would encounter in implementing this capability.

Comments. Many commenters requested that ONC not adopt a certification criterion at this time, but take the opportunity to study the role of EHRs in patient safety incident reporting in order to determine if something more reflective of EHR technology's role in such reporting as a future certification criterion would be appropriate. Many of these commenters also stated that there is insufficient experience with the AHRQ Common Format—especially in the ambulatory domain, and that extension of the Common Format would be necessary for it to be of value. Other commenters expressed additional concerns about the maturity of the Common Format, and the ability of EHR technology to generate the appropriate file format, and whether there would be any near-term value to such reports without more experience with adverse event reporting from EHR technology.

Response. We agree with these concerns and have not adopted a certification criterion for reporting patient safety events according to the Common Formats in the 2014 Edition EHR certification criteria.

- *Data Portability*

[15] *http://www.pso.ahrq.gov/formats/commonfmt.htm*

MU Objective N/A
2014 Edition EHR Certification Criterion
§ 170.314(b)(7) (Data portability).

In the Proposed Rule we sought public comment on whether we should adopt a certification criterion to focus on the portability of data stored within CEHRT. We recited the scenario where a provider might seek to change EHR technology (and EHR technology developers). We stated that in such a scenario providers should have the ability to easily switch EHR technology—at a low cost—and migrate most or all of their data in structured form to another EHR technology. We noted that in the absence of this capability, providers could be ''locked-in'' to their current EHR technology, which could ultimately impede innovation. With our belief that data portability is a key aspect of the EHR technology market that requires maturity, we sought public comment on specific questions that could inform our decision on whether to adopt a certification criterion focused on data portability. We asked: (1) Whether EHR technology is capable of electronically providing a sufficient amount of a patient's health history using export summaries formatted according to the Consolidated CDA for the scenario described above; (2) whether all of the data in a provider's EHR #1 is necessary to migrate over to EHR #2 in the event the provider wants to switch (We noted that potential effect of medical record retention laws, but sought to determine whether the loss of some data would be tolerable and if so, which data.); (3) considering the standards that have been adopted and proposed for adoption in the Proposed Rule, what additional standards and guidance would be necessary to meet market needs for data portability, including the portability of administrative data such as Medicare and Medicaid eligibility and claims; (4) whether a specific set of patient data could be used as a foundation for an incremental approach to improve data portability for the situation described above as well as other situations; and (5) whether the concept of a capability to batch export a single patient's records (or a provider's entire patient population) poses unintended consequences from a security perspective and what factors should be considered to mitigate any potential abuse of this capability if it existed.

Comments. Commenters strongly supported our efforts to improve data portability, including in the specific provider situation we outlined in the Proposed Rule. Many commenters generally noted that medical record retention laws, as well as those governing fraud and abuse investigations, largely determine the amount and type of information that must be retained, and therefore, needs to be portable. Commenters also noted that there may be other reasons for retaining longitudinal information on patient care, such as clinical trial participation, post approval study requirements and other clinical reasons.

Many commenters stated that some data loss is inevitable, with some commenters noting this was due to variations in clinical content and data schema(s) between EHR systems. Commenters gave varying responses on what specific data would be important to migrate to a new EHR. Some commenters stated the decision would be situational, best left to the provider, or, as previously noted, based on medical records retention laws and requirements. Commenters stated that demographics, problems, medications, medication allergies, allergies, immunizations, vital signs, lab results, and encounter notes would fall into the category of ''not tolerable'' to lose in transfer. For all ''other'' data, commenters stated that it would be sufficient for the data to be accessible in a human readable form through, but not necessarily stored within, the EHR. A few commenters also stated that documentation metadata should be readily available for all databases. Some commenters stated that the loss of data at a granular, visit-oriented level would be tolerable. Other commenters stated that because administrative data is normally stored in practice management systems—and not in EHRs—it would not need to be transferred from one of these systems to another.

One commenter suggested an incremental approach starting with requiring indexed and searchable documents including visit notes, letters, and reports. The commenter noted that this might require manual addition or automated generation of metadata and might need to include only documents generated after a given date for complete header information. The commenter noted that subsets of the patient's record (records of children must include immunizations and growth data) could be effective, but the commenter emphasized that the summary must be focused on the patient's lifetime data and not the most recent clinical events. Over time, the commenter stated that external standards for data portability would govern the internal structure of data within an EHR so that data can be exported and imported without data loss. The commenter stated that a good example is retention of laboratory results in LOINC® codes after import so that they can be exported in the future and used in a different EHR to identify data elements needed for clinical decision support or clinical quality measures.

Commenters stated that the Consolidated CDA would not be capable of sufficiently capturing all patient information that would be needed. Commenters stated that the Consolidated CDA is designed to be a summary and would not capture longitudinal patient information, administrative billing data, or other necessary data (e.g., trend analysis, operational data, and master file data). A few commenters noted that the CDA does not support the inclusion of information on whether meaningful use measures were applicable to or addressed for patients. Other commenters stated that CDA document types may not be the most efficient means to migrate data from one EHR to another. These commenters further stated that it is critical that such migration happens as quickly as possible. Therefore, the commenters contended that other data transfer mechanisms would be better suited for that purpose, particularly when large data volumes are in play (e.g., large multi-provider entities migrations).

A commenter stated that one possible solution would be to require EHR technology developers to tag key data elements that would typically be moved in an EHR transition with standardized XML. EHR technology developers would also need to be able to receive and process data feeds with this standardized XML, storing it in their native tables.

A few commenters stated that batch migrations are one of the more typical migration methods used when a provider moves from one EHR to another. Some commenters stated that batch exports of a patient's record poses serious security risks, while other commenters stated that current safeguards exist. These commenters pointed to the use of business associate agreements, encryption, and the use other internal controls to mitigate any security concerns.

Response. We thank commenters for the depth and breadth of their responses to our questions and proposals. In consideration of comments received, we have adopted a certification criterion for data portability. As discussed later in this final rule, we have also included this certification criterion as part of the Base EHR definition in order to ensure

that all EPs, EHs, and CAHs, have this capability as part of the EHR technology they use to meet the CEHRT definition. While we recognize that no ''silver bullet'' exists with respect to data portability, we strongly believe that more attention must be paid to this market challenge and that with the interests of EPs, EHs, and CAHs in mind, small steps can be taken to improve the data portability between EHR technologies. We intend for this certification criterion to be a starting point and have framed it in such a way as to leverage capabilities that will already be included in an EP, EH, and CAH's CEHRT.

The certification criterion leverages and requires the same capabilities specified in the ''transitions of care—create and transmit transition of care/referral summaries'' certification criterion at § 170.314(b)(2)(i). The only difference between the capability specified in the data portability certification criterion and the capability specified in the transitions of care certification criterion is that the data portability certification criterion expressly limits the scope of the data to the most current clinical information about each patient for which an export summary is created. For the purposes of certification and for all of the patients on which an EP's, EH's, or CAH's CEHRT maintains data, the EHR technology must enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the Consolidated CDA that includes each patient's most recent clinical information. While this is the minimum capability required for certification, we encourage EHR technology developers to include patients' longitudinal information for laboratory test results, immunizations, and procedures, and intend to consider including this broader requirement in the next edition of this certification criterion. We believe this initial capability provides a strong starting point for the fluid transition from one EHR technology to another. Primarily, we anticipate that this capability will be enable transitions to be more efficient by reducing the need for EPs, EHs, and CAHs to manually re-enter all of their patients' recent data into a new EHR system.

b. Ambulatory Setting

We propose to adopt 3 certification criteria that would be new certification criteria for the ambulatory setting.

- *Secure Messaging*

MU Objective
Use secure electronic messaging to communicate with patients on relevant health information.
2014 Edition EHR Certification Criterion § 170.314(e)(3) (Ambulatory setting only—secure messaging).

We proposed the 2014 Edition EHR certification criterion for secure messaging (at § 170.314(e)(3)) to support the MU objective and measure recommended by the HITPC and proposed by CMS. We agreed with the direction provided by both HITSC recommendations and merged the two into a refined proposed certification criterion. We also proposed to include in the certification criterion a baseline standard in terms of the encryption and hashing algorithms that would need to be used to implement secure messaging. More specifically, we proposed that only those identified in FIPS 140–2 Annex A be permitted to be used to meet this criterion and proposed to adopt a new standard in § 170.210(f) to refer to FIPS 140–2 Annex A's encryption and hashing algorithms. Additionally, we referenced several standards and implementations specifications that EHR technology developers could use to implement various secure messaging approaches, including IETF RFC 2246 (TLS 1.0), SMTP/SMIME, NIST Special Publication 800–52 (''Guidelines for the Selection and Use of TLS Implementations''), and specifications developed as part of nationwide health information network initiatives.

Comments. Several commenters conveyed that the certification and testing process would need to accommodate the range of messaging mechanisms permitted by CMS, while being certified within the proposed standards. One commenter asked if there were approved modes of electronic messaging and whether secured and encrypted email would be a method. Another stated that use of a secure messaging capability from within a portal application should be an acceptable method. One commenter recommended that we equally support the standards and specifications developed as part of the NwHIN Exchange with the intent to support the broadest possible adoption of health information exchange capabilities. Other commenters generally requested that we provide some examples of common access mechanisms and acceptable security protocols. Another commenter suggested that we consider particular transport methods be certified similar to the certification criteria discussed in the Proposed Rule that referenced the Direct specifications and other acceptable transport methods. One commenter stressed the importance of adequate privacy and security, but urged ONC to take a reasonable approach and not make the use of secure electronic messaging to communicate with patients unduly burdensome. One commenter stated that functionality such as a patient portal would be handled through normal browser HTTPS functionality and, therefore, should be easily managed through a visual inspection and should not require additional verification. One commenter supported secure messaging in general, but did not support secure email as the only secure messaging methodology. The commenter indicated that they currently send patients an unsecure email prompt that they have a message and that upon receipt the patient can securely log-in to their patient portal using an SSL-protected session to retrieve the message and send new ones.

Response. We share commenters' sentiment that this certification criterion needs to permit/accommodate a range of possible innovative options. To that end, we intentionally proposed this certification criterion to only specify the particular baseline security and functional capabilities we believed were necessary to require for certification. So long as the method included with EHR technology presented for certification can meet these baseline requirements it would be able to meet this certification criterion. Thus, secure email, a secure portal, even some type of mobile application could all be examples for secure messaging methods that could potentially meet this certification criterion. Along those lines, we decline to specify or restrict certification in this case to a particular transport standard because, again, we intend to permit a wide range of different secure messaging solutions, that will likely use different approaches and transport standards.

In consideration of these comments and the ones responded to below, we are finalizing this certification criterion as proposed with one exception. The only modification we have made is to explicitly note as we already have in the view, download, and transmit to a 3rd party certification criterion that it could be the patient or their authorized representative that engages in secure messaging.

Comment. A commenter stated that patients must be able to directly communicate with health professionals via patient portals and OAuth.

Response. We decline to incorporate this suggestion into the certification criterion because it would be

unnecessarily limiting. Our response, however, is not meant to preclude this type of functionality from being used to satisfy this certification criterion.

Comment. A commenter questioned how the capability to receive a secure message from a patient would be tested and what we intended to be certified. They asked whether it was a provider application that would be used to send and receive secure messages or a consumer application to do the same; or both. Further, the commenter stated that an EHR technology developer presenting EHR technology for certification may not have a patient portal or PHR technology from which to demonstrate the sending of a message to the EHR technology and that testing using a public email service is likely not to meet the FIPS 140–2 Annex A requirement for encryption. The commenter also indicated that the certification criterion presumes the EHR technology developer has a technology to support the consumer and that the EHR technology developer must have both abilities (send and receive) within its span of control to be able to present technology for certification. Ultimately, the commenter suggested that either the provider requirement to send a message be removed or that this be split into two criteria. They reasoned that from a measurement perspective, only the ''receive'' from the provider perspective is required by the Stage 2 proposed rule for the associated objective, and the measurement numerator is based on a consumer perspective and the vendor having access to event data that may only be available in a portal or similar consumer application. As an alternative to certifying send and receive as two distinct criterion (or even as a single criterion to help EHR technology developers who may only automate provider or consumer messaging), the commenter suggested that ONC consider working with NIST to provide a test harness for vendors to certify with to prove messages are successfully sent and received.

Response. The EHR technology that enables secure messages to be exchanged is what would be required to be tested and certified. Thus, whatever would be necessary for a patient to communicate with an EP (and vice versa) would need to be demonstrated for testing and certification. We do not believe that separating the capability for communication by send and receive would add any significant value or provide any additional benefit because it is the capability as a whole (to send and receive secure messages) that needs to be demonstrated for testing and certification in order for EPs to have assurance that EHR technology can enable bidirectional communication. We thank the commenter for the recommendation to work with NIST to develop testing methods that ensure messages can be successfully sent and received. We will take this recommendation under consideration in discussions with NIST and when approving a test procedure for this certification criterion. Finally, we note that to keep the final rule as current as possible at the time of publication, we have referenced the May 30, 2012 version of Annex A. The May 30, 2012 version replaces the version we adopted in the S&CC July 2010 final rule and is the only readily accessible version available. Further, NIST has included additional reference guidance for the AES standard as well as updated references to other FIPS publications that have been updated, such as changing the reference to FIPS 180–3 to FIPS 180–4.

Comments. One commenter supported the proposed certification criterion but requested clarification on the reference to the standard, which they noted is a collection of many standards in several categories. They asked if we could clarify which specific parts of FIPS Annex A are applicable to secure messaging. In addition, the commenter asked how the additional guidance we provided in the preamble related to the standard we proposed to adopt. They requested clarification as to whether we intended to say ''FIPS 140–2 Annex A plus TLS 1.0 and SMTP/SMIME and * * *.'' or whether something else was intended.

Response. As noted in the standard proposed just the encryption and hashing algorithms are in scope. Random number generator standards would not necessarily be within scope. The other guidance we referenced in the Proposed Rule is just that. It was not intended to be part of the standard as questioned by the commenter.

Comment. One commenter recommended that we discourage the use of or remove the allowance for 3DES as the encryption algorithm is on track to be deprecated by NIST in the near future.

Response. We agree, please see our response to similar comments in the ''end-user device encryption'' certification criterion.

Comment. One commenter recommended that we investigate evolving secure email and other supporting technologies to protect and verify transactions that include personally identifiable health information. They noted that current Direct Project guidance requires the use of organizational PKI certificates for which the FBCA does not include a profile in its certificate policy. They stated that certificates cited in the Direct project documentation also suggest that the encryption, digital signature and non-repudiation bits all be turned on and that this requirement is an unacceptable practice under the terms of RFC 3647. They concluded by recommending that federally approved NIST LOA 3, 2-factor credentials for patients to authenticate to secure email and or/or portals should be used to fulfill this requirement.

Response. At this point, we decline to include such a specific requirement as part of this certification criterion. As the industry gains more experience with different secure messaging approaches, we will consider whether additional specificity such as this is necessary.

Comments. A few commenters stated that because CMS' proposed rule left it to the provider to determine the ''relevance'' of information, the capability to assess or document relevance should not be in the automated measure calculation certification criterion nor be part of this certification criterion.

Response. Certification does not address the relevance of the information that is part of a secure message. Please see CMS's discussion related to secure messaging in the Stage 2 final rule published elsewhere in this issue of the **Federal Register**.

• *Cancer Case Information; and Transmission to Cancer Registries*

MU Objective
Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.
2014 Edition EHR Certification Criteria
§ 170.314(f)(5) (Optional—ambulatory setting only—cancer case information).
§ 170.314(f)(6) (Optional—ambulatory setting only—transmission to cancer registries).

We proposed to adopt two new 2014 Edition EHR certification criteria to support a new proposed MU objective and measure for reporting cancer cases to cancer registries. One certification criterion focused on the capability to electronically record, change, and access cancer care information (data capture) and the other certification criterion focused on the capability to electronically create cancer case information for electronic transmission in accordance with specified standards. Following consultation with the Centers for Disease Control and Prevention (CDC), we proposed to adopt HL7 CDA,

Release 2 as the content exchange standard. Additionally, we proposed to adopt the Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012. We stated in the Proposed Rule that the CDC would consider comments received on the Proposed Rule in finalizing the guide. We also stated that if the CDC finalized the guide, we would consider adopting the final version of the guide in this final rule with consideration of public comment received on the appropriateness of the guide for certification. Last, we proposed to adopt SNOMED CT® International Release January 2012 and LOINC® version 2.38 as applicable vocabulary standards.

Comments. Commenters expressed strong support for the proposed certification criteria. Many of the commenters that supported the certification criteria stated that they believed this requirement would increase cancer reporting and improve it in various ways, including improving the timeliness, efficiency, completeness, and quality of the data reported as well as reducing the reporting burden on ambulatory providers.

While many commenters supported the proposed certification criteria, many also requested that the certification criteria be designated ''optional'' for Complete EHR certification. The commenters requesting that the certification criteria be designated optional claimed that the certification criteria would only be relevant to a small number of providers who report to cancer registries. Further, they contended that the capability would be inappropriate for inclusion in EHR technologies that are not focused on meeting the needs of EPs who will report to cancer registries, since some of the cancer case information data utilizes extensive cancer-specific, specialized fields and vocabularies (e.g., NAACCR data standards) that are not typically captured in EHRs beyond those specifically marketed as oncology specialty products. A couple of commenters noted that few, if any, EHR technology developers provide this functionality, and most applications that are used for this purpose are not likely to meet the standard cited in the Proposed Rule. A few other commenters stated that this requirement is burdensome and should not be required.

Response. We appreciate the support expressed by commenters. We also agree with commenters that it is appropriate to designate these certification criteria as optional. By designating the certification criteria as optional, EHR technology would not need to be certified to these certification criteria in order to satisfy the Complete EHR definition. The optional designation will permit EHR technology developers that support EPs intending to report on the associated MU menu objective and measure to still get certified to these certification criteria, but will alleviate the requirement that all Complete EHRs be certified to these certification criteria. Designating these certification criteria as optional will mitigate any perceived unnecessary costs and burden mentioned by commenters. To clarify for MU purposes, if an EP seeks to meet the associated MU objective and measure, they will need EHR technology certified to these certification criteria, including the adopted standards and implementation guide, in order to have EHR technology that meets the CEHRT definition.

Comments. Many commenters supported the adoption of the proposed HL7 CDA, Release 2 and Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012 for registry reporting, stating that they had widespread support from the CDC and cancer registry community. A few of these commenters specifically stated that public health central cancer registries have been operational for many years and the cancer registry community has been preparing for the transition to CDA for some time. Commenters noted that cancer reporting in most jurisdictions requires industry and occupation information and stated that EHR technology certification to support cancer reporting by EPs would facilitate their compliance with applicable law and improve the quality and completeness of cancer reporting. One commenter recommended that cancer laboratory results reporting be included in addition to cancer case reporting.

Many commenters also pointed out that the implementation guide was still in draft format and suggested that it should be finalized before being adopted. A few commenters contended that it was premature to adopt the proposed standard and implementation guide as a basis for certification, stating that the standard was not in widespread use for reporting cancer events to registries from EHRs. One commenter stated that the proposed implementation guide is not harmonized with the Consolidated CDA guide and that harmonization should be completed before we adopted the implementation guide. A commenter stated that centralized cancer registries receive batch reports containing large numbers of cases and that the cancer-related information required by the cancer registries is dense in its level of detail. Therefore, the commenter was concerned that the CDA standard may not provide the necessary content framework or the processing efficiency necessary to transmit and receive complex, bulk data.

A commenter requested that the minimum data elements required for the transmission of cancer case information be explicitly and clearly stated. Another commenter noted concerns that the implementation guide has requirements for structured data capture for social history that may not reflect widespread current practice and, thus, represents a change in practice for EPs. Other commenters stated that there is potential for confusion in coding ''occupation'' and ''industry'' because there is a discrepancy between description and language in the implementation guide and the descriptions for the corresponding LOINC® codes. A commenter suggested that the implementation guide needed values for cancer staging variables that allow for ''not staged'' or ''unknown.'' The commenter stated that for every required field (R), the value sets should be double checked to make sure that there is a ''none'' or ''unknown'' option or the EP's EHR will not have a value all the time.

Response. The implementation guide was jointly developed by the CDC and the North American Association of Central Cancer Registries (NAACCR). It is based on many years of harmonized cancer registry reporting across the country. The finalized implementation guide, Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, Release 1, August 2012, reflects the comments received on the draft and clarifies ambiguities such as minimum data elements required and vocabularies for occupation, stage, and other data elements where none/unknown should be an option. In particular, the use of HL7 null flavor is better described such that it may be used where appropriate to indicate lack of information and clarifications were made to the use case scenarios in response to questions about workflow and triggers. While this implementation guide is based on the CDA, the guide was revised in some aspects to harmonize it with the recently developed Consolidated CDA. The implementation guide was revised to take advantage of the document format used by the Consolidated CDA, including the formatting of the data element tables and conformance statements. The new consensus conformance verbs used in Consolidated

CDA (i.e., shall, should, may, and should not) were also adopted in the implementation guide to clarify the optionality of data elements. These improvements resolve the ambiguity on required data elements and vocabularies. Overall, the revisions to the draft implementation guide that have been incorporated into the final (Release 1) improve the ability to test and certify EHR technology to the implementation guide and make it easier for EHR technology developers to implement the guide's requirements based on the corrections and clarifications. Accordingly, we have adopted Release 1 of the implementation guide for the ''transmission to cancer registries'' certification criterion.

Comments. Commenters generally supported the use of SNOMED CT® and LOINC®. One commenter recommended the use of ICD–9–CM and ICD–10–CM as well since many physician practices work with and are familiar with these standards. Another commenter acknowledged that SNOMED CT® and LOINC® are valuable for much of the required content, but believed the context of data is not necessarily included in these code systems. The commenter further noted additional data requirements (e.g., medications) which will require RxNorm, allergy data (medication in RxNorm, reaction in SNOMED CT®), procedures performed, and patient characteristics to which other sections of this report refer. One commenter stated that for dental systems the HL7 CDA and SNODENT should be required.

Response. We appreciate the support commenters indicated for SNOMED CT® and LOINC® and have adopted them as vocabulary standards for this certification criterion. We acknowledge that the implementation guide references other vocabulary standards, but believe that the vocabulary standards we have adopted in this final rule are the most important to focus on in support of cancer case reporting. We decline to adopt SNODENT for the ''transmission to cancer registries'' certification criterion for the same reasons we gave when we declined to adopt it for the ''problem list'' certification criterion in this preamble (section III.A.9.a).

Comments. Commenters noted that both SNOMED CT® and LOINC® code sets are updated regularly. Therefore, for the purposes of certification, commenters recommended that we adopt these standards in regulation as ''SNOMED CT®—current international release'' and ''LOINC®—current release.'' Commenters also recommended that we simply state in regulation that EHR technology can be certified to the most recent version of the implementation guide, which would acknowledge the evolving nature of implementation specifications.

Response. We have established a process for adopting certain vocabulary standards, including SNOMED CT® and LOINC®, which permits the use of newer versions of those standards than the one adopted in regulation. We refer readers to section IV.B for a discussion of ''minimum standards'' code sets and our new more flexible approach for their use in certification and upgrading certified Complete EHRs and certified EHR Modules. Readers should also review § 170.555, which specifies the certification processes for ''minimum standards'' code sets. In response to the commenters' suggestion that we permit the use of the ''most recent version'' of the implementation guide for certification, we refer the commenters to section III.A.5 found earlier in this preamble. This section explains why we cannot take such an approach.

Comments. A commenter recommended that CMS develop a common national data submission standard in order to limit the burden on providers and vendors operating in multiple states and therefore connecting to multiple registries and other public health organizations.

Response. We do not believe this comment fits within the scope of the proposed certification criteria. We note, however, that for all public health reporting, CDC is co-leading (with ONC) the efforts of the S&I Framework Public Health Reporting Initiative to harmonize data elements, vocabularies, and format across public health diseases and conditions. The cancer registry community is an active participant in this initiative. For cancer reporting, CDC, NCI SEER, and NAACCR have worked closely with public health cancer registries to establish a single data submission standard, which is already reflected in the implementation guide.

Comments. A couple of commenters suggested that we make clear that the state cancer registry, as it is used in the MU objective, may be operated directly by a Public Health Authority (PHA) or under contract or other delegation agreement with a designated entity, such as a university. In either case, they stated that the cancer registry is a part of the PHA and EPs should report to it if they choose this Menu objective. A few commenters recommended changing ''state cancer registry'' to ''public health central cancer registries'' to clearly distinguish from hospital-based cancer registries which they asserted should not satisfy MU requirements.

Commenters also requested clarification and guidance. A commenter requested clarification on what constituted an acceptable registry. Another commenter noted that specialized disease registries are often proprietary and require special consideration for use and suggested that we, therefore, make a distinction for the support of an open and public specialized disease registry. One commenter requested clarification as to whether the reporting institution is responsible for creating report events for residents outside of its respective state. A couple of commenters requested clarification on ''in accordance with applicable law'' and further explanation on ''except where prohibited.'' Another commenter requested clarification regarding whether state-specific requirements pertain to the state the provider is in, or to the state the patient resides in. One commenter requested guidance on meeting this objective due to new reporting methodology being created and the readiness of registries to adopt the proposed HL7 CDA standard.

Response. We appreciate the submission of these comments, but they are outside the scope of this rulemaking. This final rule does not create or modify any obligations or choices of EPs to report to disease registries or the operations of those registries. It seeks only to facilitate such reporting through CEHRT. We direct commenters to the Stage 2 final rule found elsewhere in this issue of the **Federal Register** for a discussion of the MU objective and measure and a response to these comments.

c. Inpatient Setting

We propose to adopt 3 certification criteria that would be new certification criteria for the inpatient setting.

• *Electronic Medication Administration Record*

MU Objective
Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).
2014 Edition EHR Certification Criterion
§ 170.314(a)(16) (Inpatient setting only—electronic medication administration record).

We proposed to adopt a new ''eMAR'' certification criterion with the inclusion of the ''synchronized clocks'' standard. We made this proposal based on the recommendation of the HITSC for a new 2014 Edition EHR certification criterion

to support the MU objective and measure to automatically track medications from order to administration. In our proposal, consistent with the intent of the HITSC and HITPC, we emphasized that EHR technology certified to this certification criterion must enable a user to electronically confirm the ''rights'' (i.e., right patient, right medication, right dose, right route, and right time) in relation to the medication(s) to be administered in combination with an assistive technology (e.g., bar-coding, location tracking, and radio-frequency identification (RFID)) which provides automated information on the ''rights.'' We also noted that an electronic ''checklist'' through which a user would manually confirm the ''rights'' without any automated and assistive feedback from EHR technology would be insufficient to demonstrate compliance with this certification criterion.

Comments. Commenters requested clarification on the definition of ''assistive technology.'' One suggested that we should not define assistive technology as barcode scanning, RFID or any other technology solution. Another asked whether it could be a nurse at the bedside recording medication on a handheld device such as a smart phone or tablet; a bedside computer; or if it needed to be a barcode scanner that scans the patient, the medication, and automatically records the time. A few comments noted that if there is a future requirement to progress towards RFID, advance notice would be appropriate because they consider all technologies currently acceptable, including various bar code formats.

Response. We have purposefully framed this certification criterion to leave open a range of different technologies that could be used to demonstrate compliance with the certification criterion. We do not intend to single out only one particular technology that would meet this certification criterion. We interpret ''assistive technology'' to be a technological solution that when paired with EHR technology automates the comparative aspects of the five rights that a user would otherwise have to manually complete.

Comment. A commenter requested clarification on whether ''electronically'' recording the time, date, and user ID at the time of administration is a function automatically performed by the system, or whether allowing a user to manually enter this data is sufficient.

Response. We intend for this information to be automatically and simultaneously recorded with the use of the assistive technology. A manual entry feature for emergency/unanticipated circumstances is not prohibited by this certification criterion from existing, but would not alone allow for EHR technology to meet this certification criterion.

Comments. A few comments indicated support for the clarification we issued in the Proposed Rule that ''automated'' tracking not simply be a presentation of an electronic ''checklist'' to an end user, but that it provide for electronic confirmation of the results of an automated tracking event such as to scan a patient wrist band or a medication bar code to match the right medication for the right patient. Commenters suggested that we offer some additional guidance to make it clear that the assistive technology used to automate the five rights should not be a substitute for clinical judgment and that automated does not mean to imply no user confirmatory action. They suggested that we clarify that medication administration would include at least a confirmatory step for an end user to validate the outcome of an automated check before proceeding. They stated that just as manual work steps can lead to error, automated tracking should not be relied upon absent a human element to confirm (and take responsibility for) the outcome. The commenter suggested that we strengthen the language in the certification criterion to highlight that ''automated'' also requires some type of user confirmatory action.

A couple of commenters asked whether ''automated'' means that all ''five rights'' are based on some automated method or if some manual interaction is still allowed such as patient selection, signing the administration event, performing witnessing if required for patient identification as completed and other steps that still may depend on user interaction to make an entry into the system. A commenter requested clarification on the role of the assistive technology with the care provider in ''providing information'' on the ''rights.''

Several commenters requested that we clarify the meaning of ''electronically verify'' in the certification criterion (or ''electronically confirm'' as we stated in the Proposed Rule's preamble). Additionally, commenters suggested that we specifically state that the EHR technology is not required to provide messaging to the user unless one of the ''rights'' is compromised in the medication administration process. Additionally, they stated that current systems typically do not message a user when all of the five rights are in compliance.

Response. We concur with commenters that the assistive technology used to automate the five rights should not be a substitute for clinical judgment. A professional clinical user is still responsible for his or her actions and should utilize the assistive technology to complement, not replace, his or her experience, training, and clinical judgment. Along those lines, we interpret ''electronically verify'' in the certification criterion to mean that upon the use of an assistive technology a user would be able to review and compare within the EHR technology the five rights information associated with the medication to be administered. By being able to verify this information, the user would be able to assess whether the five rights are correct and subsequently administer the medication with appropriate documentation. Consistent with the clarification requested by commenters, ''electronically verify'' does *not* require EHR technology to provide some type of explicit notification to a user if all of the five rights are correct. However, if one or more are incorrect, the EHR technology must provide some indication to a user which ''right(s)'' are incorrect/not within compliant parameters.

With respect to the automation expectations expressed by this certification criterion, yes, upon the use of an assistive technology, information about each of the rights would need to be automatically available for a user to verify. We acknowledge that there are other steps within the medication administration workflow for which user interaction with, and entries into, EHR technology may be necessary. This certification criterion is not meant to preclude those other steps nor are they within the current scope of this certification criterion.

In considering these comments, stakeholder interactions during the public comment period, and our own additional research, we would like to call to readers attention an error in the certification criterion with respect to the ''fifth right'' that we specified. Instead of specifying ''right time'' as it is commonly understood—to refer to the information about when the medication is to be administered relative to the current time—we specified ''right time'' in the proposed certification criterion as what is commonly understood to mean ''right documentation.'' In light of this oversight, and to ensure that the true ''five rights'' are included in this certification criterion, we have added in the correct description for ''right time''

into the certification criterion and revised the proposed capability to be called ''right documentation.'' This latter concept remains unchanged from our proposal and would require the EHR technology to record the time, date, and user identification when a medication is administered. We have finalized the eMAR certification criterion with the discussed revisions in § 170.314(a)(16) (the CFR paragraph was changed due to the combination of two other certification criteria).

Comment. A commenter requested clarification on how automation can determine the ''right route.'' They contended that technology can determine the ordered route, and whether the medication can be delivered via that route, but only manual actions and manual documentation can provide evidence of the route administered.

Response. The automated aspect of this certification criterion is the provision of information associated with the medication to be administered; in other words, that the dosage form of the medication is appropriate to the ordered route. Thus, when an assistive technology is used, the information about the route of medication delivery would need to be automatically available for a user to verify.

• *Electronic Prescribing*

MU Objective
Generate and transmit permissible discharge prescriptions electronically (eRx).
2014 Edition EHR Certification Criterion
§ 170.314(b)(3) (Electronic prescribing).

We proposed to adopt for the inpatient setting the same revised electronic prescribing certification criterion that we proposed to adopt for the ambulatory setting (i.e., we proposed to adopt the certification criterion at § 170.314(b)(3) for both settings). We proposed to require the use of RxNorm as the vocabulary standard and NCPDP SCRIPT version 10.6 as the only content exchange standard for this certification criterion. In our discussion of this certification criterion for the ambulatory setting, we proposed to not include the NCPDP SCRIPT version 8.1 in the 2014 Edition EHR certification criterion. This proposal was premised on our understanding that CMS was planning to propose the retirement of NCPDP SCRIPT version 8.1 for the Medicare Part D e-prescribing program soon after our proposed rule was to be published. We noted that if we received information indicating a change in CMS' plans prior to the issuance of our final rule, we may, based also on public comment, retain this standard in a final revised certification criterion. We stated that we were proposing to adopt this certification criterion for both the ambulatory and inpatient settings because it supports our desired policy and interoperability outcome for content exchange standards to be used when information is exchanged between different legal entities.

Comments. Many commenters supported our proposal to require certification to NCPDP SCRIPT 10.6 for this certification criterion. Other commenters suggested that we should continue to permit certification to NCPDP SCRIPT 8.1 until it is officially retired from the Part D e-prescribing program by CMS.

Response. We appreciate commenters support for our proposal to require certification to NCPDP SCRIPT 10.6 and have finalized the certification criterion as proposed. We are not including NCPDP SCRIPT 8.1 in this certification criterion. CMS has recently proposed (77 FR 45022) to retire version 8.1 and only permit version 10.6 as of 11/1/2013. More importantly, NCPDP SCRIPT 10.6 is backwards compatible with version 8.1, so 10.6 users will be able to communicate with version 8.1 users. Therefore, even in the event that CMS does not retire version 8.1 before the FY/CY 2014 EHR reporting period, use of version 10.6 should not have an adverse impact on stakeholders. Moreover, we understand that version 10.6 includes much needed improvements and better supports stakeholders' e-prescribing needs across a variety of health care settings.

Comments. A number of commenters requested that we establish a deeming provision as part of our e-prescribing certification criterion that would make Surescripts certification for participation in its network an acceptable method to demonstrate compliance with this certification criterion. That is, in lieu of being certified by an ONC–ACB according to the adopted certification criterion and standards, EHR technology could be deemed to be certified to meet this certification criterion if it were certified according to Surescripts certification requirements.

Response. As we did not propose deeming authorities in the Proposed Rule, these suggestions are outside the scope of this final rule. Furthermore, we believe that the best way to ensure that EHR technology includes the capabilities specified by the certification criteria adopted by the Secretary is to require EHR technology to be tested and certified to these certification criteria under the provisions and procedures specified by the ONC HIT Certification Program.

Comments. Several commenters requested that we include HL7 v2.x standards for discharge e-prescribing. They reasoned that discharge prescriptions filled by a pharmacy within the walls of a hospital facility frequently use HL7 v2.x prescribing messages. Some commenters also stated that EHR technology certified to the HL7 v2.x standards for discharge e-prescribing should be permitted even in cases where the pharmacy inside the hospital facility may be a different legal entity from the source of the discharge medication. Commenters asserted that hospitals currently use HL7 transmissions to send their prescriptions to an onsite pharmacy that is a separate legal entity. Another commenter requested clarification as to whether NCPDP SCRIPT needed to be used by an EH/CAH to transmit electronic prescriptions for discharge medications that would be filled by that EH/CAH's hospital-based pharmacy, including when that pharmacy is a separate legal entity. Other commenters supported our approach of focusing on interoperability between different legal entities and not on transactions within a legal entity.

Response. We appreciate the support for our e-prescribing approach to certification. We continue to believe, as we stated in the Proposed Rule that it would be inappropriate and without sufficient benefit to require certification of EHR technology for transmissions that would be conducted within a single legal entity. We continue to believe, as we stated in the Proposed Rule (77 FR 13845), that doing so would be inconsistent with our approach of adopting standards for the electronic exchange of health information between different legal entities. We encourage commenters to read the Stage 2 proposed rule (77 FR 13710) because it discusses the various ways in which the e-prescribing MU objectives can be met such that it should address the concerns expressed by these comments. We also encourage commenters that indicated that HL7 transmissions were used even in situations where a pharmacy is considered a different legal entity to carefully read the Medicare Part D e-prescribing rules at 42 CFR 423.160(a)(3)(iii) (noting that HL7 transmissions are only permitted when the sender and recipient are part of the same legal entity). In light of the Part D e-prescribing program bar on the use of HL7 between different legal entities, we are not considering allowing it in our certification criterion.

Comments. A commenter requested that we clarify what the use of RxNorm as the sole vocabulary would entail. The commenter asked whether RxNorm would be a drug description or a drug qualifier and urged ONC to reference RxNorm as a drug qualifier, specifically via the use of RxNorm concept unique identifiers (RXCUIs), similar to how NDC identifiers are currently being used. The commenter stated that since most EHR technologies use proprietary commercial drug databases for their clinical terminology needs, that there is a critical and urgent need for RxNorm RXCUI mappings to proprietary drug database codes to be made readily available to the industry by either drug database companies or a third party in order to foster the adoption of RxNorm.

Response. The use of RxNorm as the sole vocabulary standard would entail its use to represent medications within an electronic prescription formatted according to the SCRIPT 10.6 standard. We intend for the RxNorm concept unique identifiers (RXCUIs) to be used as drug qualifiers. Mappings are not something within the scope of this rulemaking and we decline to make any changes in response to this comment.

Comments. Many commenters agreed with our proposal to adopt RxNorm, but requested certain clarifications. These commenters noted that not all medications in source vocabularies have an equivalent RxNorm code. Further, they suggested that the standard should state that the RxNorm vocabulary will be utilized when there is an equivalent concept mapping. Others requested clarification that the reference to RxNorm means that RxNorm codes must be included in transmitted messages, not that only RxNorm codes can be transmitted because there are some prescriptions that do not have corresponding RxNorm codes and will require other code sets. A commenter expanded on these concerns with the following observation: Some drug descriptions in RxNorm are over 105 characters in length, but the NCPDP SCRIPT standard limits drug descriptions to 105 characters, which means that transmission of some e-prescriptions that include RxNorm drug descriptions would be either truncated or not possible. As such, they suggested that certification criteria for RxNorm should be limited to use of this standard for drug qualifiers only. They also cautioned that RxNorm is not yet a complete drug compendium, and that RxNorm qualifiers are not available for all prescriptions that are currently sent electronically (e.g., medical supplies). Similar to other commenters, they also suggested that we clarify that the transition to the certification criterion would not preclude use of other drug databases and qualifiers if circumstances require it.

Response. We acknowledge that all medications may not yet have an equivalent RxNorm code. We do not believe it is necessary to modify the standard to explicitly state that RxNorm ''be utilized when there is an equivalent concept mapping'' because certification is meant to verify that EHR technology can properly use this standard. This certification criterion requires the capability to use RxNorm, specifically RXCUIs as noted in our prior response. Thus, where no RxNorm code exists, nothing prohibits another code from being used. However, where corresponding RxNorm codes exist, EHR technology must be able to use those codes. As RxNorm continues to expand, we expect that the concerns raised by commenters about its comprehensiveness will subside.

Comment. Commenters noted that the same e-prescribing certification criterion applies to both ambulatory and inpatient settings. They stated that it would be important for the final rule and subsequently developed test procedures to identify any differences between the two settings.

Response. With the exception of which test data elements might be required, this certification criterion applies equally to both settings. EHR technology certified to this certification criterion will need to enable a user to electronically create prescriptions and prescription-related information in accordance with NCPDP SCRIPT 10.6 and RxNorm.

Comment. A commenter stated that there needs to be a clear way to differentiate whether a prescription is merely sent ''in house'' (scenarios 1 and 2 in the Stage 2 proposed rule or ''transmitted'' (scenario 3)).

Response. Given the flexibility provided by CMS, we believe this will need to be determined on an implementation-by-implementation basis and would be difficult to assess for the purpose of certification in a simulated testing laboratory environment.

Comment. A commenter recommended that EHR technologies support integration with HIEs in support of the e-prescribing process.

Response. This suggestion is outside the scope of our final rule. We appreciate the commenter's feedback and will consider whether a certification criterion to address this type of capability would be appropriate for a future rulemaking.

Comments. A few commenters discussed the electronic prescribing of controlled substances. Some encouraged ONC and CMS to work to include controlled substances into future meaningful use measures. Others agreed with CMS's proposal to continue to exclude controlled substances from the e-prescribing objectives and asked that we make clear that the electronic prescribing of controlled substances (EPCS) is not required (and will not be tested) from a certification standpoint. They noted that e-prescribing of controlled substances involves many other workflow requirements for prescription review and acknowledgment, technical requirements for electronic signature and security of the transmitted prescription that go well beyond the scope of what was proposed. One commenter stated that adopting NCPDP SCRIPT version 10.6 without also mandating e-prescribing of controlled substances is contradictory and will create unnecessary costs and undesirable results due to the lack of synchronization. They contended that NCPDP SCRIPT version 10.6 should not be required for certification because it will slow the progress being made by the industry as stakeholders are coupling their development efforts for NCPDP SCRIPT version 10.6 and e-prescribing of controlled substances together. Last, a commenter suggested that we should require that EHR technology that includes e-prescribing capabilities to be implemented according to the recently released DEA requirements for all e-prescribing.

Response. While we intend to continue to work with CMS on the issue of controlled substance e-prescribing, we believe it is premature to include controlled substances in the 2014 edition of the certification requirements. We will need to carefully evaluate the practicality of what would amount to duplicating DEA's regulatory requirements for certification in our regulations and the potential unintended consequences of taking such a step. Furthermore if we were to adopt some or all of the provisions in the DEA's interim final rule in our program and, if DEA were to make any changes as it finalizes its interim final rule, our adopted certification criteria would be out of compliance with DEA's requirements. Further, DEA permits a certification option in its interim final rule and has approved at least one certification body's processes to perform certifications for EPCS. Thus, we question the value in ONC replicating these already established processes.

Finally, we do not see how the adoption of NCPDP SCRIPT 10.6 without mandating EPCS could be contradictory. They are both separate and distinct regulatory requirements and one does not necessarily depend on the other to succeed.

Comment. A commenter recommended that we revise the certification criterion as follows, ''generate and transmit permissible discharge prescriptions electronically.''

Response. We do not believe that this editorial suggestion adds any tangible value or clarifies the wording in the certification criterion in a major way. Thus, we decline to modify this certification criterion in response to this suggestion.

Comment. A commenter recommended that we include a capability in the certification criterion that ensures a provider is actively alerted when an e-prescription fails.

Response. This suggested capability is beyond the scope of the proposed certification criterion and we decline to modify the certification criterion. We will consider whether such a requirement would be appropriate to include in later editions of EHR certification criteria.

Comment. A commenter recommended that there be a way for patients to review e-prescriptions and participate in medication reconciliation with both their doctors and pharmacists via a patient portal.

Response. This suggested capability is beyond the scope of the proposed certification criterion and we decline to modify the certification criterion. We will consider whether such a requirement would be appropriate to include in later editions of EHR certification criteria.

Comment. A commenter stated that they would like standards and testing to demonstrate using e-prescribing for refills that allows multiple medications to be refilled from a single screen through a single transaction. They explained that for some EHR technologies the refill process is more problematic than the initial prescription process and that certification should ensure this is not the case.

Response. We do not believe that this is an issue that can be readily addressed through certification. Rather, this comment appears to focus on a particular user interface and workflow design shortcomings of certain EHR technology. This aspect is outside the scope of what is required by this certification criterion.

• *Transmission of Electronic Laboratory Tests and Values/Results to Ambulatory Providers*

MU Objective
Provide structured electronic laboratory results to eligible professionals.
2014 Edition EHR Certification Criterion
§ 170.314(b)(6) (Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers).

We proposed a certification criterion that was similar to the one recommended by the HITSC to support the MU objective and measure recommended by the HITPC for EHs and CAHs to send electronic laboratory tests and values/results to EPs. CMS did not specifically propose the HITPC recommended MU objective and measure for Stage 2, but requested public comment on whether the objective and measure should be incorporated into MU Stage 2.

We proposed to include in the certification criterion the standards and implementation specification recommended by the HITSC and HITPC for the transmission of laboratory tests and values/results. In particular, we referenced the work of the Standards and Interoperability Framework Laboratory Results Interface Initiative which focused on the identification of a consistent set of data content that would need to be exchanged when laboratory tests and values/results are electronically delivered. We proposed to include the HL7 2.5.1 standard and the HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Laboratory Results Interface, Release 1 (US Realm) (S&I Framework LRI). We proposed to adopt LOINC® version 2.38 as the vocabulary standard, at the recommendation of the HITPC and agreement of the HITSC. We noted that the LRI specification was undergoing HL7 balloting and that we would monitor its progress in relation to the publication of this final rule.

With respect to testing and certification for this certification criterion, we stated that, among other aspects, inpatient EHR technology would need to demonstrate its compliance with the ''Common Profile Component'' and other required profiles included within the LRI implementation guide. We also noted that we had proposed to adopt a revised certification criterion for the ambulatory setting that would require EHR technology to be capable of incorporating laboratory tests and values/results according to the standards and implementation specifications we proposed for this certification criterion.

In proposing this certification criterion, we stated that requiring inpatient EHR technology to be capable of creating for transmission laboratory tests and values/results formatted in accordance with the LRI specification could make it more cost effective for electronic laboratory results interfaces to be set up in an ambulatory setting (i.e., minimal additional configuration and little to no additional/custom mapping) and that the electronic exchange of laboratory tests and values/results would improve.

Comments. Many commenters supported this certification criterion. Some commenters stated that we should not adopt this certification criterion without CMS establishing a corresponding MU objective and measure, while other commenters did not support this certification criterion for concerns related to implementation costs, the proposed standards, and the inclusion of this functionality in EHR technology.

Response. We are adopting this certification criterion for the 2014 Edition EHR certification criteria at § 170.314(b)(6). After consideration of public comments, CMS has included a corresponding objective and measure in the MU Stage 2 menu set and the adoption of this certification criterion will support that objective and measure. We discuss our responses to the other commenters' concerns in our responses below.

Comments. Commenters recommended that the transmission of electronic laboratory tests and values/results from inpatient EHR technology should follow the same standard that applies to the incorporation of laboratory tests and values/results in ambulatory EHR technology. Some of these commenters stated that this certification criterion should not be adopted without ambulatory EHR technology having the same requirements.

Response. We agree with commenters. We proposed and have adopted in the ''incorporate laboratory tests and values/results'' certification criterion (§ 170.314(b)(5)) a requirement that EHR technology designed for the ambulatory setting must be certified to be able to receive and incorporate laboratory tests and values/results in accordance with the LRI specification. The certification criterion discussed here, and which is applicable to inpatient EHR technology, requires that such EHR technology be able to create laboratory test reports in the same manner.

Comments. Many commenters supported the proposed standards and implementation guide. Other commenters stated that while the S&I Framework LRI is based on previously

used standards, it is not in widespread production and may not be sufficiently mature for nationwide use. A few commenters noted that pilots currently in process were using the LRI specification. One commenter stated that the LRI specification was developed for the types of tests commonly ordered in the ambulatory setting and does not address electronic messaging of complex test results such as molecular genetics, anatomic pathology, and cytology. The commenter contended that messaging for these test results needs further development and testing before they can be included in routine electronic messaging transmission of laboratory results from hospitals to ambulatory providers. Therefore, the commenter recommended postponing inclusion of the LRI specification until the next edition of certification criteria.

Response. We believe that the S&I Framework LRI implementation guide is mature enough for adoption and inclusion in this certification criterion. As we noted above and in the Proposed Rule, the LRI implementation guide has been undergoing balloting by HL7. The LRI implementation guide was approved by HL7 as a Draft Standard for Trial Use (DSTU) in July 2012. This confirms its adoption as a consensus-based standard ready for use. This DSTU version of the standard updates the version we proposed by correcting errors and clarifying requirements. These corrections and clarifications will assist EHR technology developers in implementing the standard and will improve testing to the standard. As noted by HL7 in its documentation, this DSTU version of the standard will be open for comment for 24 months and following this evaluation period, it will be revised as necessary and then submitted to ANSI for approval as an American National Standard (normative standard). Further, HL7 specifies that implementation of this DSTU version will be valid during the ANSI approval process and ''for up to six months after publication'' of the normative standard. Given the state at which this DSTU version of the standard is and the fact that this version alone is subject to the evaluation period, we believe that it is the best possible choice for this final rule, especially in place of the draft version we referenced in the Proposed Rule. Accordingly, we have adopted this version of the LRI implementation guide for requiring the electronic creation of laboratory tests and values/results for electronic transmission and to support the associated MU objective and measure.

As we acknowledged in a response to a comment on the revised ''incorporate laboratory tests and values/results'' certification criterion (§ 170.314(b)(5)), we erred in referencing the HL7 2.5.1 standard in addition to the LRI specification. Thus, we have removed the reference to the HL7 2.5.1 standard in this certification criterion. We also clarify that with the exception of the baseline minimum version of LOINC® that must be supported by EHR technology, we expect, in adopting this specification that it will be followed and implemented as authored.

Comments. Some commenters agreed that this certification requirement could potentially lead to reduced costs for laboratory interfaces, while other commenters thought it was unlikely to reduce costs. Commenters stated that lab system vendors are not necessarily bound to conform to the LRI specification which would create an undesirable situation where EHRs would be forced to provide conforming and non-conforming interfaces (one set to comply with certification and the other to be used for communication with lab systems). Commenter also stated that laboratory information systems (LIS) typically produce the reportable results. Commenters stated that these systems are not normally integrated with the hospital EHR. Rather these systems send lab results directly to the ordering physicians based on rules defined by CLIA (Clinical Laboratory Improvement Amendments) and are often further refined by state regulation.

Commenters noted that this certification criterion may serve to open up the strong possibility that laboratory information systems (LISs) will become certified as EHR modules on a more regular basis, and may motivate some vendors to seek certification on that basis both for this criterion as well as the public health reporting of lab results (which some LIS vendors have already done).

Response. The MU objective and measure that this certification criterion supports is in the MU Stage 2 menu set. Based on the revised CEHRT definition, the final rule provides EHs and CAHs the regulatory flexibility to determine whether to adopt EHR technology certified to this certification criterion in order to meet this MU objective and measure. Further, as noted by some commenters, the relevant LIS capabilities could potentially be certified to this certification criterion, perhaps as an EHR Module, and used to meet the associated MU objective and measure. Considering these points, we do not believe this certification criterion creates any undue burden and, as agreed to by commenters, could facilitate more cost effective electronic laboratory results interfaces in the ambulatory setting.

Comments. Some commenters suggested we focus on a ''standard receiver'' or ''universal interface'' that could accept multiple types of results in one interface. These commenters stated that it is cost-prohibitive to providers to purchase different interfaces for each set of information received. Therefore, these commenters recommended that we permit the use of existing interfaces or postpone certification and/or MU requirements related to use of the LRI, while efforts are pursued towards a ''universal interface.''

Response. The adopted LRI specification for the ambulatory setting is intended to provide the desired interface uniformity commenters have noted for the receipt of laboratory test results. We believe this standard is appropriate and mature for the purposes of EHR technology certification. As we have indicated in other responses in this final rule certification addresses the technical capabilities that EHR technology must include. It does not address how it must be used, once certified. Therefore, we do not agree with the comment that we should postpone adoption of this certification criterion until a ''universal interface'' is developed. In the Stage 2 final rule published elsewhere in this edition of the **Federal Register**, CMS specifies the requirements and flexibilities related to the incorporation of laboratory test results.

Comments. Commenters supported the adoption of the LOINC® standard for transmitting laboratory test results. Commenters stated, however the full LOINC® coding of all tests and analytes is unnecessary. Rather, the commenters stated that the subset that accounts for most frequent ambulatory use and alignment with quality measures and public health requirements should be the requirement.

Response. To meet this certification criterion, EHR technology must meet the LRI specification using LOINC®. For the purposes of testing and certification, we expect that EHR technology will be evaluated based on its ability to use most commonly reported LOINC® codes. We expect that the test procedure developed for this certification criterion will leverage LOINC® materials published by the Regenstrief Institute and available through the National Library Medicine,[16] which in this case

[16] *http://www.nlm.nih.gov/healthit/meaningful_use.html*—click on helpful subsets under the LOINC heading.

would be the ''LOINC® Top 2000+ Lab Observations and Mapper's Guide.'' This guide is an empirically-based list of the most common LOINC® result codes for laboratories, practices, researchers, and others who wish to map their laboratory test codes to universal LOINC® codes. This list contains over 2000 of the most commonly reported LOINC® codes that represent about 98% of the test volume carried by three large organizations that mapped all of their laboratory tests to LOINC® codes. We believe this scope for testing and certification will help aid EHR technology developers and focus development efforts toward these top 2000+ codes first.

Comments. Commenters suggested that we simply state in regulation that EHR technology can be certified to the most recent versions of LOINC®.

Response. We have established a process for adopting certain vocabulary standards, including LOINC®, which permits the use of newer versions of those standards than the one adopted in regulation. We refer readers to section IV.B for a discussion of ''minimum standards'' code sets and our new more flexible approach for their use in certification and upgrading certified Complete EHRs and certified EHR Modules. Readers should also review § 170.555, which specifies the certification processes for ''minimum standards'' code sets.

Comment. A commenter requested a list of CPT codes that define imaging studies and a listing of CPT codes that define a laboratory test.

Response. The commenter did not provide any supporting rationale as to why a list of CPT codes would be relevant to the capabilities expressed by this certification criterion. Thus, we decline to provide any additional information.

Comments. A commenter recommended inclusion of a date/time stamp on all values sent to ambulatory providers.

Response. The LRI specification's message header includes a required date/time stamp and the result segment (OBX) includes a test performed date/time stamp that is required if it exists.

Comments. A commenter suggested that NwHIN query-and-response protocol be required for use in sharing laboratory test results as part of this certification criterion. The commenter stated that such a requirement would encourage EHR technology developers to use the NwHIN protocol to have providers in different care settings access clinical information, including laboratory tests.

Response. We appreciate the commenter's suggestion, but did not propose specific transport approaches to require for certification and intend to focus certification on the proper implementation of the LRI specification.

Comments. Commenters requested clarification about to whom the transmission may occur, whether directly to EPs or through an HIE structure.

Response. This certification criterion focuses on the proper implementation of the LRI specification. How or by what means the laboratory test report gets to an EP is not currently within the scope the certification criterion and, in part, is likely dictated by other regulatory requirements, such as the CLIA rules.

Comments. A few commenters suggested that ONC work with CMS to encourage laboratories to adopt and use the S&I Framework LRI specification. They contended that without the ''source systems'' on board that requiring capabilities on receiving systems (EHR technology) would fall short of the intended purpose of reducing development time and costs and improving quality.

Response. We appreciate these comments and will continue to work with our sister agencies in HHS to advance health IT policy in other programs and regulations that affect stakeholders that are not eligible to receive EHR incentive payments.

Comment. A commenter stated that patients should also have access to all laboratory tests and results immediately, both inpatient and ambulatory, as a matter of patient safety.

Response. We appreciate this comment, but it is not something a capability in EHR technology, per se, can resolve. Through the EHR Incentive Programs, EPs, EHs, and CAHs, will have to provide online access to patients to view their electronic health information. This should provide a means for patients to get prompt access to their laboratory test results. We also note that CMS and OCR have engaged in rulemaking to permit patients to directly access their lab test reports (75 FR 56712).

10. Revised Certification Criteria

In the Proposed Rule, we described certification criteria that we considered ''revised.'' We noted the following factors that we would consider when determining whether a certification criterion is ''revised:''

- The certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion;
- The certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion; or
- The certification criterion was previously adopted as ''optional'' for a particular setting and is subsequently adopted as ''mandatory'' for that setting.

For clarity, we explained that, in some cases, a certification criterion could be both ''revised'' and ''new.'' For example, a previously adopted certification criterion could have been adopted for only the ambulatory setting. Subsequently, we could revise the certification criterion by adding a new capability and making it mandatory for both the ambulatory and inpatient settings. Once adopted, the certification criterion would be ''new'' for the inpatient setting and ''revised'' for the ambulatory setting.

Comments. We did not receive comments questioning our description of revised certification criteria.

Response. Given that we received no comments, we will continue to use this description of revised certification criteria to categorize the following certification criteria we have adopted as part of the 2014 Edition EHR certification criteria. We note that the following adopted revised certification criteria included certification criteria that were not only proposed as revised certification criteria, but also certification criteria that were proposed as unchanged certification criteria in the Proposed Rule.

a. Ambulatory and Inpatient Setting

We propose to adopt the following revised certification criteria for both the ambulatory and inpatient settings.

- *Vital signs, body mass index, and growth charts*

MU Objective
Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0–20 years, including BMI.
2014 Edition EHR Certification Criterion
§ 170.314(a)(4) (Vital signs, body mass index, and growth charts).

We proposed the ''vital signs, body mass index, and growth charts'' certification criterion (§ 170.314(a)(4)) of the 2014 Edition EHR certification criteria as an unchanged certification criterion. We proposed to replace the terms ''modify'' and ''retrieve'' with ''change'' and ''access,'' respectively. We also proposed to add the alternative term ''length'' to go with ''height'' as it

is the clinically appropriate term for newborns and assisted in clarifying the intent of the ''vital signs'' capability. The only other refinements that we proposed were for the plot and display growth charts capability. First, we proposed that this capability be designated ''optional'' within this certification criterion because some EPs, EHs, and CAHs would not (or would never) use such a capability due to scope of practice or other reasons. Thus, to reduce regulatory burden and to not require EHR technology developers to include a specific growth chart capability when they do not intend to market their EHR technology to EPs, EHs, or CAHs that would use such a capability, we proposed to designate growth charts as ''optional'' for certification. Second, we proposed to remove the age range reference (2–20 years old) from this capability. We noted that this proposed refinement was consistent with other certification criteria such as ''smoking status'' where the MU objective it supports specifies an age threshold (13), but the capability is not dependent on a patient's age.

Comments. Many commenters recommended that this certification criterion remain unchanged. A couple of commenters recommended the use of the LOINC® (for observations), SNOMED CT® (for qualitative results), and UCUM (for units of measure), as applicable, for the recording of the data elements specified in this certification criterion. One commenter recommended that requirements for specific data elements that would be included as part of vital signs data in MU Stage 2, such as ECG waveforms, be defined so that the appropriate device integration standards can be developed to support interoperability and certification standards and criteria for these important physiologic signals.

A commenter stated that the capability to plot and display growth charts should be a required capability and should be specified in more detail. Another commenter requested clarification on what type of growth charts were applicable based on age ranges. In particular, the commenter pointed to the World Health Organization for growth standards for children 0 to 2 years old and CDC growth charts for ages 2 and older.[17] Another commenter requested clarification that growth charts would not need to be included in a transition of care/referral summary formatted in accordance with the Consolidated CDA because they are not listed as a ''vital sign'' in the Consolidated CDA. Commenters also requested guidance on how the optional capability of plotting and displaying growth charts would be indicated in an EHR technology's certification and for marketing purposes.

Response. We thank commenters for generally supporting this certification criterion. We decline to revise this certification criterion in response to the comment that recommended we require EHR technology to natively record vital signs data in specific vocabularies. We did not propose this requirement and believe that the complexity of wholesale change to the data capture processes of existing EHR technologies for this purpose cannot be understated. Additionally, it is our understanding that many EHR technologies capture this information, but do not currently map it to standardized terminologies such as LOINC®—and there are currently many different workflows, templates, and forms that are used to capture this information. Thus, we believe that requiring vital signs data that is recorded to, for example, be mapped to LOINC® is too burdensome a requirement to impose for certification to the 2014 Edition EHR certification criteria. Moreover, our concern stems from the possibility that such a requirement could cause EHR technology developers to map vital signs capture to a standardized terminology in one workflow but perhaps not others—which would then cause providers to be forced to use a given workflow/form/template to achieve MU that is not consistent with optimal workflow/usability. We do intend, however, to require as part of the next edition of EHR certification criteria that EHR technology would need to be able to record all vital signs according to standardized terminologies. Further, we emphasize to EHR technology developers that nothing precludes you from taking this step for certification to the 2014 Edition EHR certification criteria.

Nonetheless, in response to these comments we evaluated the specificity and clarity of the certification criterion and believe that it needs to be revised. First, we believe the grammar in the certification criterion makes it more difficult than necessary to read. Second, while we have declined to revise this certification criterion in the way commenters suggested (that we require explicit recording of vital signs in standardized codes), we believe that an important, but modest, intermediate step must be taken to improve the certification criterion's specificity and its ability to affect patient safety. Accordingly, we have revised this certification criterion to explicitly state that the data recorded by EHR technology for height/length, weight, and blood pressure must be in numeric values only (i.e., alphabetic characters such as ''lbs,'' ''kg,'' or ''cm'' would not be permitted to included as part of the value recorded). This restriction has significant clinical and patient safety benefits because it prevents the inappropriate recording of text in fields that should be constrained to numeric values. Additional attributes that may be used to document (e.g., which arm a blood pressure is taken from, whether the patient is sitting or standing, or a reason that the value could not be obtained) should be recorded in a supplemental field rather than the field for the value itself. We expect that a significant majority of EHR technologies already function this way. Thus, we anticipate that this revision poses little, if any, practical burden to most EHR technology developers. However, in cases where this revised certification criterion will cause EHR technology to be updated for certification, we believe that better patient safety outweighs the burden.

With respect to the commenter's recommendation for defining and including data elements such as ECG waveforms as part of vital signs data in MU Stage 2, we note that this data element goes beyond the requirements of the associated MU objective and measure. Thus, we have not made any changes in response to this recommendation.

We do not believe that the capability to plot and electronically display growth charts should be a required capability because, as we noted in the Proposed Rule, not all EP, EHs, and CAHs will necessarily need this capability. For certification to this certification criterion, we clarify that EHR technology is not required to demonstrate the capability to provide growth charts based on subsets of age ranges within the 0–20 age range required by the MU objective. However, we encourage EHR technology developers to include the specificity that best addresses their customers' needs. We further clarify that the growth chart capability included in this certification criterion requires EHR technology to be capable of plotting and electronically displaying growth charts of patients. We do not expect growth charts to be transmitted in a transition of care/referral summary formatted in accordance with the Consolidated CDA. Last, we expect that certifications issued to EHR technology certified to this certification criterion will indicate

[17] *http://www.cdc.gov/growthcharts/who_charts.htm.*

whether the EHR technology is capable of plotting and electronically displaying growth charts and that such information would be accessible on the CHPL.

• *Drug-Formulary Checks*

MU Objective
Implement drug formulary checks.
2014 Edition EHR Certification Criterion
§ 170.314(a)(10) (Drug formulary checks).

We proposed the ''drug-formulary checks'' certification criterion (§ 170.314(a)(10)) of the 2014 Edition EHR certification criteria as an unchanged certification criterion.

Comments. Many commenters supported this certification criterion remaining unchanged for the 2014 Edition EHR certification criteria. A few commenters suggested that EHR technology developers who had completed Surescripts' Eligibility and Formulary certification could be permitted to attest to this certification criterion. Commenters recommended that EPs be able to obtain drug-formulary information that is accurate, in real-time, and includes the necessary details for the prescriber's review. One commenter recommended that we specifically include a capability in this certification criterion to capture the plan name, plan identification number, group identification number, and pharmacy benefit management care coverage in structured data. A couple of commenters recommended that we adopt the NCPDP Formulary and Benefit Standard Implementation Guide, Version 3.0, or alternatively, at a minimum, the NCPDP Formulary and Benefit Standard Implementation Guide, Version 1.0 as the standard to enable electronic formulary checking. A commenter suggested that we require EHR technology to be capable of making available all necessary formularies, which the commenter stated would help address situations where there is a lack of consistent access to Medicaid formularies, including Medicaid Managed Care formularies.

Response. We appreciate the support expressed for the certification criterion and the specific feedback commenters provided. In response to this feedback and clarifications issued by CMS in its final rule for the MU objectives and measures this certification criterion supports, we have determined that it is necessary to revise this certification criterion. The revised certification criterion is designed to ensure that a drug formulary check poses minimal burden on EPs, EHs, and CAHs. Further, the revision we have included specifies that EHR technology must perform an automated check for the existence of a drug formulary that is specific to a patient for the medication to be prescribed. In other words, an EHR technology would not satisfy this revised certification criterion if it provided a hyperlink to a patient's drug formulary that an EP, EH, or CAH then had to manually open and navigate. With respect to commenters' suggestions to further modify this certification criterion to include additional capabilities, such as those that would ensure real-time information, capture of specific information (e.g., plan name, plan identification number, etc.) in structured data, and making available all necessary formularies, we believe these suggestions exceed the baseline requirements for certification that we have included to support MU. Thus, we decline to make any further revisions to the certification criterion except those noted above. As discussed in the e-prescribing comment and responses part of this final rule, CMS has issued a proposed rule (77 FR 45022) that would update Medicare Part D e-prescribing standards, including a new version of the formulary and benefit standard. We strongly encourage EHR technology developers to utilize these standards, but do not believe that it is necessary at this time to require them as a condition of certification—as having current drug formularies stored locally in the EHR technology would also be a permitted approach. Further, as we discussed in the S&CC July 2010 final rule (75 FR 44602), because some EPs, EHs, and CAHs, do not have external access to a drug formulary and would be able to satisfy the MU requirements by checking an internally managed drug formulary, we believe the flexibility provided by the certification criterion is still warranted. We intend to seek recommendations from the HITSC on further requirements related to this certification criterion in developing the next edition of our EHR certification criteria.

Last, the ONC HIT Certification Program does not include any form of reciprocity for certification under other private sector certification programs, including Surescripts' certification program. The ONC HIT Certification Program will be a ''new'' certification program that will replace the temporary certification program upon the effective date of this final rule. At its onset, we believe that the best way to ensure that EHR technology has the capabilities included in the certification criteria adopted by the Secretary is to require the EHR technology to be tested and certified to the certification criteria under the provisions and procedures specified by the ONC HIT Certification Program.

• *Smoking Status*

MU Objective
Record smoking status for patients 13 years old or older.
2014 Edition EHR Certification Criterion
§ 170.314(a)(11) (Smoking status).

The 2011 Edition EHR certification criterion for smoking status (§ 170.302(g)) specifies a list of six smoking status types that EHR technology must be capable of recording, modifying, and retrieving. For the 2014 Edition EHR certification criteria, we proposed a ''smoking status'' certification criterion that replaced the terms ''modify'' and ''retrieve'' with ''change'' and ''access,'' respectively. We also proposed to specify the six smoking status types included in the 2011 Edition EHR certification criterion as a standard at § 170.207(l). We stated that this refinement would provide additional clarity for the certification criterion and consistency with the structure of similar certification criteria.

Comments. Multiple commenters expressed agreement with this certification criterion as proposed. More commenters, however, recommended that we adopt an industry developed and accepted standard and pointed to SNOMED CT® as the appropriate standard. If SNOMED CT® was not adopted, commenters asked that we provide a crosswalk from the smoking status types included in the certification criterion to the appropriate SNOMED CT® codes.

Commenters raised questions about the definitions/categories of the smoking status types. One commenter suggested that all tobacco use should be captured. Another commenter recommended that the smoking status types reflect the questions used in community health assessment that track smoking and tobacco use cessation interventions or medical assistance such as: (a) Advising smokers and tobacco users to quit ''patient has been offered a smoking cessation program;'' (b) discussing smoking and tobacco use cessation medications; (c) discussing smoking and tobacco use cessation strategies or ''assistance in setting a quit date.'' A few commenters asked whether mapping to the smoking status types included in the certification criterion would be permitted for certification and, if so, for further clarification of potential categories that would suitably

map to the smoking status types included in the certification criterion. For example, commenters asked whether mapping would apply to only cigarettes or other forms of combustible tobacco use as well.

A few commenters noted that the smoking status types adopted for the 2011 Edition EHR certification criteria and proposed for the 2014 Edition EHR certification criteria do not align with those used in the quality measures in Stage 1 and proposed for Stage 2, such as NQF 0028 (Preventive Care and Screening: Tobacco Use: ''Screening and Cessation Intervention (percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user''). The commenters noted that NQF 0028 goes beyond documenting smoking status to encourage cessation counseling. Consequently, the commenters suggested that we could alleviate reporting burdens and workflow issues by agreeing on a single tobacco use value set for all meaningful use objectives and clinical quality measures.

Response. We thank commenters for their feedback and agree with much of what was said. We have now provided mappings to a set of SNOMED CT® concepts to assist the developers and implementers of EHR technology in the implementation of this requirement. We have also expanded the number of available concepts from six to eight in order to better reflect the way that many EPs capture smoking status. We clarify that the eight smoking statuses provided here need not be the exact words that are displayed for a user. Rather, any appropriate concept or concepts that the EHR technology displays for an EP may be mapped to one or more compatible smoking status codes, but if an alternative approach is used, the EHR technology must ultimately be able to record the semantic representation of a patient's smoking status in at least one of these eight status. Further, these eight codes must be used as specified elsewhere in this final rule when smoking status is referenced, such as within the transitions of care certification criterion. We clarify that smoking status includes any form of tobacco that is smoked, but not all tobacco use. Working with CMS, we have added these eight value sets to NQF 0028, so that (for the portion of NQF 0028 that captures smoking status) an EP or EH can capture this data only once rather than twice.

Description	SNOMED CT® ID
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
Light tobacco smoker	428061000124105

As described above, these eight smoking statuses have been provided in order to permit EHR technology developers to incorporate the capture of smoking status as part of an efficient, fluid user experience. We have added two smoking statuses to the standard adopted in § 170.207(h) in order to better reflect clinically relevant differences between smokers, and provide options that may in fact be preferable to many providers, while retaining the existing six codes from the 2011 Edition certification program in order to give EHR developers the option of migrating to the newer codes over time. ''Light smoker'' is interpreted to mean fewer than 10 cigarettes per day, or an equivalent (but less concretely defined) quantity of cigar or pipe smoke. ''Heavy smoker'' is interpreted to mean greater than 10 cigarettes per day or an equivalent (but less concretely defined) quantity of cigar or pipe smoke. Since many EHR technology developers have asked questions about this certification criterion, we offer the following example of an implementation that would be acceptable: an EP user of CEHRT ABC is taking the social history from patient XYZ. The EP is using a template for facilitated data entry in the CEHRT. The template has options such as ''smoker'' and ''nonsmoker.'' When the EP selects ''smoker,'' several other options become available including ''1–9 cigarettes/day'' and ''½ pack/day'' and ''1 pack/day'' and ''greater than 1 pack/day.'' The EP selects ''1 pack/day,'' and moves on to other parts of the discussion with the patient. The CEHRT records (and displays) ''1 pack/day'' and maps this internally as SNOMED CT® concept 428071000124103 (''Current Heavy Smoker''). When a transition of care/referral summary is generated for exchange, the SNOMED CT® concept must be included, as well as the text description ''heavy smoker'' (''1 pack/day'' and any other metadata could also be included as appropriate). Note that ''heavy smoker'' is not the only concept that is appropriate here, and we leave the decision regarding which of the eight codes is the most accurate descriptor of clinical intent to the judgment of those implementing the form, template, or other EHR data capture interface. In the case above, the developer of the template chose ''heavy smoker'' rather than ''current every day smoker'' because this is more clinically relevant with respect to the patient's risk for disease and the urgency of intervention. Nonetheless, ''Current every day smoker'' would have been technically acceptable and would therefore be acceptable for certification testing.

• *Patient List Creation (proposed ''Patient Lists'' and ''Patient Reminders'')*

MU Objective
Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.

2014 Edition EHR Certification Criterion
§ 170.314(a)(14) (Patient list creation).

We proposed the 2014 Edition EHR certification criteria for ''patient'' lists and ''patient reminders'' as ''unchanged'' certification criteria (as described in section III.A.11 of this preamble). In our proposal for the ''patient reminders'' certification criterion, we clarified and emphasized that EHR technology certified to this certification criterion would need to be capable of creating a patient reminder list that includes a patient's communication preferences, which would be consistent with current testing procedures for this capability as included in the 2011 Edition EHR certification criterion (§ 170.304(d)). We also noted that, consistent with patient communication preferences, we would

anticipate that EPs, EHs, and CAHs could use communication mediums made available by EHR technology certified to the proposed ''secure messaging'' certification criterion (§ 170.314(e)(3)) or the ''view, download and transmit to 3rd party'' certification criterion (§ 170.314(e)(1)) to send patient reminders. Last, we stated that we anticipated that other modes of communication would be available and may be preferred by patients for sending patient reminders, such as regular mail.

We also proposed the ''patient lists'' certification criterion for the 2014 Edition EHR certification criteria as unchanged and without any refinements. The proposed ''patient lists'' certification criterion specified that EHR technology enable a user to electronically select, sort, access, and create lists of patients according to, at a minimum, the data elements included in: (i) Problem list; (ii) Medication list; (iii) Demographics; and (iv) Laboratory tests and values/results.

Comments. One commenter agreed that being able to provide information to patients in the manner they prefer is important, but expressed concern about the adoption of the ''patient reminder'' certification criterion for Stage 2. They stated that their comments to CMS indicated that non-CEHRT systems that provide the actual reminders should be exempt from certification criteria.

Response. This adopted 2014 Edition EHR certification criterion focuses on an EHR technology's capability to electronically create a patient reminder list for preventive or follow-up care according to patient preferences based on certain data elements. It does not focus on the IT systems that may be used to provide the reminders.

Comment. A commenter suggested that the proposed ''patient reminders'' certification criterion include the element of when patients were last seen so that the EHR technology user can perform date range searches (i.e., diabetics not seen for 6 months).

Response. We agree with this commenter's suggestion. Although we proposed the ''patient reminders'' certification criterion as an unchanged certification criterion, we believe this commenter has identified a critical flaw in the way the certification criterion is currently expressed. We interpret the commenter's request to mean that as an EHR technology user they would want to be able to create a patient reminder list on an ad-hoc basis according to at least the parameters specified in the certification criterion. As we considered this comment and analyzed the way the certification criterion is specified, we realized that it does not necessarily express this outcome, which was our intent for this certification criterion. Rather, we believe that as currently worded, the certification criterion could permit an EHR technology developer to design and get EHR technology certified that could only permit a user to generate patient reminder lists based on a few static reports. We believe that kind of outcome is unacceptable and does little to support an EP's ability to engage in follow-up care communications—especially if the EP wants to focus on a patient population that should be supported by virtue of certification, but is not because the EP cannot dynamically (i.e., on-the-fly) and while interacting with the EHR technology add or subtract certain factors from the underlying query. Additionally, in the continued context of reducing redundancy and regulatory burden as well as our continued efforts to improve the clarity of our regulation, we compared this certification criterion with the ''patient lists'' certification criterion (proposed at § 170.314(a)(14)) and have determined that these two certification criteria should be combined into a single certification criterion. At a high-level, both require EHR technology to be able to electronically create a list of patients. However, where the ''patient lists'' certification criterion includes more specific filtering, the ''patient reminders'' does not, but it does include two additional data elements (medication allergies, patient's communication preference).

Accordingly, we have finalized a single certification criterion that merges the strengths of each certification criterion as well as this commenter's suggestion for a date/time component. We believe this single certification criterion will be clearer for EHR technology developers and will more clearly express the kind of capability EHR technology must include in order to be certified. Within the certification criterion, we interpret ''select'' to mean filter and ''sort'' to mean that the user gets to provide a sequence or range (e.g., by hemoglobin A1C levels). For consistency purposes, we have included the same revisions we have made in other certification criteria and state ''each one and at least one combination* * *'' to indicate that EHR technology must be able to create a list based on each element separately as well as based on at least one combination of any of the data. Finally, we seek to indicate our expectation that for the next EHR certification criteria edition, we would propose that EHR technology be able to initiate a patient reminder based on a patient's identified communication preference (where it is electronically feasible).

Comment. A commenter asked that we provide additional guidance as to what constitutes ''patient preference.''

Response. In the Proposed Rule we indicated that patient preference constituted the communication method by which the patient preferred to be contacted. This could include but is not limited to: email, secure messaging, regular mail, phone, and text message. EHR technology designed for an ambulatory setting must support an EP, EH, or CAH's ability to record a patient's communication preference, which we believe is now explicitly clear in the revised combined certification criterion. We encourage EHR technology developers to include a variety of the most common choices patients may select.

Comments. Many comments were not focused on the capability that EHR technology would need to provide a user in order to meet the certification criterion, but on: how a reminder needed to be provided; what an acceptable reminder would be; whether the purpose of the reminder and its clinical relevance mattered; how a reminder could be reported; and that exclusions to the meaningful use objective and measure should be established for specialists.

Response. All of these comments go beyond the scope of capabilities for which EHR technology certification is required.

• *Drug-Drug, Drug-Allergy Interaction Checks*

MU Objective
Implement drug-drug and drug-allergy interaction checks.
2014 Edition EHR Certification Criterion
§ 170.314(a)(2) (Drug-drug, drug-allergy interaction checks).

We proposed a ''drug-drug, drug-allergy interaction checks'' certification criterion (§ 170.314(a)(2)) that included the recommendations of the HITSC to eliminate for certification the ability for EHR technology to permit users to adjust drug-allergy interaction checks, replace the term ''real-time'' with ''before the order is executed,'' revise the language to specify that notifications should happen during CPOE, specify that the level of severity of the notifications is what can be adjusted, and limit the ability to make adjustments to an identified set of users or available as a system administrative function. We also expressed agreement with the HITSC that drug-allergy

contraindications should be interpreted to include adverse reaction contraindications. We also clarified that the phrase ''identified set of users'' means that the EHR technology must enable an EP, EH, and CAH to assign only certain users (e.g., system administrator) with the ability to adjust severity levels. We noted that in other certification criteria that use the phrase ''identified set of users,'' a similar principle would apply (i.e., assigning the capability to only certain users).

Comments. Of the comments received on this proposed certification criterion, many supported it as proposed. A set of commenters recommended that we change the language at the beginning of the certification criterion to state, ''Before an order is being completed and acted upon * * *'' instead of ''Before a medication order is placed * * *.'' They noted that this change would clearly define the interaction notification's ''real-time'' nature and make it clear that the licensed provider would need to see the interaction intervention and be able to act on it. Similarly, with respect to this proposed language, a commenter questioned how EHR technology workflow would be tested to know if the check is completed before the order is entered.

Response. We appreciate this detailed feedback and agree with commenters' revisions. We have modified this language in the certification criterion to reflect the recommended text by replacing ''placed'' with ''completed and acted upon.'' We believe that this revision should also address the testing timing question raised by the last comment. Additionally, due to this revision, we removed ''at the point of care'' from the certification criterion's language because we believe the prior clarification appropriately indicates when the drug-drug or drug-allergy interaction needs to be indicated to a user.

Comments. Some commenters focused on our proposal to not include in the 2014 Edition EHR certification criterion the capability for EHR technology to permit users to adjust drug-allergy interaction checks. One commenter stated that it was unclear in the Proposed Rule whether this also applied to drug-drug interactions. The commenter appeared to presume that we were also applying this proposal to drug-drug interactions because the commenter explained that such a limitation would not comport with the current state of interaction databases available in practice. Specifically, the commenter stated that current systems, especially those based on shared excipients (i.e., substances) or other components across formulations, are often strongly biased toward sensitivity (i.e., an alert is generated even when a low probability of a clinically significant interaction exists). As a result, the specificity of alerts, and hence their positive predictive value, is low. The commenter stated that the phenomenon of ''alert fatigue'' is well-documented and the inflexible approach promoted by the Proposed Rule contributes to this phenomenon. Similarly, another commenter expressed concern that EHR technology developers may interpret this section to prohibit physicians in small practices from tailoring alerts to fit their practice. The commenter also noted that alert fatigue is a well-known problem and expressed concern that our proposal may lead to a diminution in safety through alert fatigue rather than an improvement.

One commenter stated that we should reword paragraph (ii)(B) to ensure that EHR technology has the capability to permit a limited set of users to make adjustments to the severity levels of drug-allergy interaction checks, in addition to drug-drug. In contrast to this position, another commenter expressed agreement with the proposed change from the 2011 Edition EHR certification criterion to the 2014 Edition EHR certification criterion and stated that adjusting notifications of drug-allergy interaction checks is inconsistent with clinical work and confusing in the current certification process.

One commenter contended that providers should retain the ability to define thresholds for *any* alert which they would like to receive. Without this capability, the commenter argued EPs are liable to experience ''alert fatigue'' due to high ''noise to signal''; that is, the presentation of a large number of alerts which are simply irrelevant to the care which the physician is providing.

Response. On our proposal to remove the drug-allergy adjustment capability expressed in the 2011 Edition version of this certification criterion, we believe that the negative reaction expressed is due to misinterpreting our proposal. We are fully aware of the concerns expressed regarding alert fatigue. The certification criterion addresses this concern by requiring that EHR technology include the capability to adjust the severity level of interventions provided for drug-drug interaction checks. This capability should allow for EPs, EHs, and CAHs to find an appropriate balance with respect to the frequency of interventions. In regards to severity level adjustments for drug-allergy interactions, the proposal in question sought to remedy a concern raised by the HITSC and other stakeholders after the S&CC July 2010 Final Rule that certification focused on ensuring that EHR technology had the capability to adjust the severity of drug-allergy interventions when there were few clinical reasons to do so. Unlike drug-drug alerts, the rationale we provided was that it is important for drug-allergy interventions to be indicated and continue to believe that this will generally be the case. Thus, we have finalized the ''adjustments'' paragraph (§ 170.314(a)(2)(ii)) as proposed and decline to include for the purposes of certification a severity adjustment requirement for drug-allergy interventions.

Comment. A commenter requested clarification on paragraph (a)(2)(ii)(A). They asked whether the certification criterion would require that the severity level be able to be changed from what a pharmaceutical company's research recommended. Additionally, they asked if we were suggesting that a provider or person with appropriate administrative privileges be able to downgrade that alert level to moderate or minor or simply that they be able to modify the type of interaction that triggers a warning. They concluded by stating that a valid clinical use case is that many commonly prescribed combinations are labeled as having a potential drug-drug reaction and the provider wants to prevent being alerted each time.

Response. The certification criterion does not specifically address a particular drug-drug intervention. Rather it is meant to ensure that EHR technology that meets this certification criterion includes a capability that permits certain users to adjust the severity level of interventions. So in response to the commenter's question, this certification criterion is meant to make it possible for a health care provider to reduce the frequency of/threshold for certain interventions.

Comments. A commenter asked that we clarify the definition of ''adverse reaction contraindication.'' Additionally, they asked what vocabulary or vocabulary subsets would be used for the input of the adverse reaction and whether EHR technology would need to be able to distinguish between alerts for allergy contraindications and alerts for adverse reaction contraindications. They stated that many EHR technologies are not configured to register other reactions that are not true allergies. A second commenter stated that we should recommend specific vocabularies/codes and referenced RxNorm for the drugs as well as the drugs to which the patient is allergic and SNOMED CT® for the type of allergy.

Response. We agree that there is a clinical distinction between ''adverse reaction'' and ''allergic reaction,'' and we hope to be able to support such a distinction in future rulemaking. However, for the purpose of this certification criterion, we do not make a clinical distinction between ''medication adverse reaction'' and ''allergic reaction.'' In many cases, the use of a medication will be contraindicated because a patient has a history of an adverse reaction to the medication. While this may be clinically distinct from an allergic (antibody-mediated hypersensitivity) reaction, it is a contraindication nonetheless. The same clinical vocabulary (e.g., RxNorm) that would be used for allergic reactions will be required for adverse reactions.

Comment. A commenter requested that we clarify the meaning of ''identified set of users'' with respect to the severity adjustments. They asked whether each facility would have the ability to define this for its users.

Response. As stated in the Proposed Rule, identified set of users means that the EHR technology must enable an EP, EH, and CAH to assign only certain users (e.g., system administrator) with the ability to adjust severity levels. With respect to the follow-up question, EHR technology certified to this certification criterion would need to enable certain users to be assigned with the ability to adjust the severity levels of interventions provided for drug-drug interactions. How that capability is subsequently implemented and used is not within the scope of certification and we are unable to determine what the commenter had in mind when they referenced ''each facility.''

Comment. A commenter requested that we clarify the alignment of drug-drug, drug-allergy alerts with CDS. Specifically, they asked us to confirm that the proposed adoption of the HL7 ''Infobutton'' standard for retrieving referential information would not apply to the drug-drug, drug-allergy alerts certification criterion.

Response. As with the past edition of EHR certification criteria, the drug-drug, drug-allergy certification criterion is a separate and distinct certification criterion from the CDS certification criterion. We did not propose the adoption of the HL7 Infobutton standard for this certification criterion and its use would not be necessary to demonstrate compliance with this certification criterion.

Comment. A commenter agreed with the certification criterion but recommend that we consider expressing additional capabilities to support food-drug interactions (i.e., changes in how medications work caused by food, caffeine or alcohol).

Response. We appreciated this comment but decline to make such changes at this time. EHR technology developers are encouraged and free to include this functionality which would be outside the scope of certification. We will keep this addition in mind as we work with the HITSC on the next edition of EHR certification criteria.

Comment. A commenter suggested that it is important to specify in this certification criterion and the CDS certification criterion that EHR technology be able to provide timely access to FDA Drug Safety Alerts (Boxed Warnings, Risk Evaluation and Mitigation Strategies (REMS) programs and Drug Safety Alerts). Further, they stated that these FDA Drug Safety Alerts include drug-drug interactions, allergic reactions and critical safety information directly related to clinical decision making.

Response. We wholeheartedly agree with this comment and encourage EHR technology developers to make FDA Drug Safety Alert information accessible to health care providers as part of their normal workflows. We believe this capability and the availability of such information is best addressed by the specific capability included in the CDS certification criterion related to referential CDS. Additionally, as part of an EHR technology's CDS we could see this capability being enhanced through the use of the HL7 Context-Aware Knowledge Retrieval (''Infobutton'') Standard so that EHR technology could gain access to new REMS/drug alerts on an ongoing and dynamic basis.

• *Demographics*

MU Objective
Record the following demographics: preferred language; sex; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.
2014 Edition EHR Certification Criterion
§ 170.314(a)(3) (Demographics).

We proposed to adopt the ISO 639–1 code set as the vocabulary standard for preferred language [18] based on the recommendation of the HITSC. We also proposed to adopt ICD–10–CM for recording the preliminary cause of death, stating that its use will permit additional specificity.

[18] *http://www.loc.gov/standards/iso639-2/php/code_list.php*—Also note that The Library of Congress has been designated the ISO 639–2/RA for the purpose of processing requests for alpha-3 language codes comprising the International Standard.

As for the Office of Management and Budget (OMB) standards for the classification of federal data on race and ethnicity, we noted that the standard for classifying federal data according to race and ethnicity requires that the option for selecting one or more racial designations be provided. The standard also permits the use of more than the minimum standard categories for race and ethnicity as long as the data can be aggregated to the minimum standard categories, which would be confirmed through the testing and certification processes. We proposed to clarify the reference to the adopted standard as the ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity,'' which was issued on October 30, 1997, as referenced at § 170.207(f). Last, we proposed to revise the certification criterion to require that EHR technology be capable of recording that a patient declined to specify his or her race, ethnicity, and/or preferred language.

We received comments that generally applied to the certification criterion and comments that focused on each of the specific data elements in the certification criterion. We have categorized and respond to these comments in a similar manner.

Comments. A few commenters expressed general agreement with the proposed certification criterion, while a commenter recommended that this certification criterion should remain unchanged.

Response. We appreciate the commenters support for the proposed certification criterion and our adopting it as a revised certification criterion for the reasons discussed below.

Preferred Language

Comments. Some commenters expressed support for the ISO 639–1 standard. One commenter recommended the ISO 639–3 standard as being more comprehensive. Another commenter suggested adopting the 2009 IOM recommendations on how to ask for language data. Multiple commenters suggested that we should use ISO 639–2. The HITSC clarified in their comments that their recommendation to ONC was that preferred language should be expressed by constraining 639–2 to those that are in ISO 639–1, noting that 639–1 includes only active languages, while 639–2 includes languages no longer in use. A few commenters asked for clarification as to whether all languages listed in the standard must be visible for a customer to select.

Response. We agree with the clarification provided by the HITSC. Accordingly, we are adopting ISO 639–

2 constrained by ISO 639–1. This will constrain ISO 639–2 to only the active languages in ISO 639–1, but will permit the use of the alpha-3 codes of ISO 639–2. As such it is a better approach than adopting solely ISO 639–2 or 639–1. We believe that ISO–639–3 exceeds the baseline we seek to specify for certification and have not adopted it. Last, in response to the commenters' request for clarification, EHR technology is not required to display all the languages of the standard to meet the certification criteria. But, it must be capable of recording a patient's language according to any of the languages in the standard.

Race and Ethnicity

Comments. Some commenters suggested the use of other vocabulary standards such as CDC vocabulary standards, standards based on the 2009 IOM recommendations, or the HHS survey standards recently adopted by HHS in compliance with ACA section 4302. A few commenters recommended that EHR technology only record the ''primary'' race and ethnicity value as identified by the individual and that the eligible professional regards as clinically significant because the commenters contended that most EHR technology is unable to accommodate multiple values for patients. Commenters also suggested that a multiple question approach for patients that may wish to designate multi-race or ethnicity be acceptable. A commenter asked for clarification as to whether the data elements must be stored as aggregated to the standard (i.e., it must be done this way), or could it be aggregated to the standard by a third party and not the EHR technology. Commenters also requested clarification as to how the OMB race and ethnicity codes must be used in conjunction with providing patients the option to not respond to questions regarding race and ethnicity.

Response. The OMB race and ethnicity codes constitute a government-unique standard. We have adopted this standard because it provides an easily understood structure and format for electronically transmitting the data elements identified by the associated MU objective. The standard is readily available, was previously adopted as part of the 2011 Edition EHR certification criteria and, in general, provides the best standard to use to support our policies goals. Therefore, we believe this standard is more appropriate than the alternative CDC, IOM and HHS survey standards.

EHR technology must be capable of meeting the standard and the other requirements of the certification criterion in order to be certified. As such, EHR technology must record race and ethnicity according to the OMB standard by providing the option for one or more racial designations to be selected in a manner consistent with the standard. EHR technology must also be capable of aggregating/mapping more granular race and/or ethnicity data to the minimum race and ethnicity categories in the standard if an EHR technology developer implements such an approach. Additionally, to meet the certification criterion, EHR technology must, in conjunction with complying with the OMB standard, be capable of recording that a patient declined to specify his or her race and/or ethnicity. As noted in the Proposed Rule, this ensures inclusion of such patients in the numerator of the MU percentage-based measure.

Gender/Sex

Comments. Commenters requested clarification regarding the data element ''gender,'' asking whether it was intended that sex and/or gender be collected.

Response. We have clarified that the certification criterion requires the recording of sex, which is consistent with the change made by CMS for its MU objectives and measures.

Comments. Commenters recommended that gender identity and/or sexual orientation be recorded.

Response. We appreciate the submission of these comments, but the certification criterion includes only data required to support the associated MU objective and measure. Therefore, we decline to include these additional data elements.

Preliminary Cause of Death

Comments. A few commenters stated that ICD–10, not ICD–10–CM, was the appropriate standard. A commenter stated that the preliminary cause of death should be in the same vocabulary standard as the problem list (i.e., SNOMED CT®). Conversely, many commenters stated that no standard should be required. These commenters suggested that a text entry for ''preliminary cause of death'' is most appropriate. These commenters stated that this would avoid the need for provider education on the use of the standard, the difficulty in narrowing down the standard code list to one that might be usable for coding the preliminary cause of death, and workflow changes. Commenters stated that the significance of the preliminary cause of death being a codified value is not of great importance when compared to the final cause of death determined by a coroner through autopsy or as may be required for death certificate purposes. Commenters further stated that the information required by this capability is preliminary and by its very nature will not carry the same weight as a later more final determination. Overall, commenters questioned the cost and burden involved in collecting this information in accordance to a standard versus any perceived benefit as a means of meeting this certification criterion.

Response. We agree with the commenters that the burden and costs, as outlined by commenters, outweigh the potential benefits of recording the preliminary cause of death in accordance with a standard. Therefore, we are not adopting a standard for this data element and free text entry will continue to be permitted.

Comments. A few commenters stated that the preliminary cause of death should not be collected as a data element. A commenter stated that if EHs are not required to record a preliminary cause of death within a specified timeframe from the death, then the commenter requested confirmation that deceased patients must simply have a preliminary cause of death recorded in their charts in order to be included in the MU measure. Otherwise, the commenter stated that it was unclear how EHs would be expected to report on patients who died near the end of the reporting period and have not yet had a cause of death recorded. Commenters also requested clarification for the proposed exclusion that specified if a demographic element is prohibited to be captured by state law, that the EP or EH is excluded from capturing that demographic. Commenters asked if it was acceptable to note once in CEHRT the state law prohibition or if it needed to be recorded for each patient.

Response. Collection of preliminary cause of death data supports the associated MU objective and measure and, therefore, EHR technology must be capable of collecting it. Comments on when the preliminary cause of death must be recorded and the measure exclusion are beyond the scope of this rulemaking. We direct commenters to the Stage 2 final rule for a discussion of the MU objective and measure and responses to these comments.

Additional Data Elements

Comments. Commenters recommended a wide range of additional data elements for inclusion in the certification criterion based on the rationale that the capturing of the data elements could contribute to

identifying health disparities and potential reasons for the health disparities. The recommended additional data elements are: residency information (state, county, zip code, street address); country of origin; nationality; type of employment; primary place of employment; highest education level completed; and hobbies.

Response. We appreciate the recommendations for inclusion of additional data elements, but have chosen to limit this certification criterion's scope to only include the data required to support the associated MU objective and measure. Therefore, we decline to include any of the recommended additional data.

- *Problem List*

MU Objective
Maintain an up-to-date problem list of current and active diagnoses.
2014 Edition EHR Certification Criterion
§ 170.314(a)(5) (Problem list).

In the Proposed Rule, we proposed to replace the terms ''modify'' and ''retrieve'' in the certification criterion with ''change'' and ''access,'' respectively. Consistent with the interpretation we provided in the S&CC July 2010 final rule, we also reiterated and clarified that ''longitudinal care'' is used to mean over an extended period of time. For the ambulatory setting, we stated that this would be over multiple office visits. For the inpatient setting, we stated that this would be for the duration of an entire hospitalization, which would include the patient moving to different wards or units (e.g., emergency department, intensive care, and cardiology) within the hospital during the hospitalization. We noted that the HITSC suggested we consider longitudinal care to cover multiple hospitalizations, but we stated that this could be difficult to achieve and may not offer added value based on the duration of time between a patient's hospitalizations and the reason for the hospitalizations. We stated that our clarification of the meaning of longitudinal care also applies to its use in the certification criteria for medication lists and medication allergy lists. We further stated that if we were to interpret longitudinal care as suggested by the HITSC, it would apply to these certification criteria as well and could constitute a change in the capabilities included in the criteria, which in turn would cause them to become revised certification criteria.

We proposed to adopt the International Release January 2012 version of SNOMED CT®.[19] We stated that we agreed with the HITSC that the use of ICD–9–CM should no longer be required due to the pending move to ICD–10–CM, but also stated that it would be inappropriate to require the use of ICD–10–CM for problem lists. We stated that SNOMED CT® (and not ICD–10–CM) would be required for calculation of CQMs and proposed only SNOMED CT® as the appropriate standard for the recording of patient problems in a problem list. We noted that this proposal did not, however, preclude the use of ICD–10–CM for the capture and/or transmission of encounter billing diagnoses.

Comments. One commenter asked why it is necessary to specify a vocabulary for the problem list within an EHR. The commenter agreed with the necessity of SNOMED CT® for exchange, but suggested that we permit the flexibility to either use the vocabulary internally or map to it when exchanging information.

Response. We agree with this commenter that SNOMED CT® is the best vocabulary to use in those certification criteria that focus on electronic health information exchange. It is necessary that we specify a vocabulary for the problem list within EHR technology because it supports the current requirement that EPs, EHs, and CAHs need to meet to demonstrate MU. Since CMS's initial proposal for meaningful use Stage 1 (75 FR 1860), it has explicitly prioritized recording problems in the adopted standards. Further, at 75 FR 44337, CMS states ''[w]e further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH *must use the* capabilities Certified EHR Technology includes as specified and standards at 45 CFR 170.302(c)'' which is the 2011 Edition EHR certification criterion for problem list that requires EHR Technology be able to record problems in either ICD–9 or SNOMED CT® in order to be certified. We also responded to similar questions such as this in our S&CC July 2010 final rule (75 FR 44603).'' In the Proposed Rule, we proposed to only permit EHR technology to be certified to record, change, and access problems in SNOMED CT® because we believe that it is the best vocabulary standard for the representation of clinical data and should be used to represent problems beginning in FY/CY 2014. We clarify that this certification criterion does not preclude the use of interface terms, local terms, or other terms from being displayed to a health care provider in lieu of SNOMED CT® to find, select, or view a patient's problem list. However, if such an approach is taken, the EHR technology must ultimately be able to record the semantic representation of the problem list in SNOMED CT®. For example, if a user of a given EHR technology is using a set of interface terms or any other clinical vocabulary that has been mapped to SNOMED CT®, this user may perform a search for a term that represents the patient's problem, select the appropriate term, and ''save'' that term to the patient's problem list, where it may be displayed. The EHR technology is required to record the problem in SNOMED CT® because this is the requirement described above for alignment with the EHR Incentive Programs. For information exchange, the EHR technology must send the problem in SNOMED CT® because this is the requirement of other certification criteria specified elsewhere in this final rule.

Comments. Commenters expressed support for use of only SNOMED CT® and stated that it is the best standard for optimal clinical data capture and reuse of information captured in problem lists. Some of these commenters stated that the use of a classification system such as ICD–10–CM limits data analysis for clinical research, quality of care measurement and communication between care providers and patients. These commenters stated that ICD–10–CM is a classification, and it is still designed to capture diagnoses and reasons for encounters, not every ''problem.'' The commenters recommended that ICD–10 CM and PCS, where appropriate, should continue to be required for billing purposes. The commenters also recommended that EHR technology developers should not utilize the problem list for billing since billing practices and national coding guidelines require that claims only reflect those conditions attended to during the encounter being billed and the problem list includes all conditions that may or may not be active and may or may not have been attended to during the encounter.

Conversely, commenters were concerned that they would face additional costs and burden by having to adopt and implement SNOMED CT® as well as ICD–10–CM or ICD–9–CM until ICD–10–CM is required for implemented. Commenters also stated that SNOMED CT® is not currently in widespread use among hospitals. For these reasons, commenters suggested that they be able to use ICD–10–CM for problem lists in lieu of adopting

[19] *http://www.nlm.nih.gov/research/umls/licensedcontent/snomedctfiles.html.*

SNOMED CT®. A few commenters suggested this same approach, but also recommended signaling a move to adopt only SNOMED CT® for the next edition of certification criteria. One commenter suggested that we pursue development of a national problem list and centralized services developed and maintained by a cooperative partnership between the public and private sectors.

Response. We appreciate the comments supporting the use of only SNOMED CT®. We agree with commenters that SNOMED CT® provides much better clinical data capture than ICD–10 CM, ICD–9, and ICD–10 PCS, while ICD–10–CM is more appropriate for encounter billing purposes. With the adoption of the 2011 Edition EHR certification criteria we permitted the use of either ICD–9–CM or SNOMED CT® to demonstrate compliance with this certification criterion. In our response to comments in the S&CC July 2010 final rule, we stated that a single standard for clinical information would be desirable in the long term. While SNOMED CT® may not currently be used by a majority of EPs, EHs, and CAHs, we cannot expect its usage to dramatically increase without some encouragement. By requiring EHR technology to be certified to this standard, soon all EPs, EHs, and CAHs will have the capability to record patient problems with SNOMED CT®. This will improve the semantic interoperability of clinical systems, improve the accuracy of data capture, and may in fact provide a better transition to ICD–10–CM. With mapping tools from SNOMED CT® to ICD–10–CM, available from the National Library of Medicine, we anticipate that clinical users will be able to use a clinician-friendly terminology (SNOMED CT®) while administrative users can interact with ICD–10–CM, an administrative terminology. Guidance from the HITSC and our own research has indicated a clear need for clinicians to interact with SNOMED CT® rather than ICD–10–CM, and we view this as an opportunity to improve the usability, accuracy, and safety of problem list management.

The development of a national problem list and centralized services is beyond the scope of our certification program and this rule, but we will consider this as we look to how ONC and other Federal agencies can best prepare the industry for successful EHR technology development and implementation.

Comment. A commenter stated that while SNOMED CT® is the appropriate standard for clinical use (as opposed to ICD for billing and epidemiological purposes), clinicians' experience with this standard is limited, and therefore suggest that we consider requiring the addition of a mapping tool within the EHR technology.

Response. We agree with this commenter, as stated above, that SNOMED CT® is the appropriate standard for clinical use, and we agree that mapping from SNOMED CT® to appropriate administrative codes such as ICD–10–CM will be necessary. The National Library of Medicine is developing mapping tools, and such mappings are also available from commercial vocabulary vendors. We do not, however, intend to require the use of such mappings as part of this 2014 Edition EHR certification criterion.

Comment. A commenter suggested that for dental systems, SNODENT, the dental subset of SNOMED CT®, is the appropriate code set for the recording of dental patient problems in a problem list.

Response. While the commenter may be correct in regards to SNODENT, certification to this certification criterion requires that EHR technology be able to record a patient problem list in accordance with SNOMED CT®. It is our understanding that novel SNODENT content produced by the American Dental Association will be incorporated into SNOMED CT® or the U.S. Extension to SNOMED CT®. This will cause all dental diagnoses to be available in SNOMED CT®. We believe this will be beneficial to EPs that rely more on SNODENT. We also encourage EHR technology developers to include SNODENT in EHR technology when it would be beneficial to providers.

Comments. Commenters stated that SNOMED CT® codes should not be required for display in the EHR. Commenters explained that an EP, EH, or CAH should be able to use whichever code set they prefer for display.

Response. We agree with commenters. As noted above, SNOMED CT® codes are not required for display in the EHR technology in order for it to meet this certification criterion.

Comments. Commenters stated that the SNOMED CT® standard should include the U.S. Extension to SNOMED CT® (citation to National Library of Medicine) and apply to all uses of the standard in certification criteria. Commenters stated that the US extension includes terms important for the MU program, specifically those used in the US but not found in the SNOMED CT® International Release (e.g. for adopting pre-coordinated terms in SNOMED CT® to match those found in ICD–10–CM).

Response. We agree with the commenters that, although not proposed for use, the U.S. Extension is necessary to support the MU program and, therefore, have adopted it in conjunction with SNOMED CT®.

Comments. Commenters stated that to accommodate the regular updates that occur to SNOMED CT® we should establish a mechanism for updating the minimum regulatory standards. Alternatively, a commenter suggested we simply adopt ''SNOMED CT®—current International release'' as the vocabulary standard.

Response. We appreciate the suggestions by commenters. We have established a process for adopting certain vocabulary standards, including SNOMED CT®, which permits the use of newer versions of those standards than the one adopted in regulation. We refer readers to section IV.B for a discussion of ''minimum standards'' code sets and our new more flexible approach for their use in certification and upgrading certified Complete EHRs and certified EHR Modules. Readers should also review § 170.555, which specifies the certification processes for ''minimum standards'' code sets. In response to the commenter's suggestion that we adopt in regulation ''the current release of SNOMED CT®'' as the standard, we refer the commenter to section III.A.5 earlier in this preamble. This section explains why we cannot take such an approach.

Longitudinal Care

Comments. Commenters expressed agreement with our clarification of the meaning of the term ''longitudinal care'' for the purposes of this certification criterion and the certification criteria for medication lists and medication allergy lists. However, commenters recommend that we eliminate the term ''longitudinal care'' from this certification criterion and the ''medication list'' and ''medication allergy list'' certification criteria. Commenters stated that our use of the term as described in the Proposed Rule was inconsistent with the common understanding of the term among the health care community. These commenters stated that ''longitudinal'' should be reserved for referring to care provided across care settings and across episodes or encounters of care. Some commenters suggested replacing the term with ''encounter of care,'' ''episode of care,'' or ''durational care.'' A commenter suggested that for hospital patient problems that are longitudinal across encounters be acceptable given ONC's proposed definition of longitude for hospital inpatients of an admission. This commenter noted that some EHRs are designed such that problems as clinical data objects are distinct from

encounter diagnosis, and are longitudinal in concept and design.

Response. We agree with commenters that our use of longitudinal care in this certification criterion and in the certification criteria for medication lists and medication allergy lists has the potential to create confusion. Accordingly, we have replaced this term in the certification criteria with the descriptions we provided in the Proposed Rule and with a terminology change recommended by commenters. Specifically, for the ambulatory setting, we have replaced the term ''longitudinal care'' with ''over multiple encounters.'' We believe using ''encounters'' instead of ''office visits'' is a more clinically appropriate. We note that this revision has no substantive impact on current or future testing and certification processes. For the inpatient setting, we have replaced the term ''longitudinal care'' with ''duration of an entire hospitalization,'' which would continue to include situations where the patient moves to different wards or units (e.g., emergency department, intensive care, and cardiology) within the hospital during the hospitalization and continue to maintain that it would *not* cover multiple hospitalizations for the purpose of certification. As we stated above and in the Proposed Rule, capturing patient problems over multiple hospitalizations could be difficult to achieve and may not offer added value based on the duration of time between a patient's hospitalizations and the reason for the hospitalizations.

• *Clinical Decision Support*

MU Objective
Use clinical decision support to improve performance on high-priority health conditions.
2014 Edition EHR Certification Criterion
§ 170.314(a)(8) (Clinical decision support).

We proposed to adopt a revised clinical decision support (CDS) certification criterion as part of the 2014 Edition EHR certification criteria. We noted in the Proposed Rule that we refined the HITSC's recommended certification criterion to provide a clearer understanding of the capabilities that must be tested and certified and to provide greater flexibility to EHR technology developers in designing EHR technology to meet this proposed certification criterion. We proposed to replace the term ''clinical decision support rule'' used in the 2011 Edition EHR certification criteria and the HITSC recommended criterion with the term ''clinical decision support intervention'' to better align with, and clearly allow for, the variety of decision support mechanisms available that help improve clinical performance and outcomes. We described that a CDS intervention is not simply an alert, notification, or explicit care suggestion. Rather, it should be more broadly interpreted as the user-facing representation of evidence-based clinical guidance. Our goal in clarifying the nomenclature was to focus more on the representation of the guidance (the CDS intervention) that the EHR technology should offer to the user rather than prescribe the form of either the logical representation of the clinical guidance or how the intervention interacts with the user.

We also proposed to require the use of the HL7 Context-Aware Knowledge Retrieval (''Infobutton'') Standard, International Normative Edition 2010, for retrieving diagnostic or therapeutic reference information and proposed to require the use of CDS when a summary care record was incorporated. We noted that the Infobutton standard has been in active use for several years with many reference content vendors now providing their products in this form, and we proposed to adopt its most recent edition (International Normative Edition 2010) in order to enable a user to retrieve diagnostic or therapeutic reference information. We stated our belief that the use of standard reference information retrieval formats would accelerate the delivery of content to providers and hospitals, and would enhance the flexibility of such implementations because these formats reduce the need to ''hard wire'' the content databases to installed EHR technology. We indicated that this flexibility would allow EPs, EHs, and CAHs more choices and easier migration across content providers, encouraging innovation and competitiveness among these content providers.

We asserted that it is important for CDS interventions to be triggered when new information is incorporated into EHR technology as a result of a care transition. Consistent with this belief, we proposed that EHR technology enable interventions to be triggered when the specified data elements are incorporated into a summary care record pursuant to the capability specified at § 170.314(b)(1). In consideration of whether EHR technology should be capable of importing or updating value sets for the expression of CDS vocabulary elements using the HL7 Common Terminology Services, Revision 1, standard, we requested comment on industry readiness to adopt this standard and on the benefits it could provide if required as a part of this certification criterion.

Consistent with the HITSC's stated intent, for EHR technology to be certified to this criterion we proposed that it must be capable of providing interventions and the reference resources in paragraph (a)(8)(ii)(A) of § 170.314 by leveraging each one or any combination of the patient-specific data elements listed in paragraphs (a)(8)(i) and (ii) of § 170.314 as well as one or any combination of the user context data points listed in paragraph (a)(8)(iii)(A) of § 170.314. We asserted that EHR technology must also be capable of generating interventions automatically and electronically when a user is interacting with the EHR technology.

Last, expanding on the HITSC's recommendation that the source attributes of suggested interventions be displayed or available for users, we proposed that, at a minimum, a user should be able to review the: bibliographic citation (i.e., the clinical research/guideline) including publication; developer of the intervention (i.e., the person or entity who translated the intervention from a clinical guideline into electronic form, for example, Company XYZ or University ABC); funding source of the intervention development; and release and, if applicable, revision date of the intervention. We asserted that the availability of this information would enable the user to fully evaluate the intervention and enhance the transparency of all CDS interventions, and thus improve their utility to healthcare professionals and patients.

To aid readers, we have done our best to group comments and corresponding responses under subheadings that align with the specific capabilities proposed for the CDS certification criterion.

General Comments on CDS Interventions

Comments. There was overwhelming support for replacing the term ''rule'' with ''intervention.'' A few commenters suggested that we provide an expanded list of example CDS interventions such as patient-specific order sets, dosing guidance, documentation forms, and display of patient-specific relevant information.

Response. We appreciate the support for the more expansive term, ''CDS intervention'' and have used it in the final rule. We would like to note that the examples of CDS interventions in the NPRM were illustrative only, as our focus is not the type of intervention but the clinical intent of an intervention that offers guidance.

Comments. Several commenters commented on the specific capability proposed at § 170.314(a)(8)(i) ''Evidenced-based decision support interventions.'' They stated that they were confused by and would like clarification on the statement ''each one or any combination of the following.''

Response. As noted in the section III.A.4 of this preamble (''Explanation and Revision of Terms Used in Certification Criteria''), in any certification criterion where we had this or similar language, we have revised it to clarify its intent. We refer readers to this section of the preamble for further clarification.

Comments. We received many comments and questions about the mechanism of counting or measuring that the CDS event was enabled or activated. Many commenters believed that that it would be very difficult to track CDS interventions ''live'' in multiple locations within the EHR technology and within many workflows. As such, some commenters believed this requirement should just be met thorough provider attestation, while others commented that the occurrence, rather than the enabling, of the CDS intervention should be measured. Commenters expressed concern about providers needing or choosing to modify or replace interventions during a reporting period based on quality improvement or clinical needs and how that might endanger their ability to meet MU requirements.

Response. The Stage 2 final rule, published elsewhere in this edition of the **Federal Register**, provides guidance regarding how an EP or EH would report CDS interventions, or how activation would be managed relative to the EHR reporting period. We thank commenters for their suggestions regarding other methods of tracking CDS, but we believe that the best method of tracking CDS interventions is to capture when they are enabled. So long as EHR technology is capable of recording such an event, then the EHR technology will be capable of generating a report that expresses the CDS interventions that were enabled across a given time-frame such as during an EHR reporting period. In response to these comments, we have revised the first specific capability of this certification criterion to clarify two points: 1) that we intended for an identified set of limited users to be able to select CDS interventions (thus, per the statements above, it should be apparent when these users have enabled certain interventions); and 2) when we used the parenthetical (or activate) we did not mean to imply that activate was a separate functionality from select. In that respect we have clarified the parenthetical to say (i.e., activate).

Comments. Some commenters requested that we not limit CDS interventions to only those tied to CQMs so that providers, hospitals, and specialists could target specific areas where they feel improvement is needed. Other commenters asked that we permit locally defined and developed CDS content and references.

Response. We appreciate both of these suggestions. We refer readers to the EHR Incentive Programs final rule published elsewhere in this edition of the **Federal Register** for a description of CDS objectives for Meaningful Use. Locally defined and developed CDS content and references are certainly permitted to be used with the capabilities for which certification is required by this certification criterion.

Comments. Several commenters were concerned about ''hard coding'' CDS to CQMs in EHR technology.

Response. We share this concern and agree that EHR technology presented for certification should leverage standards where possible to retrieve CDS content from external sources (which can be maintained and updated independently from the software release cycle). The Proposed Rule noted that referential sources such as medical texts, primary research articles, and clinical practice guidelines have long been available in electronic form, but the means and manner of accessing them have historically been disconnected from the points in providers' patient care workflows when the immediate availability of the reference sources would optimize clinical decisions. We noted that these tools are being made available through links in EHRs, offering information at relevant points within the clinical workflow. The Infobutton standard was proposed in order to enable a user to retrieve diagnostic or therapeutic reference information. We suggested that the use of standard reference information retrieval formats would accelerate the delivery of content to providers and hospitals, and would enhance the flexibility of such implementations because these formats reduced the need to ''hard wire'' the content databases to installed EHR technology. This flexibility would allow EPs, EHs, and CAHs more choices and easier migration across content providers, encouraging innovation and competitiveness among these content providers.

Comment. One commenter requested clarification concerning proposed § 170.314(a)(8)(i), expressing an interpretation that an EHR Module can be certified to this paragraph (as well as meeting other 4 paragraphs) if it implements one or more CDS interventions, that none of the interventions need be drug-drug or drug-allergy related, but only if it uses data from the enumerated list in § 170.314(a)(8)(i)(A)–(F). This commenter noted that the EHR Module may address high priority health conditions not included by CMS as a Clinical Quality Measure, and recommended that there not be any inconsistency between the two rules (i.e. a CQM that does not use one of the enumerated data elements present in § 170.314(a)(8)(i)(A)–(F)).

Response. This certification criterion specifies the minimum capabilities EHR technology needs to include in order to be certified. It does not preclude the incorporation of CDS interventions that address health conditions not included in CQMs identified in the EHR Incentive Programs. We expect to have tighter alignment with CDS and CQM in future editions of EHR certification criteria.

Comment. One commenter noted that there would be ''mixed ability to meet'' several of the specific capabilities proposed in § 170.314(a)(8).

Response. We thank the commenter for their feedback, and understand the concern. We have modified several of the specific capabilities expressed by this certification criterion as well as clarified them in our responses to provide better guidance and more flexibility.

HL7 Common Terminology Services

Comments. Many commenters expressed that additional, ground-laying work would be necessary before the adoption of the HL7 Common Terminology Services could be a requirement for certification. These commenters noted that there would need to be a standardization of value sets, certification of a value set service, and mechanisms to update, maintain, and distribute value sets.

Response. We thank commenters for their feedback and agree that there is not currently a set of publicly available resources that are accessible using this standard. We are coordinating efforts with other Federal agencies to create a value set repository that will be hosted by the National Library of Medicine. This repository will provide value sets in a manner consistent with the HL7 Common Terminology Services in the very near future, and we encourage EHR technology developers to use this valuable resource in order to capture and maintain value sets for CDS and CQM in the future. We intend to reconsider this for certification in a future edition of certification criteria.

Linked Referential CDS

Comments. Many commenters expressed concern that our reference to the HL7 Context-Aware Knowledge Retrieval (''Infobutton'') standard was intended to be required for interactive CDS interventions, and suggested that it was an inappropriate standard for such interventions. Some commenters disagreed with our inclusion of linked clinical references in the CDS certification criterion. Several commenters expressed support for the ''Infobutton'' standard for referential CDS, while some did not because they were concerned that there was insufficient industry adoption for this standard to be a requirement. One commenter suggested that while this standard is appropriate for linked referential CDS, there may be other methods of providing access to relevant clinical references, and that we should allow for other methods as well.

Response. We agree that the HL7 Infobutton standard is an inappropriate standard for ''interactive'' CDS interventions. As we described in the Proposed Rule, we intended to require this standard be applied only for referential CDS. Thus, for the purposes of referential CDS, we agree with commenters that expressed concern as to whether there is sufficient industry adoption of this standard. We agree that there may be other methods of providing context aware reference information and, that in some cases, it may be appropriate to use other methods. Nonetheless, we remain convinced that the widespread adoption of HL7 Context-Aware Knowledge Retrieval standard for the retrieval of clinical reference information is an important capability for EHR technology to include. In response to commenters concerns, we have adopted this standard as an alternative to a general capability for referential decision support that does not require a standard. We took this approach because we recognize that in order for CDS to benefit from the HL7 Context-Aware Knowledge Retrieval standard a large enough pool of publishers providing content in a standards-compliant manner need to be available. Thus, had we required that the HL7 Context-Aware Knowledge Retrieval Standard be implemented in order to meet this certification criterion, our requirement could have caused many EHR technology developers to invest in work that would have resulted in no clinical value to an EP or EH—as there may not be a desirable selection of referential CDS content available for consumption through the use of this standard. In future rulemaking, we do expect to require this standard for certification, and we encourage EHR technology developers to begin plans to implement functionality that would support the incorporation of knowledge resources made available with this standard, and seek optional certification for 2014. While we do not certify knowledge publishers, we also encourage such organizations to adopt this standard as a method of providing patient and/or provider facing clinical content to EHR technology. We clarify that because we have expressed the HL7 Context-Aware Knowledge Retrieval Standard-enabled capability in the certification criterion with an ''or,'' EHR technology that is presented for certification with this capability would not also need to meet the general capability in order to be certified (i.e., one capability or the other will be sufficient to satisfy the certification criterion). Finally, we note that consistent with our adoption of the HL7 Context-Aware Knowledge Retrieval implementation guides (discussed in the patient-specific education resources certification criterion), we have also applied both implementation guides to this standard here.

CDS Configuration; CDS Interventions Automatically and Electronically Occur

Comments. Commenters requested that we clarify our language regarding the configuration of CDS for a given ''setting,'' when CDS interventions occur in the workflow, and requested that we clarify ''user'' to mean licensed healthcare professional.

Response. After further evaluation and consideration as to whether they could be unambiguously tested, we have removed references to setting and workflow from this portion of the certification criterion. However, we have retained the first requirement—that CDS can be configured ''based on a user's role.'' We do not constrain ''user'' to mean ''licensed healthcare professional,'' because some users of CEHRT may not be licensed healthcare professionals. For example, a clerical user or a patient user may interact with CEHRT in some way, and there is no reason that the CDS should not be configurable to expose appropriate interventions (screening reminders, for example) to a patient or clerical user. Our requirement here is simply that the system be capable of configuration based on the user's role in the system. We expect that a physician, nurse, clerical worker, and patient would all have different settings, as the CDS interventions to which they should be exposed may differ—or may have different presentation formats.

Comments. Many commenters expressed concern about the term ''when incorporated'' and the timing of CDS interventions being ''triggered'' based on data incorporated from the transition of care/referral summary.

Response. We agree that reconciling information into EHR technology requires many steps in order to determine what information is clinically significant and valid. We also understand that there are semantic interoperability challenges for data at this granular level that may make accurate and responsive CDS intervention triggers overly difficult and/or unreliable. In the Proposed Rule, we proposed that EHR technology would need to be able to ''enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i) of this section, when a transition of care/referral summary is incorporated pursuant to § 170.314(b)(1).'' We have revised this language to make explicit three instances that this certification criterion implicitly required:

(1) CDS interventions must be triggered based on data that is already recorded and stored within EHR technology;

(2) CDS interventions must be triggered when a patient's medications, medication allergies, and problems have been incorporated by EHR technology upon receipt of a transition of care/referral summary formatted in accordance with the Consolidated CDA; and

(3) For the ambulatory setting only, CDS interventions must be triggered when laboratory test results/values are incorporated by EHR technology upon receipt of a laboratory test report formatted in accordance with the LRI specification.

We clarified our interpretation of the term ''incorporate'' earlier in this final rule and have also clarified that the only time incorporation is implicated by the adopted certification criteria is for the incorporation of certain data as a result of a transition of care and, for the ambulatory setting only, when lab results/values are received and incorporated by EHR technology according to the LRI specification. This modification reduces the ''incorporated data'' that would be expected to trigger a CDS intervention to at most four out of the six originally proposed data elements (three out of six for inpatient EHR technology) (i.e., for the ambulatory setting it would be problems, medications, medication allergies, and laboratory tests and

values/results and for the inpatient setting it would be problems, medications, and medication allergies). Thus, for the purposes of this certification criterion, we clarify that EHR technology must be capable of demonstrating that it behaves differently in two states: before and after the incorporation of new information. We make no specification regarding the timing of events. That is—we do not specify that the EHR technology must ''trigger'' an intervention at the time of incorporation. For example, if a transition of care/referral summary is incorporated into a patient's record with a new medication allergy, the EHR technology will behave differently in this state (would alert the EP who attempts to prescribe this medication) than it did before the transition of care/referral summary had been incorporated.

CDS Source Attributes

Comment. Many commenters expressed support for transparency of the source attributes for CDS interventions. Some commenters expressed concern that requiring the display of such information could be distracting and not well accepted by end users. Commenters wanted clarification that the EHR technology must only enable the display, not be required to supply the content of the CDS intervention and reference source attributes.

Response. The intent of the source attribute requirement is to permit end users of EHR technologies to have transparent access to information about their CDS resources, interventions, and reference information. We do not require the automatic display of the source attributes, just the availability of the information to the end-user. For example, additional action may be required for a user to ''drill down'' or ''link out'' to view the source attributes of CDS. We are also not requiring that the EHR technology create the content for the source attributes. In a scenario where the EHR technology developer uses a third party content provider for a clinical reference or interventions it would be the third party from which the EHR technology developer would get this information.

Comment. One commenter suggested that the CDS source attributes should supply not only (A)–(D) but also the specific CQMs associated with the CDS intervention.

Response. We appreciate this comment, which aligns with the direction we stated in the Proposed Rule to align the capabilities of EHR technology, CQMs, and CDS for future stages of the EHR Incentive Programs. Since many CDS interventions are not today directly linked to CQMs, we will not implement this as a certification requirement. This does not prevent CDS intervention developers or EHR technology developers from providing and leveraging this additional attribute to assist EPs, EHs, and CAHs in meeting the expectations of the EHR Incentive Programs.

Comment. Several respondents wanted to eliminate the source attribute requirements for drug-drug and drug-allergy CDS interventions.

Response. Drug-drug and drug-allergy interventions are clinical decision support resources. We proposed that EHR technology be required to enable the user to review the attributes for each intervention or reference source for all CDS resources. We believe that this is important because most EHR technology developers acquire the clinical knowledge that is represented in CDS from external sources. These sources should be available to the EP, EH, or CAH for reasons stated in the Proposed Rule and above. We agree with the commenter that it may be unnecessary or inappropriate for each and every such intervention to offer all of the source attributes. For example, a drug-allergy alert that warns a user not to prescribe a medication to which that patient is allergic may not merit the same scrutiny by the EP, EH, or CAH as an intervention that informs a provider of an opportunity to prescribe a new medication for which a given patient may be a candidate. We therefore have modified this criterion to constrain the required information to a bibliographic citation and identification of the developer of the intervention, and further clarify that global citations are permitted in cases where all interventions of a given type are provided by the same reference. For example, if all drug-drug and drug-allergy alerts are part of product ABC, provided by company XYZ, then one global statement that attributes these references to this product and company is acceptable, and need not be made available for each and every intervention.

Comment. Some respondents requested additional clarity regarding the source attribute requirement. One commenter noted that further clarification is required for ''revision dates'' ''funding source,'' and ''developer of the intervention'' and noted that some CDS recommendations are developed in-house and may not be the result of published work. Additionally, they noted that ''developer of the intervention,'' and ''funding source'' may not be easily obtained.

Response. We describe these requirements as follows:

- ''Bibliographic citation'' (clinical research/guideline) is a reference (if available) to a publication of clinical research that documents the clinical value of the intervention. If no such reference exists, as may be the case for a locally developed intervention, the EHR technology should make this information available as well. In this scenario, an EP, EH, or CAH who is interacting with guidance offered by the EHR would see that there is no clinical evidence available. The absence of such information is, in this case, valuable information and may (or may not) cause the EP, EH, or CAH to heed or ignore the guidance. Note that our goal here is not to assess the quality or evidence basis of decision support, but to enable the EP, EH, or CAH to do so.
- ''Developer of the intervention (translation from clinical research/guideline)'' is the team, person, organization, department, or other entity that interpreted the clinical research and translated it into computable form. In some cases, this is a ''knowledge vendor.'' In some cases, this is the EHR technology developer, and in some cases it is an EP or an employee of an EH/CAH. In all cases, there is interpretation and translation from prose to logic that can be interpreted and managed by the EHR technology.
- ''Funding source of the intervention development technical implementation'' is the source of funding for the work performed by the ''developer of the intervention.'' In many cases, this will be the same organization as the developer of the intervention, but in some cases, this may be a government agency or Department of Health, commercial insurance carrier, employer, or biomedical product developer. For example, if the Health Department of State XYZ funds company JKL to create an intervention that translates a clinical practice guideline for management of disease ABC that can be incorporated into certified EHR technology as decision support, company JKL would be the ''developer of the intervention,'' while Health Department of State XYZ would be the ''funding source.'' In cases where this information is unknown, then the EP, EH, or CAH should have access to the fact that this information is unknown.
- *Patient-Specific Education Resources*

MU Objective

Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.
2014 Edition EHR Certification Criterion § 170.314(a)(15) (Patient-specific education resources).

We proposed to adopt a revised 2014 Edition EHR certification criterion that does not have the language ''as well as provide such resources to the patient'' at the end of the paragraph. This language is in the 2011 Edition EHR certification criterion, but is redundant of the capability expressed at the beginning of the paragraph. Additionally, we proposed to adopt the HL7 Context-Aware Knowledge Retrieval (Infobutton) standard, International Normative Edition 2010, as the required standard. We stated that HL7 Context-Aware Knowledge Retrieval standard is being increasingly used by more providers to electronically identify and provide patient-specific education resources. Therefore, we stated that it was appropriate to require EHR technology to enable a user to identify and provide patient-specific education resources based on the specified data elements and in accordance with HL7 Context-Aware Knowledge Retrieval standard.

Comments. With respect to patient-specific education materials, commenters focused on some aspect, or the potential affect, of the proposed inclusion of the HL7 Context-Aware Knowledge Retrieval standard. Some commenters supported its adoption as part of this certification criterion. Many commenters requested clarification on whether the use of the HL7 Context-Aware Knowledge Retrieval standard was mandatory (as a replacement of existing functionality). They qualified their support for the standard by suggesting that EHR technology developers (and their customers) be permitted to present education materials for any reference content using existing product capabilities or through a partnership with a content provider of such reference materials. These commenters reasoned that many EHR technologies are designed to allow for self-developed content or for use of third party content without the EHR technology having to go an external source. Some commenters suggested that the HL7 Context-Aware Knowledge Retrieval standard be positioned to augment, rather than completely replace other patient education mechanisms currently in place (e.g., vendor supplied, physician defined). Other commenters opposed the standard's adoption with some stating that its adoption was immature and that limiting the certification to just this standard would create limitations that could have negative effects on workflow and efficiency.

Response. Our goal is to enable EPs, EHs, and CAHs to provide patients with the best possible information in the most efficient and cost-effective ways possible. While we believe Infobutton meets this goal, we also agree with commenters that alternative means for identifying patient-specific education materials could meet this goal and should be available to EPs, EHs, and CAHs. Therefore, we are adopting a certification criterion that requires EHR technology to demonstrate a capability to identify patient-specific education materials using the HL7 Context-Aware Knowledge Retrieval standard (with the applicable implementation guide) as well as through another means (i.e., at minimum, 2 different ways, one of which is through the use of the HL7 Context-Aware Knowledge Retrieval Standard). By doing so, we believe EPs, EHs, and CAHs will have added flexibility in meeting the MU objective and measure and an improved ability to provide quality care to patients.

Comments. A few commenters recommended that we change the wording in the certification criterion. Specifically, they recommended that we change the phrasing in the proposed certification criterion from ''each one of the data elements'' to ''one or more of the data elements.''

Response. As noted above, we have revised the certification criterion to require that EHR technology demonstrate the capability of using HL7 Context-Aware Knowledge Retrieval Standard and another means to identify patient-specific education resources. We have also revised the language referenced by this certification criterion to make it clearer. The certification criterion requires that EHR technology be capable of identifying patient-specific education resources based on data included in a patient's problem list, medication list, and laboratory tests and values/results. To clarify, EHR technology must be capable of identifying patient-specific education resources based on data from any one of these categories. The identification of patient-specific education resources based on a combination of data from these categories would also be acceptable, but in order to demonstrate compliance with this certification criterion EHR technology must be able to identify patient-specific education materials, in some manner, for all of the categories (i.e., a combination of 2 out of 3 categories would be insufficient to satisfy this certification criterion's requirements).

Comments. A commenter stated that the HL7 Context-Aware Knowledge Retrieval Standard, International Normative Edition 2010 (Infobutton) by itself is not implementable, but it can be implemented in conjunction with one of the two available implementation guides: the URL-based Implementation Guide and/or the SOA-based Implementation Guide. They recommended that the certification criterion explicitly require implementation to at least one of the two implementation guides. Other commenters echoed the same point and recommended that the URL-based Implementation Guide as the best implementation guide to accompany the standard.

Response. We agree with the commenters that guidance is necessary for the implementation of the Infobutton standard. Accordingly, as recommended by the commenters, we are adopting the URL-Based Implementation Guide and the SOA-based Implementation Guide. We have adopted them as an ''or'' meaning that only one would need to be used to demonstrate compliance with this certification criterion. While we recognize that more EHR technology developers may use the URL-based version, we also wanted it to be possible for EHR technology to get certified to the SOA-based version.

Comment. One commenter suggested that CEHRT should permit integration of MedlinePlus Connect to enhance patient education with other languages and topics that may not be available in the vendor's patient education product. They reasoned that this would also help standardize patient education content across different EHR technology developers.

Response. We do not preclude the integration of MedlinePlus Connect in EHR technology and note that MedlinePlus Connect supports the Infobutton standard.

Comments. One commenter recommended that we amend the certification criterion to require that EHR technology identify patient-specific education resources that are compliant with low health literacy standards and provide those resources to the patient in the patient's preferred language. Another commenter provided an opposing view in stating that meaningful users should not be required to provide materials at specific reading and cultural competency levels. They reasoned that for short hospital visits (such as emergency department visits) identifying patients who would need

materials at different levels could be difficult.

Response. We appreciate the commenters' recommendations on both sides of the matter. The capability we require EHR technology to demonstrate to meet this certification criterion for the 2014 Edition EHR certification criteria sufficiently supports the correlated MU objective and measure. Therefore, we decline to require a more explicit capability at this time. We note, however, that a patient's preferred language should be recorded per the ''demographics'' certification criterion (§ 170.314(a)(3)). We would anticipate that, in an effort to be responsive to a patient and provide quality care, EPs, EHs, and CAHs would take the patient's recorded preferred language into consideration when providing patient education materials.

Comments. Many comments also included aspects about: The MU numerator and denominator associated with this certification criterion; the proposal to move the meaningful use objective to core from menu; when education materials needed to be provided; how they needed to be provided; principles behind providing education materials; the quality of the education materials; and that patient educational material need to be provided digitally and free of charge as well as free of any advertising and produced either without sponsorship by parties with conflicts, or with full editorial control vested in the authors, not the sponsors.

Response. We do not believe it is within the purview of certification to regulate some of these matters in the manner suggested by the commenters (e.g., requiring all education materials be free) and believe it best to have the policy for providing education materials set first through MU and then supported by certification. We direct commenters to the Stage 2 final rule for a discussion on the MU objective and measures, including how to interpret the measure, its requirements, and the numerator and denominator of the measure.

- *Transitions of Care*

MU Objective
The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.
2014 Edition EHR Certification Criteria
§ 170.314(b)(1) (Transitions of care—receive, display, and incorporate transition of care/referral summaries).
§ 170.314(b)(2) (Transitions of care—create and transmit transition of care/referral summaries).

We proposed two revised certification criteria for the 2014 Edition EHR certification criteria at § 170.314(b)(1) and (2). The first certification criterion we proposed would have required EHR technology to be able to incorporate a summary care record formatted according to the Consolidated CDA. The second certification criterion we proposed would have required that EHR technology be capable of creating and transmitting a summary care record in accordance with the Consolidated CDA, with certain specified vocabulary standards, and two specified transport standards. As noted in the Proposed Rule, the HITSC recommended a merged revised certification criterion for the 2014 Edition EHR certification criteria that would be generally applicable to both the ambulatory and inpatient settings, with a deviation based on the setting-specific information that would be included in the summary care record. However, based on stakeholder feedback received after the publication of the S&CC July 2010 final rule, we stated our belief that the criterion should be split into two separate certification criteria based on the capabilities required. We explained that this approach would provide developers greater flexibility for certification.

For the same reasons we discussed in the proposal for the new ''view, download, and transmit to 3rd party'' certification criterion (§ 170.314(e)(1)), we proposed to adopt the Consolidated CDA for this certification criterion because its template structure can accommodate the formatting of a summary care record that includes all of the data elements that CMS proposed be available for inclusion in a summary care record. We acknowledged that care plan, additional care team members, referring or transitioning provider's name and contact information as well as certain hospital discharge information are not explicitly required to be captured by separate certification criteria, unlike most other data included in the summary care record. We noted that the ability to capture these data elements is both implicit and necessary to satisfy this certification criterion (as well as the other certification criteria that rely on the same data). Therefore, we considered, but did not propose, adopting separate data capture certification criteria for each of these data elements in order to make it clear that they are required to be captured. We requested public comment on whether we should create separate certification criteria for all of these data elements in this final rule.

For certain other data elements in § 170.314(b)(2), we proposed to require that the capability to provide the information be demonstrated in accordance with the specified vocabulary standard. We noted that these vocabulary standards were either previously adopted or proposed for adoption in the Proposed Rule, consistent with HITSC recommendations. Additionally, we requested public comment on whether we should require, as part of the ''incorporate summary care record'' certification criterion proposed at § 170.314(b)(1), that EHR technology be able to perform some type of demographic matching or verification between the patient in the EHR technology and the summary care record about to be incorporated. We believed this would help prevent a summary care record from being combined with or attributed to the wrong patient.

We proposed that EHR technology would need to be capable of transmitting a summary care record according to both of the Direct Project's specifications for secure transport. We also proposed to adopt as an optional standard at § 170.202(a)(3) the SOAP-Based Secure Transport RTM version 1.0 [20] which was developed under the nationwide health information network Exchange Initiative and to which we stated EHR technology should be able to be certified. We included this option to provide added flexibility to those EPs, EHs, or CAHs that may seek to use EHR technology with the ability to transmit health information using SOAP as a transport standard in addition to SMTP to meet MU. We noted that, while we would only permit EHR technology to be certified to these two transport standards, we intended to monitor innovation around transport standards and would consider including additional transport standards, such as a RESTful implementation in this certification criterion.

Further, we requested public comment on whether equivalent alternative transport standards exist to the ones we proposed to exclusively permit for certification. We also requested comment on our proposed approaches for deciding whether additional transport standards would be appropriate and for adopting any such standards through interim final rulemaking with comment.

[20] *http://modularspecs.siframework.org/NwHIN+SOAP+Based+Secure+Transport+Artifacts.*

Additionally, in the context of the proposed limitations included as part of the proposed MU Stage 2 measure associated with this objective (which is percentage-based), we requested public comment on any difficulties EHR technology developers might face in determining the numerator and denominator values to demonstrate compliance with the automated numerator calculation or automated measure calculation certification criteria we proposed to adopt.

General Summary

Many commenters reiterated or pointed to the comments they issued in response to the view, download and transmit to a 3rd party certification criterion. Many commenters also repeated points about a consistent set of data to be referenced across the certification criteria that proposed the adoption of the Consolidated CDA. In that respect, we do not repeat those responses where we have already addressed comments in other parts of this preamble that would also be applicable to the transitions of care certification criteria. Similar to the other certification criteria where we received detailed groups of comments on distinct concepts, we have used subheadings to improve the preamble's overall readability.

Receipt/Receive

Comments. Some commenters expressed that the certification criterion proposed at § 170.314(b)(1) was ambiguous. They also indicated that ''upon receipt'' in the certification criterion implied a capability that should be explicitly stated—that the EHR technology be able to receive a transition of care/referral summary according to the same transport standards we require (and permit) for certification for the transmission of a transition of care/referral summary. These commenters argued that we needed to include this specificity because EHR technology should be tested for both its ability to send and receive data. Further they suggested that we change the paragraph heading to include ''receive.''

Response. We agree with commenters that the capability to receive transition of care/referral summaries according to the proposed transport standards was implied and that we should make it explicit. Further, in revising the proposed certification criterion to do so, we also noticed that § 170.314(b)(1) should mirror the same structure as § 170.314(b)(2) with its ''ambulatory setting only'' and ''inpatient setting only'' because we had just included a list of data in our proposal that mixed both settings. We are finalizing these changes as well as changing the paragraph heading to better describe the overall capabilities specified by this finalized certification criterion. Any changes to § 170.314(b)(2) in response to public comments, such as the applicability of certain transport standards are discussed in our responses below.

Display

Comments. Several commenters recommended that, at the very least, we include some form of ''backwards compatibility'' in this certification criterion by requiring EHR technology to be able to display transition of care/referral summary formatted according to the standards adopted as part of the 2011 Edition EHR certification criteria. They reasoned that many EPs, EHs, and CAHs will have 2011 Edition CEHRT capable of creating and displaying a transition of care/referral summary according to the CCD/C32 and CCR. Additionally, they stated that by not doing so, we would significantly limit the ability of trading partners to continue to communicate with each other as they each separately upgraded their EHR technology to the capabilities required by the 2014 Edition EHR certification criteria. These commenters indicated that this requirement would be a relatively low burden since it is already required for certification.

Response. We agree with commenters. We have revised the final certification criterion to require that EHR technology must be able to display in human readable format the data included in transition of care/referral summaries received and formatted according to each of the transition of care/referral summary standards we have adopted (i.e., CCD/C32; CCR; and Consolidated CDA). We believe this modification to the certification criterion, as expressed by commenters, results in a significant benefit while imposing very limited practical burden because it essentially builds on the 2011 Edition version of the certification criterion that we proposed to revise.

Comments. A couple of commenters expressed concern regarding hospitalizations with large volumes of data such as lab results and how this information would display in a summary document of considerable length.

Response. This certification criterion expresses that EHR technology must be able to display transition of care/referral summaries received according to any one of the three adopted standards mentioned in the above response. It does not, however, dictate how that information is displayed to a user. Those design decisions are fully within an EHR technology developer's discretion.

Incorporate

Comments. We received a significant number of comments related to the specific ''incorporate'' capability expressed in this certification criterion. Many contended that the general description we provided at the beginning of the Proposed Rule was too generic, ambiguous, or inconsistent with their understanding of what it meant to ''incorporate'' data as this certification criterion described. Commenters offered many perspectives on what incorporation should mean for this certification criterion. Most commenters described incorporation to mean the EHR technology's ability to store and reference data from a transition of care/referral summary.

Many commenters stated that this proposal went far beyond what was required in the 2011 Edition EHR certification criterion's requirements and that it seemed to require that each and every data element referenced be incorporated as structured data. These commenters argued that for the 2011 Edition certification criterion, EHR technology only had to be able to incorporate the CCD or CCR transition of care/referral summary as a whole, thus maintaining its integrity. Some commenters stated that incorporating an entire clinical summary might trigger the creation of a new encounter. Further, they added that for the 2014 Edition version, the only data that should be required to be incorporated (and that should be decomposed from the transition of care/referral summary) should be the same data specified in the ''clinical information reconciliation'' certification criterion (i.e., problems, medications, and medication allergies) and focus on these data ''at a minimum.'' Other commenters argued that it made no sense to incorporate all of the data specified in the Proposed Rule because the data would be contextually specific—and could lose its semantic value if removed from the context of the whole document.

Response. We agree with commenters that the single description for ''incorporate'' in the Proposed Rule was insufficient to provide the clarity necessary for this certification criterion. As many comments expressed, and as we clarified in the beginning of this final rule, we intended for the term ''incorporate'' to mean that EHR technology would be able to process the structured data contained in those three

Consolidated CDA sections (medications, problems, medication allergies) such that it could be combined (in structured form) with data already maintained by EHR technology and would subsequently be available for use, such as to be used as part of the clinical information reconciliation capabilities (expressed in the certification criterion adopted at (§ 170.314(b)(4)). We have revised this certification criterion to make this distinction clear.

In consideration of comments, such as those that indicated it may make no sense to incorporate specific data, we believe that there is clinical value to the extraction and individual display of the individual sections of the Consolidated CDA. To ensure that an EP, EH, or CAH, can reap the most benefit from a Consolidated CDA formatted transition of care/referral summary, we have added to this certification criterion a specific capability that EHR technology 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. For example, if 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), such as a patient's procedures and smoking status, EHR 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. We intend for testing and certification to verify that the document header information can be displayed with whatever individual sections are selected, but leave the ultimate quantity of header data to be displayed through implementation up to the EHR technology developer and its customers' preferences.

We recognize this certification criterion is more rigorous than the 2011 Edition EHR certification criterion, but believe that it is necessary to continue to introduce more demanding certification requirements for interoperability in order to advance our policy objectives for widespread electronic health information exchange. We stress that an EHR technology's ability to incorporate data for medications, medication allergies, and problems in structured form from a Consolidated CDA formatted document is the bare minimum necessary for EHR technology to meet this certification criterion. Even though we do not explicitly require more data to be incorporated in a structured form from a Consolidated CDA formatted document, we highly encourage EHR technology developers to go beyond this minimum as we intend to consider a more rigorous incorporation requirement in our next edition of EHR certification criteria. Finally, we believe our response under the ''display'' heading addresses the comments about incorporating a transition of care/referral summary as a whole, since such a capability would be addressed by the display requirement in this certification criterion.

Comments. A few commenters stated that incorporation should not be automated and that there is a potential safety issue with bringing in data elements that have not been reconciled. Another commenter noted that one of the reasons incorporation cannot be automated is because many EHR technologies require that a term be in their ''problem list master file'' in order to get onto the problem list and that many EHR technologies have local problem terms that are mapped to SNOMED–CT. As a result, they stated that one cannot assume that two CCDs, each having a problem mapped to the same SNOMED–CT code, are both referring to exactly the same thing. They suggested that this capability be designated as optional. A couple of commenters noted that EPs, EHs, and CAHs should have some control over how exactly they want to be able to incorporate data into their EHR technology as part of their practice/organization.

Along these same lines, commenters responded to our question regarding whether some form of demographic matching would be important to include for this certification criterion. Commenters responded favorably, but requested that we not dictate a standard or any particular matching methodology so as to permit a range of different options and to let innovation continue in this area. One commenter stated that EHR technology must perform patient matching in order to aggregate PHI from multiple sources that provide electronic feeds into the EHR technology. Additionally, the commenter noted that the EHR technology developer typically determines the most appropriate patient matching algorithm based on a number of factors relating to the data available in order to facilitate a correct patient match. They also stated that some EHR technology developers may choose a very robust matching capability based on available demographics or practice size. Another commenter requested guidance on what data would be used for patient demographic matching. While a different commenter recommended that we establish a minimum set of demographic information that could be used to accurately match patient records.

Response. We appreciate commenters' feedback and expressed concerns. We anticipate that EHR technology developers will be able to automate the incorporate capability in some manner, but this certification criterion does not necessarily require that it be fully automated. It is our understanding and, it was implied by the certification criterion, that some form of matching would occur when a transition of care/referral summary is received in order to correctly determine that the document as a whole (as discussed under the ''display'' heading) was attributed to the right patient. Further, that upon receipt of a transition of care/referral summary is the appropriate point at which to verify that the transition of care/referral summary is being attributed to the correct patient. Accordingly, we have not included this type of matching as part of the clinical information reconciliation certification criterion since the data will have already been attributed to a particular patient at the point in time reconciliation is executed. Finally, we have revised this certification criterion to include a general statement that the EHR technology must be able to demonstrate that a transition of care/referral summary received is or can be properly match to the correct patient. As requested by commenters, we have intentionally left this requirement flexible to permit many different ways for this capability to be designed. As such, we decline to provide specific guidance on particular demographic information except to note that the demographics certification criterion would be a good starting point in addition to any data that may be available in the header of a transition of care/referral summary. We encourage EHR technology developers to apply this specific capability to other capabilities where it may prove beneficial.

Comments. Some commenters asked that we clarify that information made available in an HIE or a portal counts as incorporation for this certification criterion.

Response. Considering the response above and how we have explained our interpretation of ''incorporate,'' we do not believe or see how this could satisfy the capability required by the certification criterion.

Comment. A commenter in support of incorporating problems, medications,

and medication allergies suggested that this data should be incorporated into EHR technology in such a way that those data elements can be used for real-time clinical decision support and recommend that the ONC consider this as an additional criterion.

Response. We refer readers to our discussion of the clinical decision support certification criterion.

Create and Transmit (now Also Applicable To Receive as Part of § 170.314(b)(1))

Comments. As noted in the view, download, and transmit to a 3rd party certification criterion's comment and response section, we indicated that the only place where the data type ''encounter diagnoses'' would be included was as part of a transition of care/referral summary in the transition of care certification criterion. Similar to the comments we received and discussed related to ''procedures,'' some comments supported the use of ICD–10–CM while others stated that we should refer to SNOMED CT® and only SNOMED CT® for the same reasons they stated before (e.g., clinical accuracy versus a billing diagnosis code set). One commenter stated that both ICD–10–CM and SNODENT should be a requirement for diagnoses coding in dental systems. They reasoned that SNODENT has been mapped to ICD–9–CM and the mappings between SNODENT and ICD–10–CM are being developed.

Response. We appreciate commenters' feedback. As with procedures, commenters provided many different perspectives on the appropriate vocabulary to adopt for encounter diagnoses. Because this is a billing data type, we have decided to finalize our proposal to allow for the use of ICD–10–CM to represent encounter diagnoses in addition to permitting SNOMED–CT. We believe this is the best approach to take for all parties involved. Additionally, the National Library of Medicine has created a publicly available mapping from SNOMED–CT to ICD–10–CM, available at *http://www.nlm.nih.gov/healthit/meaningful_use.html.* This mapping is available to any EHR technology developer, or practice management/billing system developer for the translation of SNOMED CT® to ICD–10–CM. In this way, EHR technology may send a representation of encounter diagnosis using either SNOMED–CT or ICD–10–CM. Since providers will most likely be using SNOMED CT® for the selection of problems, this criterion allows for the use of only clinical vocabularies in such clinical systems and the association of problems with encounters, thereby encouraging the translation of SNOMED CT® to ICD–10–CM to occur in an administrative system. By permitting ICD–10–CM to be used to represent encounter diagnosis for certification, we also accommodate EHR technology developers who choose to make this translation within the clinical system as well. We decline to accept the recommendation for us to adopt SNODENT for the same reasons we provide elsewhere in this final rule in response to this comment.

Comments. In response to our question as to whether we should create separate certification criteria for the data elements implicit and necessary to satisfy this certification criterion (as well as the other certification criteria that rely on the same data) some comments expressed support while others opposed doing so and suggested it was unnecessary. Those who opposed the adoption of separate certification criteria for the additional data (e.g., care plans) stated that while standards do not exist at the present time for these elements, they can be incorporated in the Consolidated CDA as text. They did, however, add that because no standards exist, we should consider deferring their adoption until the next edition of EHR certification criteria.

Response. We thank commenters for responding to the question we posed. As suggested by those commenters that opposed the adoption of explicit certification criteria for each of these additional elements, we have not done so. We agree with the logic provided by commenters. So long as the Consolidated CDA can support this information, we believe it is sufficient to continue our approach of referencing this data within the applicable certification criteria. Consistent with our general approach to support MU, we have made sure to align all of the data specified and expected by CMS in applicable certification criteria. Thus, unless CMS removed a particular data element/type, we have included the data element/type in our final rule for the applicable certification criteria.

Comment. A commenter stated that there appeared to be a hidden requirement for CEHRT to translate local codes to standard codes for all data in all instances, including when the original source of the data did not provide the data in standard codes. They suggested that in instances where the EHR technology simply passes-through the data that the requirement to use a standard vocabulary for outbound data exchange be waived. They further explained that when source data such as laboratory results or documentation from non-CEHRT/HIT is received by the CEHRT it may not contain data according to the adopted standard vocabulary. They contended that translating such data to a standard vocabulary should be the responsibility of the data source (to ensure the standard vocabulary is used most appropriately). They noted that downstream translation may not capture the translation subtleties that are clear within the source system's environment. They concluded by stating that it was unreasonable for us to implicitly or explicitly require that outbound data exchange from the CEHRT always apply a standard vocabulary to data that the CEHRT did not itself create until all relevant source systems utilize standard vocabularies.

Response. We agree that there could be scenarios in which an EP, EH, or CAHs CEHRT receives data from a source that has not formatted the data according to the applicable adopted vocabulary standard. In instances where the EP, EH, or CAH's CEHRT receives data from an outside source, we acknowledge that requiring the CEHRT to translate the data into an adopted standard vocabulary could alter its intended meaning. We understand that there may be scenarios in which local or proprietary codes are transmitted in a transition of care/referral summary, laboratory report, or other exchanged document. Further, we agree with this commenter that the responsibility of the sending EP or EH/CAH is to send information with standard terms, and in the case when such standard terms are not used, it should not be the responsibility of the receiving EP or EH to translate local or proprietary codes into standard codes. However, we emphasize that for the purposes of certification, and demonstrating compliance with this certification criterion, EHR technology will need to be tested and certified as being able to apply all of the adopted standard vocabularies to data required to be included in a Consolidated CDA formatted transition of care/referral summary. This response is applicable to the other certification criteria to which this clarification would apply.

Comments. Many commenters supported our proposal to require the Applicability Statement for Secure Health Transport specification (the primary Direct Project specification) and the second Direct Project specification (XDR and XDM for Direct Messaging). Others supported our reference to the SOAP-based transport standard as well. Some commenters contended that we should require both transport approaches for certification. Other commenters stated that we should only

require the primary Direct Project specification. While others specified that we should reference the XDR and XDM for Direct Messaging specification as a bridge for the primary Direct Project specification and the SOAP-based transport standard.

Response. In considering the range of comments received, we have finalized a modified certification approach with respect to transport standards. We have adopted, as proposed, that the Applicability Statement for Secure Health Transport specification be a required condition of certification as part of this certification criterion. We have removed the XDR and XDM for Direct Messaging specification as also being required in lieu of a broader range of options for certification. Thus, to be certified to this certification criterion an EHR technology must enable a user to electronically transmit a transition of care/referral summary in accordance with the Applicability Statement for Secure Health Transport specification. This requirement sets a baseline for EHR technology certification and enables simple and secure SMTP-based exchange. Additionally, because this certification criterion is part of the Base EHR definition, all EHR technology used by EPs, EHs, and CAHs and that meets the CEHRT definition will, at a minimum, be capable of SMTP-based exchange. For the reasons we discussed under the ''view, download, and transmit to 3rd party'' certification criterion earlier in this preamble, we have adopted the updated version of this specification that was established by the stakeholder community during this final rule's drafting.

To permit additional flexibility and options for EHR technology developers to provide their customers with EHR technology that has been certified to support an EP, EH, or CAH's achievement of the ''transitions of care'' MU objective and associated measure, we have adopted two optional certification approaches for transport standards. For each option, EHR technology would need to demonstrate its compliance with both of the identified specifications in that option in order to be certified to the option.

- The first option would permit EHR technology to be certified as being in compliance with our original proposal: Certification to both the Applicability Statement for Secure Health Transport specification and the XDR and XDM for Direct Messaging specification.
- The second option would permit EHR technology to be certified to: The Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 standard and the XDR and XDM for Direct Messaging specification.

We have included the XDR and XDM for Direct Messaging specification as a required specification for both of these options because it serves as the bridge or translator for electronic exchange partners that engage in SMTP to SOAP and SOAP to SMTP exchanges.

Comments. A few commenters noted that the proposal to adopt the Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification was confusing and requested that we clarify whether its adoption permitted the use of other nationwide health information network specifications to be used (e.g., patient discovery, document query, document retrieval). Some of the same commenters also suggested that we added the IHE–XDR profile as an implementation guide for the proposed standard. Last, these commenters requested that we change the paragraph heading for the transport standards so as not to imply their use is limited to directed exchange.

Response. We seek to clarify any confusion that may have been caused by our proposed adoption of the SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification. As indicated within the specification, its purpose is to ''define the primary set of security and transport protocols needed to establish a messaging, security, and privacy foundation for health information exchange.'' Further, it is ''constrained to technical specifications for security and transport protocols and does not address any content specifications.'' Last, it is ''intended to provide an understanding of the context in which the web service interface is meant to be used, the behavior of the interface, the Web Services Description Language (WSDLs) used to define the service, and any Extensible Markup Language (XML) schemas used to define the content.

This specification, and not IHE designated specifications, was purposefully adopted because it serves as the baseline SOAP specification on top of which other (March 1, 2012 effective) Nationwide Health Information Network Exchange specifications can be implemented. If an EHR technology is presented for certification to this optional transport standard, we intend for testing and certification to establish that the SOAP specification is properly implemented (i.e., EHR technology's ability to send and receive messages in accordance with the specification). Because this specification serves as the underlying set of web services protocols for other more detailed context/use case specific specifications, we clarify that so long as EHR technology is certified to this baseline SOAP specification other more detailed/use case specific specifications may be used in addition to, or on top of, this specification (i.e., not in lieu of).

With respect to the recommended IHE profile, we did not accept this recommendation. We have included the bridge specification in the XDR and XDM for direct messaging specification and have concerns about the testability of the IHE–XDR profile. As we understand it and as currently described in the IHE Technical framework, the IHE XDR is a ''pattern'' of a transaction that can be tailored and implemented by EHR technology developers as they wish, based on a particular use case. Additionally, both of the transport standards adopted in this final rule can be used independent of IHE XDR profile. This does not preclude EHR technology developers from also implementing it outside of certification, but we decline to require it as a condition of certification.

Finally, we have removed the paragraph heading in § 170.202 as indicated by commenters so as not to imply that the specifications can only be used in the context of directed exchange.

Comments. Commenters raised several questions and concerns related to the proposed Direct Project specifications and how EHR technology would be tested and certified to the transitions of care certification criteria. Commenters indicated that there are multiple ways to deploy, configure, and implement EHR technology to meet the specifications. Some asked that we clarify whether all implementation options must be simultaneously supported or if some were intended to be prohibited. Further these commenters stated that only one test of a particular implementation/configuration would be necessary to verify that an appropriate SMTP + S/MIME communication was correctly structured, but all implementations would rely on that capability to be present. Commenters recommended that we clarify what would be required to demonstrate compliance with these certification criteria. They recommended that testing and certification focus on EHR technology's ability to correctly create and receive messages formatted in accordance with the Applicability Statement for Secure Health Transport specification. They concluded by stating that this approach would enable EPs, EHs, and CAHs to utilize other email infrastructures without requiring EHR technology

developers to test with multiple infrastructures.

Response. We thank commenters for the detailed comments and in some cases illustrations to describe the different deployment and configurations anticipated by the Applicability Statement for Secure Health Transport specification. These detailed comments greatly aided our policy deliberations. We agree with commenters on the approach that should be used to test and certify whether EHR technology is in compliance with the Applicability Statement for Secure Health Transport specification. Specifically, we agree that testing and certification should not focus on particular deployments or configurations, but rather on what will remain constant across those variances—EHR technology's ability to correctly produce and receive SMTP + S/MIME messages formatted in accordance with the Applicability Statement for Secure Health Transport specification. We further clarify that we do not intend for testing and certification to focus on the particular email protocols that may be implemented to support the routing of these messages, such as Internet Message Access Protocol (IMAP), Post Office Protocol (POP) and other vendor-specific proprietary protocols. These capabilities and others such as mailbox management, storage, and forwarding of received messages that would be implementation or deployment specific would not be assessed as part of testing or as a condition of certification.

Further, we expect that the National Coordinator will approve a test procedure for the transitions of care certification criteria that rigorously assesses EHR technology's ability to transmit and receive electronic health information according to the adopted transport, content exchange, and vocabulary standards. We anticipate that this test procedure will be specified to ascertain the EHR technology's ability to engage in standards-based exchange with any other EHR technology that has also implemented the standards we have adopted. To enable this form of electronic testing, the NIST has developed a conformance test tool that receives and validates a Consolidated CDA formatted file from the EHR technology under test. The conformance tool will be a part of a ''test bed'' that simulates exchange between a test EHR technology and a standards-compliant EHR technology. This will eventually allow for all levels of interoperability to be assessed in the electronic exchange of transition of care/referral summaries. This capability will also provide a future platform for testing more comprehensive forms of interoperability between EHR technologies.

Comment. A commenter requested that we clarify whether a health information exchange using only CONNECT to exchange could meet the certification criterion. Another commenter asked that we confirm that the transport capabilities can be demonstrated by a Complete EHR or EHR Module itself, or through demonstration by the Complete EHR or EHR Module to achieve the transport capability through integration with a service provider—such as a network or health information service provider (HISP). They stated their interpretation that the current definition of an EHR Module permits a combination of a service and a component to be certified.

Response. While we would need to examine a specific fact pattern to issue a definitive response, it seems possible for a health information exchange using CONNECT to seek certification to this certification criterion. We have always maintained and reaffirm that any EHR technology that can demonstrate compliance with a certification criterion can be issued an EHR Module certification as evidence that the capability the EHR technology included was certified. We interpret and use the term EHR technology (and intentionally not the term EHR) broadly so as to permit innovative market-based electronic exchange solutions to be paired with other EHR technology that performs clinically focused capabilities. Thus, to the degree that a HISP or like entity would be performing a capability for which certification is required and an EP, EH, or CAH would like to use the entity's technological capabilities as a way to meet the definition of CEHRT, the entity would need to seek certification for the technical capabilities that its systems can perform as if those capabilities were natively part of the EP, EH, or CAH's CEHRT. In these situations, we highly encourage EHR technology developers to work together to make the use of these capabilities as seamless as possible.

Comments. Commenters suggested that ONC offer guidance on how the sending system will know the transport protocol understood by the receiving system unless that is something the Health Information Service Provider (HISP) would be responsible for indicating so the sending system sends using XDR or XDM appropriately.

Response. Pursuant to our responses above, we believe this comment drifts into a specific implementation dependent scenario. However, we will consider whether additional guidance is required after this final rule to assist stakeholders.

Comments. Several commenters stated that they reviewed potential RESTful transport alternatives and concluded that the alternatives lacked maturity and sufficient testing. A few commenters supported RESTful as an optional standard.

Response. We agree with those commenters that have concluded potential RESTful transport alternatives lack sufficient maturity at this time for adoption. We will, however, continue to monitor the testing and implementation of RESTful transport alternatives to determine whether they have reached a maturity sufficient enough to consider for adoption.

• *Clinical Information Reconciliation*

MU Objective
The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.
2014 Edition EHR Certification Criterion
§ 170.314(b)(4) (Clinical information reconciliation).

In the Proposed Rule, we proposed to revise this certification criterion and adopt as part of the 2014 Edition EHR certification criteria an expanded version that focuses on the reconciliation of data in each of a patient's medication, problem, and medication allergy lists. We proposed to adopt a revised certification criterion at § 170.314(b)(4) which we labeled as ''clinical information reconciliation'' to express the three specific capabilities that EHR technology would need to include.

We specified that EHR technology would first need to be able to electronically display the data from two or more 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 of the information. We proposed that the second specific capability EHR technology would need to include would be to enable a user to merge and remove individual data. We clarified that, while not required or expected for certification, this capability could be designed to automatically suggest to the user which medications could be merged or removed. The third and final specific capability we proposed that EHR technology would need to include would be to enable a user to review and validate the accuracy of a final set of data elements and, upon a user's confirmation, automatically update the patient's medication, problem, and/or medication allergy list.

In our proposal, we emphasized that EHR technology's role is to be assistive and not to determine without human judgment which data elements should be reconciled. Thus, we noted that this third specific capability would require EHR technology to present a final set of merged data for a user to validate and confirm before updating the prior list. Finally, we requested public comment on whether as part of this certification criterion we should require EHR technology to perform some type of demographic matching or verification between the data sources used.

Comments. Commenters were generally in favor of the proposed clinical information reconciliation certification criterion. Many agreed with our proposal to expand reconciliation to include problems and medication allergies, but some stated that it exceeded what was minimally required for meaningful use and that we should just keep the certification criterion focused on medication reconciliation. A couple of commenters stated that the certification criterion was over specified, premature, and prescribed workflow. One followed suit and stated that the requirement to merge the data from a source and automatically update from a foreign source requires common data models and terminology sufficient to instantiate the medication, medication allergy, or problem into the receiving system and that these models and terminologies are not fully defined.

Response. We appreciate commenters support and constructive feedback. We have finalized this certification criterion with specific modifications as detailed below in other responses. We believe these changes may address some commenters concerns, however, we have maintained this certification criterion's scope to include medications, medication allergies, and problems. We believe this is the minimum that EHR technology should be able to assist EPs, EHs, and CAHs reconcile. Further, as we have noted in the transitions of care certification criterion § 170.314(b)(2), we intend for these same three data types to be able to be incorporated from a transition of care/referral summary formatted according to the Consolidated CDA standard and subsequently available to use for reconciliation as part of this capability. We anticipate that test procedures will be developed to thread these steps together where EHR technology presented for certification includes both capabilities (transitions of care incorporation and clinical information reconciliation). While we typically do not express capabilities in certification criteria that exceed what would be necessary to support meaningful use, we remind readers that our authority to adopt certification criteria is not limited by meaningful use. That is, meaningful use does not set a ceiling for certification. Rather, we generally use it as the baseline upon which we propose and adopt, in some cases, more rigorous requirements.

Comments. Some commenters asked for clarification regarding the term ''source'' in the certification criterion and what would be used to indicate source. They asked if the information would be needed in the future, would be stored as part of the patient record, or if a link could be used to get to the source. Some did not support including this information.

Response. We believe that, at a minimum, EHR technology needs to be able indicate to a user the data's source (i.e., where the data came from). For the purposes of this certification criterion and its linkage to the transitions of care certification criterion (§ 170.314(b)(2)), we intend to focus certification on the identification of the source from the transition of care/referral summary's header. However, we do not preclude other sources, such as patients from being able to be identified as part of this certification criterion. Given the additional specificity in this 2014 Edition version, we intend to incrementally increase and enhance the assistive power of this capability over time.

Comments. Commenters asked what ''last modification date'' in the certification criterion meant. They asked whether it was the last date of medication reconciliation or the date that the medication was added or updated. Some did not support including this information.

Response. For the purpose of this certification criterion, ''last modification date'' should be interpreted differently for each data type. For medications, it should be interpreted as the last date the medication was documented, ordered, prescribed, refilled, dispensed or edited. For problems it should be interpreted as the last date the problem was documented or edited. For medication allergies, it should be interpreted as the date that the medication allergy was last documented, edited, or updated.

Comments. Some commenters requested clarification on the term ''merge'' in the certification criterion and what our expectation was for merge. They also asked that we clarify that merging would only be for medications, medication allergies, and problems.

Response. We interpret ''merge'' to generally mean that EHR technology assists a user in creating a single list that is representative of the medications, medication allergies, or problems that are relevant to a patient. However, we believe that an approach using plain language to express the desired outcome would make this certification criterion clearer. It would also represent the many acceptable approaches we had in mind when we drafted this proposed certification criterion. Accordingly, we have modified § 170.314(b)(4)(ii) to state that EHR technology would need to enable a user to ''create a single reconciled list of medications, medication allergies, or problems.'' How this would be accomplished is up to the EHR technology developer, but could include a user's ability to merge equivalent elements and remove/deactivate no longer relevant information.

Comments. Some commenters requested clarification that ''confirm'' was meant to be interpreted as the list itself and not each individual element within the list.

Response. Confirm is meant to apply to the single reconciled list (not each element) once it meets a user's satisfaction.

Comments. A couple of commenters requested that we expand this certification criterion to require that EHR technology be capable of conducting medication reconciliation using electronic health information exchange to obtain a medication history.

Response. We appreciate this suggestion and recognize its value, however, we did not propose this type of extended capability, nor does meaningful use presently require it. Thus, we encourage EHR technology developers to consider including this capability if they have not already and we intend to bring this topic to the HITSC for recommendations on our next edition of certification criteria.

Comments. Commenters requested that we clarify that the reconciliation process does not require all reconciliation activities to occur in one system function but may be performed in more than one function so that the functions can be placed in appropriate workflows. Commenters also asked that we clarify that each list type was expected to be separately reconciled and not that we expected two or more different list types to be reconciled at the same time (e.g., medication list and problem list). They suggested that we revise the certification criterion to expressly indicate that it would be at least two lists or at least two sources.

Response. To clarify, we did not intend to imply that the reconciliation capability had to happen all in one step. For instance, if medications are reconciled at a different points in the

clinical workflow than problems, this would not be precluded by the certification criterion. However, the same underlying reconciliation capability required by the certification criterion would need to be initiated for each of those different list reconciliations. To make this clear we have modified the certification criterion, as commenters suggested to say ''from at least two list sources.'' We also wish to further explain for commenters that as the certification criterion begins to express each specific capability there is the following introductory text, ''For each list type:'' This should and is meant to be interpreted as separately applying to each list type. For instance, (b)(ii) would be interpreted as ''For each list type enable a user to create a single reconciled list of medications, medication allergies, or problems''. As in, there would be a single list for medications, a single list for medication allergies, and a single list for problems.

Comments. A few comments asked that we provide an example for what an acceptable capability for this certification criterion would be. A commenter explicitly suggested (as part of our example) we clarify that, at a minimum, the EHR technology should have the ability to simultaneously display and update the appropriate list type.

Response. First, we agree with the commenter that EHR technology should have the ability to simultaneously display the list type that is actively being reconciled. We have modified the certification criterion to make this implicit requirement explicit. We believe this is a critical clarification so as to prevent EHR technology from being certified that requires a user to toggle between different views to reconcile data for one list type. As far as an example goes, (and keeping in mind the revisions we have made to this certification criterion) assuming a transition of care/referral summary has been received as part of a transition of care, an EP's CEHRT would need to be able to receive the transition of care/referral summary and make a logical identification of the medications, medication allergies, and problems from the Consolidated CDA formatted transition of care/referral summary pursuant to the incorporation requirement. Next, at the appropriate points in the EP's workflow, the EP would be able to interact with CEHRT to create a single reconciled list for each of the data included in the medication, medication allergy, and problem lists. For each of these lists, once the EP has the data reconciled to his or her satisfaction, the EP would be able to review the list and confirm the reconciled list, which would then be updated and saved as the single medication, problem or allergy list.

Comments. Commenters requested clarification regarding the scenario where the source list is unstructured data. One stated that if the source list is unstructured, then whatever manner the EHR enables unstructured data to be presented which could subsequently be reconciled through manual transcription should be acceptable for certification. One commenter suggested that medications should be reconciled in whatever process the EHR technology supported for the 2011 Edition EHR certification criterion. Other commenters requested clarification that a document received as a Consolidate CDA must contain structured data. They stated that for unstructured data, certification should not require corresponding items to appear on the reconciliation screens.

Response. We agree with commenters suggestions. In the event that data is in unstructured form, any method implemented by which the EHR is capable of assisting in reconciliation is acceptable. Presumably, this is how (at a minimum) reconciliation is performed in accordance with the 2011 Edition EHR certification criterion. With respect to data received from a document formatted in accordance with the Consolidated CDA, we expect EHR technology to be tested on its ability to utilize structured data to assist in the reconciliation process.

Comment. One commenter stated that reconciliation based on two or more lists has been and would continue to be artificial. They stated that the purpose of reconciliation is to reset and consider the patient at transitions of care. Further, they stated that a transition of care may or may not require reconciliation between two or more autonomous, overlapping lists. As an example they indicated that they support both ambulatory and acute care and that a transition from ambulatory to acute care involves a pruning, adding, and filtering the problem list from the ambulatory setting to a working problem list in the acute care setting. They stated that this does not require a demographic match nor does it involve foreign lists. They stated that if the intent of the Proposed Rule was to include lists coming from different legal entities or systems that we should state that it is.

Response. While we understand this commenter's concern, we believe it is somewhat misdirected. This certification criterion is appropriate and broadly applicable to a vast majority of EPs, EHs, and CAHs, many of which will be getting data from multiple sources. Further, this certification criterion applies to EHR technology as a capability required for certification and does not prevent the actions described by the commenter from taking place.

• *Incorporate Laboratory Tests and Values/Results*

MU Objective
Incorporate clinical laboratory test results into Certified EHR Technology as structured data.
2014 Edition EHR Certification Criterion
§ 170.314(b)(5) (Incorporate laboratory tests and values/results).

In the Proposed Rule, we noted that, although the HITSC did not recommend that we revise the ''incorporate laboratory test results'' certification criterion (adopted as part of the 2011 Edition EHR certification criteria at 45 CFR 170.302(h)), we believed that we should leverage the significant progress made by the S&I Framework LRI initiative. We believed that we could achieve this by proposing revisions to this certification criterion for the ambulatory setting. We acknowledged that, by requiring ambulatory EHR technology to be capable of receiving laboratory tests and values/results formatted in accordance with the HL7 2.5.1 standard and the LRI implementation guide, it would be significantly easier and more cost effective for electronic laboratory results interfaces to be set up in an ambulatory setting (i.e., minimal additional configuration and little to no additional/custom mapping). Moreover, we stated that it would increase the likelihood that data would be properly incorporated into ambulatory EHR technology upon receipt and thus, facilitate the subsequent use of the data by the EHR technology for other purposes, such as CDS. We proposed to adopt LOINC® version 2.38 as the vocabulary standard, because the LRI specification requires the use of LOINC® for laboratory tests. We requested public comment on whether the proposed standards for the ambulatory setting should also apply for the inpatient setting and whether the LRI specification (even though it was developed for an ambulatory setting) could be adopted for certification of the inpatient setting as well. Besides the proposed revisions discussed, we also proposed to use the term ''incorporate'' to replace the terms ''attribute,'' ''associate,'' and ''link'' which were used in the 2011 Edition EHR certification criterion.

In the Proposed Rule, we acknowledged that the LRI specification was undergoing HL7 balloting and stated that we intended to continue to monitor its progress and anticipated that a completed specification would be available prior to the publication of this rule.

Comments. A few commenters commented on our proposal to specify HL7 2.5.1 as the content exchange standard for the receipt of laboratory test results. A couple of these commenters recommended that we should permit HL7 2.3.1 and signal a direction to the market. Another opposed this requirement because they opposed any meaningful use requirement that would restrict laboratory results sent in HL7 2.5.1 to count towards the meaningful use objective this certification criterion supports. They contended that a vast majority of lab results are in HL7 2.3.1.

A couple of commenters indicated that we had erred in specifying HL7 2.5.1 because the Laboratory Results Interface (LRI) specification references both HL7 2.5.1 elements and HL7 2.7.1 elements. Thus a literal interpretation of what we proposed would create conflicts for implementers. These commenters suggested that only the LRI specification should be referenced as the standard. Another commenter suggested that we clarify that code sets should be used in accordance with the guidance provided in the LRI specification. One commenter recommended that we reference a transport standard to transmit laboratory test results.

Response. As we have stated in other places in this final rule, just because EHR technology is required to demonstrate certain capabilities for certification, it does not necessarily mean that those capabilities must always and only be used to demonstrate MU. Those policies are established by CMS.

After conducting additional research, we agree with commenters that we erred in referencing the HL7 2.5.1 standard in addition to the LRI specification. We have removed the reference to the HL7 2.5.1 standard in this certification criterion. We also note, for the same reasons we discussed earlier in this preamble in adopting it for the ''transmission of electronic laboratory tests and values/results to ambulatory providers'' certification criterion (§ 170.314(b)(6)), we have adopted for this certification criterion the LRI implementation guide approved as a Draft Standard for Trial Use in July 2012 by HL7. We clarify that with the exception of the baseline minimum version of LOINC® that must be supported by EHR technology, we expect, in adopting this specification that it will be followed and implemented as authored. Further, we note that consistent with other certification criteria that rely on lab test results, we expect that EHR technology certified to this certification criterion will be able to make available for subsequent use (such as clinical decision support) the structured laboratory tests and values/results data received. Because we have specified a standard by which EHR technology designed for an ambulatory setting must be capable of receiving lab results, we clarify that testing and certification for this setting will examine whether EHR technology can properly extract lab tests results/values and incorporate the data from the LRI specification for subsequent use. We have included the term incorporate in this portion of the certification criterion for clarity. Last, because this certification criterion only focuses on receipt and not transmission of laboratory orders we decline to modify this certification criterion in response to the commenter's recommendation that we reference a transport standard for transmission of laboratory orders.

With the exception of the change already noted, the only additional modification we have made in response to public comment was to reinsert the phrase ''attribute, associate, or link'' in 170.314(b)(5)(iii) to reflect the 2011 Edition version of this certification criterion due to the confusion we caused by overloading the term ''incorporate.''

Comments. Commenters supported the adoption of LOINC® but expressed concern that LOINC® is subject to frequent updates and that the version we adopt in the rule would be quickly out dated.

Response. We refer commenters to our responses later in this document on our approach to ''minimum standards'' code sets.

Comments. A few commenters suggested that ONC work with CMS to encourage labs to adopt and use the S&I Framework LRI specification. They contended that without the ''source systems'' on board that requiring capabilities on receiving systems (EHR technology) would fall short of the intended purpose of reducing development time and costs and improving quality.

Response. We appreciate these comments and will continue to work with our sister agencies in HHS to advance health IT policy in other programs and regulations that affect stakeholders that are not eligible to receive EHR incentive payments.

Comment. A commenter asked that we confirm that ''internal exchanges'' within an organized health care arrangement (OHCA) (e.g., between the OHCA's clinical laboratories and its EHR systems) are not subject to this certification criterion.

Response. This certification criterion specifies the capabilities that EHR technology must include in order to be certified. It does not implicate organizational exchanges.

Comments. Several commenters echoed that the LRI specification should not be applied for the inpatient setting.

Response. We agree and have not referenced it for the inpatient setting in the final certification criterion.

Comment. A commenter requested a list of CPT codes that define imaging studies and a listing of CPT codes that define a laboratory test.

Response. We received this same comment on the ''transmission of electronic laboratory tests and values/results to ambulatory providers'' certification criterion. As with the comment on that certification criterion, the commenter did not provide any supporting rationale as to why a list of CPT codes would be relevant to the capabilities expressed by this certification criterion. Thus, we decline to provide any additional information.

Comments. A couple of commenters stated that the LRI specification includes a number of different ''profiles'' that provide options for users. They added that this approach was taken because the authors of the LRI specification recognized that not all systems or users would or should be able to meet a single set of requirements. These commenters recommended that the profile choice be left to the EHR technology developer and that we not require all combinations of all profiles to be required.

Response. We do not intend to specify a particular profile or limit the use of the LRI specification to only one profile at this time. We understand that the LRI specification was drafted to create a path toward more constrained and specific implementations, the most rigorous being the Base + GU + RU (GU = Globally Unique Identifiers and RU = Unique Filler or Order Number Required). We intend to move toward this direction in our future rulemakings. We also seek to clarify for EHR technology developers that we do not expect the optional portions of the LRI specification/profile to be tested.

Comment. A commenter asked that we clarify that the certification criterion only applies to the electronic receipt of

laboratory results and does not apply to the electronic transmission of the laboratory test order to the laboratory.

Response. This certification criterion only applies to the electronic receipt of laboratory tests and does not focus on the transmission of orders.

Comments. A couple of commenters requested we clarify that because EHR technology would need to include the capability to display all of the test report information specified in the CLIA rules at 42 CFR 493.1291(c)(1)–(7) in order to meet this certification criterion, that doing so with transport standards that provided an acknowledgement back to the laboratory that the complete message was received as sent would satisfy the CLIA requirements for the delivery of a laboratory report.

These same commenters touched on a different point and suggested that because the capability expressed by this certification criterion required EHR technology to be capable of displaying all of the test report information specified in the CLIA rules at 42 CFR 493.1291(c)(1)–(7), that such capability should be enabled by default and must not be capable of being changed, overwritten, or deleted. They suggested this modification to the certification criterion because ''CLIA mandates that the physician actually view the information.''

Response. As we stated in the S&CC July 2010 Final Rule (75 FR 44608) ''the scope of our authority under this final rule only applies to capabilities that Certified EHR Technology must include. As a result, we cannot provide the regulatory relief that these commenters seek.'' However, we would note that what the commenters have described could go a long way towards meeting the requirements set forth in 42 CFR 493.1291. We encourage commenters to consult with CMS regarding particular implementations and questions with CLIA regulatory compliance. We also note that significant progress has been made to ensure that Direct Project specifications can be implemented in a CLIA compliant manner.

With respect to the interpretation provided by the commenters, that ''CLIA mandates that the physician actually view the information,'' we have consulted with CMS and seek to clarify that this interpretation is incorrect. The CLIA rules do not specify how results can be viewed by a provider, just that they can be accurately, timely, confidentially and reliably transmitted to the final destination. Laboratories need to verify that this occurred, as well as that the CLIA required elements were sent, but there is no requirement in the CLIA rules that a provider must be able to immediately view all of the information. Thus, we did not modify this certification criterion in response to the additional requirements suggested by the commenters as they would artificially lead to design limits that are unnecessary to impose as part of certification. We do, however, encourage EHR technology developers to present the laboratory test data in a format that is most useful to the provider who will use them.

• *Clinical Quality Measures*

MU Objective
N/A.
2014 Edition EHR Certification Criteria
§ 170.314(c)(1) (Clinical quality measures—capture and export).
§ 170.314(c)(2) (Clinical quality measures—import and calculate).
§ 170.314(c)(3) (Clinical quality measures—electronic submission).

For the 2014 Edition EHR certification criteria, we proposed to revise previously adopted CQM certification criteria for the ambulatory and inpatient settings to more explicitly specify the capabilities EHR technology would need to include. These revisions focused on:

• Data capture—the capability of EHR technology to record the data that would be required in order to calculate CQMs.

• Export—the capability of EHR technology to create a data file that can be incorporated by another EHR technology which could be used to calculate CQMs.

• Calculate—the capability of EHR technology to incorporate data (from other EHR technology where necessary) and correctly calculate the result for CQMs.

• Report—the capability of EHR technology to create a standard data file that can be electronically accepted by CMS.

We noted that by explicitly proposing separate CQM certification criteria focused on these discrete capabilities user experiences relative to CQMs could be enhanced, the burden of capturing data elements necessary for CQMs could be reduced, and ultimately, EPs, EHs, and CAHs would be better positioned to assess in real-time the quality of care they provide.

Data Capture

We explained in the Proposed Rule that prior to the EHR Incentive Programs, measure stewards did not routinely or traditionally specify CQMs with consideration of EHR technology and its capacity to capture certain data. We further explained how the National Quality Forum (NQF), under contract with CMS, created the Quality Data Model (QDM),[21] which today serves as the information model from which new CQMs are specified. We explained that because older CQMs were not specified as ''EHR-ready'' when initially developed, they may implicitly specify certain data capture requirements that most EHR technologies cannot perform (or do not perform in any structured way) as well as constructs that would still require human intervention or judgment (i.e., ''chart abstraction''). Despite the best efforts to ''re-tool'' older measures for inclusion at the beginning of the EHR Incentive Programs, we acknowledged in the Proposed Rule that we understood that the CQMs required for certification as part of the S&CC July 2010 final rule did not, in some cases, adequately reflect a pure ''EHR-ready'' CQM. We further noted that as a result, EHR technology developers created new data fields and/or advised their customers to use specified (and in some cases alternative and atypical) workflows, templates, or form elements to capture these data in a consistent manner in order to facilitate CQM calculation.

In the Proposed Rule, we explained that the CQM lifecycle in the EHR starts with the determination of data to be captured and the subsequent capture of clinical or demographic data. Thus, the first specific capability we proposed for CQM certification (§ 170.314(c)(1)(i)) focused on the capability of EHR technology to electronically record all of the data elements that are represented in the QDM. More specifically, we stated that EHR technology would need to be able to record data in some representation that can be associated with the categories, states, and attributes represented by the QDM. We provided the following simple example: EHR technology would need to be able to record a representation of ''Medication *active''* or ''Problem *active''* where the first term represents the QDM category and the second represents the QDM ''state of being.'' We noted that in certain cases, such as in the prior example with ''Problem *active,''* the data capture necessary is already specified by another certification criterion proposed for adoption as part of the 2014 Edition EHR certification criteria (i.e., § 170.314(a)(5) to record active problems). However, we acknowledged that in other cases an EHR technology developer would need to review the QDM to ensure the EHR technology presented for certification captures data elements that are not

[21] Quality Data Model—National Quality Forum: *http://www.qualityforum.org/Projects/h/QDS_Model/Quality_Data_Model.aspx.*

explicitly required to be recorded in other proposed certification criteria. We explained that because the QDM is agnostic to health care settings (e.g., ambulatory and inpatient settings) and all of the CQMs ultimately adopted by CMS in a final rule would be based on the QDM, we did not believe that it would be necessary or possible to propose specific separate ambulatory and inpatient setting certification requirements as we have with other proposed certification criteria. Thus, we stated that all EHR technology regardless of the setting for which it is designed would need to meet § 170.314(c)(1)(i) if it is presented for certification to this certification criterion.

We recognized in the Proposed Rule that the gap between the data defined by the QDM and the data traditionally captured in EHR technology is, in some areas, broad. We requested comments regarding: (1) Industry readiness for the expansion of EHR technology data capture; (2) how this would impact system quality, usability, safety, and workflow; and (3) how long the industry believes it would take to close this gap. We also acknowledged that some specialty-focused EHR technologies may not need to capture all of the data that the QDM describes and requested public comment on how certification could accommodate specialty EHR technology developers so that they would not have to take on development work (solely to get certified) for functionality that their customers may not require. Finally, we requested public comment with respect to whether we should pursue one or more of the alternative approaches below for certification in the final rule and made specific requests for public comment on those alternatives.

- *CQM-by-CQM Data Capture:* As an alternative to our proposal on certification for data capture, we considered a data capture approach that would be based on the data elements reflected in the individual CQMs selected by CMS instead of the entire QDM.
- *Explicit Certification Criteria:* We recognized that, in some cases, many EHR technologies already capture data elements included in the QDM even though they are not explicitly required by an adopted certification criterion. In these cases, we considered and believed that it would be clearer (and easier for EHR technology developers) if we were to either add specific CQM data capture requirements to already existing certification criteria or adopt new certification criteria in order to explicitly require the data that is specified by the QDM to be captured. In other cases, we noted that despite a measure steward specifying that certain data capture occur, we are unaware of a consistent or established method with which EHRs capture certain information. For example, we stated that most EHR technology of which we are aware does not consistently capture why a particular medication was not prescribed, nor do they systematically make a distinction between ''patient reason,'' ''system reason,'' and ''medical reason.''
- *CQM Exclusions:* In cases where a CQM specifies a negation exclusion,[22] we proposed that EHR technology would not be required to capture the ''reason'' justification attribute of any data element in an encoded way. Rather, we proposed to permit ''reason'' to allow for free text entries. For calculation and reporting purposes, we proposed that the presence of text in the ''reason'' field may be used as a proxy for any ''reason'' attribute.
- *Constrain the QDM:* Based on our work with CMS and NQF, we considered the creation of a draft ''style guide'' to constrain the QDM in a manner that would identify a subset of data types and their associated attributes that we believe EHR technology could reasonably be expected to be captured. We noted that measure stewards would then need to constrain CQMs to reference only data elements that are within the boundaries of the data types/attribute pairs expressed in the constrained QDM style guide. We expressed that such CQMs would be identified as ''2014–EHR-ready'' while other CQMs would not. We stated that we would subsequently collaborate with CMS to remove CQMs that did not qualify as ''2014–EHR-ready'' from the EHR Incentive Programs requirements and, as discussed above, could add certification criteria in our final rule in order to explicitly define the data types and attributes that will be necessary for complete CQM data capture according to the constrained QDM style guide. We believed this option would serve to align the capabilities of EHR technology with the expectations of CQMs and would provide a solid path toward an additional alignment of CQMs with CDS for future stages of the EHR Incentive Programs. We suggested that CDS could provide the interactive capability that would be required in order to capture the granular exclusion data that is expected today by many CQMs. We noted that with the inclusion of CDS in the clinical quality improvement strategy for future stages of this program, we expected to be able to remove the flexibility for the capture of ''reason'' attributes. This would improve the accuracy of CQMs while retaining optimal clinical workflow because CDS would ideally be engaged to prompt for this information only where indicated rather than in all cases.
- *Explicit Data Capture List:* The last approach we considered was (instead of specifying the QDM) to publish the complete list of unique data elements that would be required for data capture in order to be assured that CQMs could be calculated. We explained that the advantage of this list is that it would provide explicit guidance to EHR technology developers and could potentially reduce the upfront work that each individual EHR technology developer would need to do in order to prepare their EHR technology for certification.

Data Export

In addition to being able to capture data elements for CQMs, we proposed that EHR technology presented for certification must be able to export this data in the event that an EP, EH, or CAH chooses to use a different certified EHR Module to perform the calculation of CQM results. We included the export capability as part of the certification criterion proposed at § 170.314(c)(1). We indicated that this approach would preserve portability and flexibility and offer the EPs, EHs, and CAHs the option of using regional or national CQM calculation and/or reporting solutions, such as registries or other types of data intermediaries that could obtain an EHR Module certification for the services that they offer. We acknowledged that we were unaware of the existence of a widely adopted standard to export captured CQM data. We also proposed that it would be at the EHR technology developer's discretion to determine the format of the data file that its EHR technology would be able to produce as well as whether the data would be exported in aggregate or by individual patients. We recognized that this

[22] A negation exclusion or exception is a factor that removes a given patient from the denominator of a CQM with a statement about why a given event or intervention did not occur. For example, a CQM may state that all patients with X condition must have Y intervention, except patients who did not receive the intervention for reason Z. A CQM may state that all patients over the age of 6 months should have an influenza vaccine between October and February (Y intervention), except patients with allergy to egg albumin (reason Z–1) or patients who decline vaccination (reason Z–2). In some measures, the unit of analysis is not a patient, but an encounter or a procedure. In such measures the exclusion or exception can apply to individual patient factors or factors affecting the specific unit of analysis. Additionally, exclusions for ratio measures can also remove a patient from the numerator.

scenario would not be ideal, but we believed that it could also create a market in which EHR Modules focused on CQM calculation (and reporting) could be designed to exploit the disparate data files that EHR technologies produce. Finally, we requested comment on whether any standards (e.g., QRDA category I or III, or Consolidated CDA) would be adequate for CQM data export as well as whether Complete EHRs (that by definition would include calculation and reporting capabilities) should be required to be capable of data export.

Import and Calculate

In the S&CC July 2010 final rule (75 FR 44611) and finalized in the respective certification program rules (75 FR 36170, 76 FR 1276), we discussed requirements that ONC-Authorized Testing and Certification Bodies (ONC–ATCBs) and ONC-Authorized Certification Bodies (ONC–ACBs) must report to ONC the CQMs to which a Complete EHR or EHR Module has been certified and that ONC–ATCBs and ONC–ACBs must ensure that Complete EHR and EHR Module developers include on their Web sites and in all marketing materials, communications statements, and other assertions related to a Complete EHR or EHR Module's certification the CQMs to which the Complete EHR or EHR Module was certified. These requirements can be found at § 170.423(h)(5) and (k)(1)(ii) and § 170.523(f)(5) and (k)(1)(ii). The posting of this information on the Certified HIT Products List (CHPL) combined with Complete EHR and EHR Module developers making this information available in association with their certified Complete EHRs and EHR Modules provides both transparency and useful information for potential purchasers (e.g., EPs, EHs, and CAHs) that are trying to determine what EHR technology best meets their needs.

We discussed that we previously adopted at § 170.304(j) the CQM certification criterion for EHR technology designed for an ambulatory setting and expressed that it was treated as a threshold. We explained that, if an EHR technology included all 6 of the core CQMs specified by CMS and at least 3 other additional CQMs, it could meet the certification criterion. We noted that if there was an additional CQM that the EHR technology included, CMS permits the EP to report on that CQM, even though it was not expressly listed on the CHPL. We also explained that some EHR technology developers sought certification to only the 9 CQMs required to meet the threshold, and thus the criterion, but subsequently communicated to EPs that their EHR technology was certified for all of the CQMs it included. We noted that other EHR technology developers took the opposite approach and sought certification for more than the 9 CQMs and consequently, those EHR technologies were listed on the CHPL as being certified to more CQMs.

We sought to eliminate this disparity by proposing that EHR technology presented for certification to § 170.314(c)(2) would need to be certified to each and every individual CQM for which the EHR technology developer seeks to indicate its EHR technology is certified. We believed this approach would provide transparency and greater certainty regarding the ''certified CQMs'' that EHR technology includes, given CMS' proposal to only permit EPs, EHs, and CAHs to report on CQMs with EHR technology that has been certified to capture and calculate those CQMs.

We proposed a separate certification criterion at § 170.314(c)(2) for the calculation of CQMs in anticipation that, in many cases, the calculation of CQMs could be performed by an EHR technology that is different from the one that was certified to capture the CQM data. For example, the calculation of CQMs could be performed with a commercial solution or the popHealth tool.[23] The certification criterion we proposed included two specific capabilities. The first capability (§ 170.314(c)(2)(i)) would require that EHR technology presented for certification would need to be able to electronically incorporate all of the data elements necessary to calculate CQMs for which it is to be certified. We explained that, for cases where an EHR technology developer presents an EHR technology for certification that is also being certified to § 170.314(c)(1) and (3) (i.e., the EHR technology would be able to do all three capabilities: capture, calculate, and report), we did not believe that it would be necessary for an EHR technology to demonstrate its compliance to § 170.314(c)(2)(i). However, we specifically requested public comment on this assumption before we added this exception to the certification criterion. In all other cases, an EHR technology would need to meet § 170.314(c)(2)(i) and (ii).

The second specific capability (§ 170.314(c)(2)(ii)) we proposed focused on an EHR technology's ability to calculate each CQM for which it is presented for certification. We clarified that if an EHR technology is presented for certification with test results for 20 CQMs, then the most CQMs that could be included as part of its certification and listed on the CHPL would be 20. Furthermore, we emphasized that an ONC–ACB would need to review each of the 20 CQMs for which the EHR technology is presented for certification and make a separate determination as to whether the calculation test results for each CQM are satisfactory and accurate. We expressed our expectation that EHR technology certified to this criterion would be capable of accurately, and without errors, calculating CQMs and that the accuracy of these calculations would be verified through testing. We requested public comment, especially from measure stewards and EHR technology developers, on the best way for CQM test data sets to be developed.

Given the separation between capture and calculation, combined with CMS's policy that only CQMs calculated by CEHRT would count for attestation and electronic submission, we acknowledged that a scenario could arise where an EP's, EH's, or CAH's CEHRT (composed of certified EHR Modules—perhaps from different vendors) could capture more data than it is certified to calculate. Recognizing that this scenario could present challenges for providers who possess licenses to such mismatched certified EHR modules, we requested comment regarding this scenario and its likelihood and any additional methods we could employ to mitigate this risk.

Reporting

We proposed a certification criterion at § 170.314(c)(3) to require EHR technology to enable a user to electronically create for transmission CQM results in a data file defined by CMS. We noted our expectation that this capability would require EHR technology to generate an eXtensible Markup Language (XML) data file with aggregate CQM calculation results in the format CMS would have the capacity to accept. We also anticipated that CMS would make available the XML data file template in time for us to adopt it in our final rule. We believed that this approach would give EPs, EHs, and CAHs a default solution for reporting CQMs electronically. We noted that if EPs, EHs, and CAHs elect to use their CEHRT to pursue an alternative reporting mechanism permitted by CMS for the EHR Incentive Programs, then it would be the EP, EH, or CAH's responsibility for ensuring compliance with the alternative mechanism's requirements.

We organized the comments and responses below using the same

[23] *http://projectpophealth.org/.*

subheadings we used in the Proposed Rule as well as other more specific subheadings on particular topics.

Capture

Comments. Many commenters stated that certification to the entire QDM would place too much of a burden on EHR technology developers, noting that the QDM includes many data elements not traditionally captured in the EHR. Many commenters stated that ONC should require capture of only data elements that are contained within the CQMs that EHR technology developers chose to implement for calculation via their technology as opposed to a requirement that EHR technology capture all of the data elements required for calculation and reporting for all of the clinical quality measures or the entire QDM. Some commenters also noted that design and development for capture of the entirety of the QDM would be a distraction from much needed development of features and enhancements to existing technology. Many commenters also expressed concern with the clinical relevance of the entire QDM. Several commenters suggested ONC require EHR technology to capture to a constrained QDM as described in our Proposed Rule.

Several commenters noted that the QDM is not intended as a certification standard, but as an extensible model for discussing the types of data that are included in quality measures, and that for an EHR to be usable, each of these pieces of information would need to be captured with appropriate standard terms, at appropriate points in the appropriate user's workflow. These commenters also stated that the scope of the work to be done to capture all of the data elements envisioned in the QDM is ''enormous.'' One commenter compared the capabilities of EHR software today against 2,100 of the category and attribute combinations in the QDM, and found that only 400 of the 2,100 were always or usually captured in EHR workflows. More than half were never captured in EHR workflows. This commenter suggested that we publish a list of all data elements required for the CQMs included in the Stage 2 final rule rather than reference the QDM.

One commenter suggested that ONC work to constrain the QDM by aligning parts of the QDM with ''core'' and ''optional'' CQMs.

Some commenters suggested that EHR technology be required to capture all data elements that are components of the EHR Incentive Programs CQM measure set.

One commenter suggested that we perform a full assessment of the data elements and associated attributes that are required by the QDM to determine if each of these are appropriate and required for CQM reporting.

Some commenters stated that all EHR technology developers should be required to certify their EHR technology to all CQM data elements in the EHR Incentive Programs measure set to ensure that EPs, EHs and CAHs have the flexibility of selecting appropriate CQMs from the entire set to avoid situations where EHR technology developers have too much influence over provider quality improvement measures rather than the local institutions' quality improvement goals.

One commenter stated that some Stage 1 CQMs require a level of clinical documentation and the capture of data that are far more extensive than the 2011 Edition EHR certification requirements and are not necessarily in common use. Furthermore, this commenter stated that some data for the inpatient measures comes from documentation that may be contained in written or dictated notes in the EHR and therefore not available in encoded form.

A commenter stated that is critical that EHR systems support the collection of data from all sources, including from patients, nurses, other providers, and other systems and that quality measurement should not be dependent on the direct entry of data by EPs.

Response. We agree that capture of the entirety of the QDM as a requirement for certification is not appropriate, and we know of no systematic constraints to the QDM, including a distinction between ''core'' and ''optional'' measures that would meet the needs of our certification program for 2014. Yet, we are optimistic that a future version of the QDM may provide guidance for CQM developers on the feasibility of certain elements or element types for EHR technology. We may therefore incorporate the QDM and a QDM ''style guide'' in future rulemaking. We do not believe that it is appropriate for all EHR technology developers to have to seek certification for their EHR technology to all of the data elements necessary for all CQMs included in the Stage 2 final rule. We understand that there exist many EHR technologies that have been developed for specialty markets such as chiropractics, dentistry, ophthalmology, and wound care. Some CQMs are not relevant to the providers in these specialties and are therefore unnecessary to be built into the systems that they purchase. Such a requirement would cause these EHR technology developers to divert development resources away from the features and functionality that these providers need in future releases to functionality that would be present only for certification—and would never be used. It is our intent that this program aligns the functionality of CEHRT with the true clinical needs of EPs, EHs, and CAHs and, by extension, their patients. We agree that EHR technology developer selection of measures may impact the options available to providers, and we encourage the developers of EHR technology submitted for certification to present the broadest range of measures for certification possible, in order for EPs, EHs, and CAHs to have as much flexibility as possible in selecting measures for reporting under the EHR Incentive Programs. If EHR technology developers create sufficient functionality to meet EP, EH, and CAH needs in the future, we will not need to mandate an expansive requirement (such as a requirement to certify EHR technology for all CQMs selected for the EHR Incentive Programs) in subsequent rulemaking.

We will therefore require EHR technology submitted for certification to § 170.314(c)(1)(i) to be capable of capturing the data elements specified in the standard adopted at § 170.204(c) (Data Element Catalog) [24] as required for each and every CQM for which the technology is to be certified (the ''CQM-by-CQM Data Capture'' option discussed in our Proposed Rule (77 FR 13851)). For example, if EHR technology developer XYZ is seeking to certify their EHR technology for CQMs 1 through 10, 13, 15 and 22, then the EHR technology developer will need to review the list of data elements in the standard adopted at § 170.204(c) for each of these CQMs and demonstrate that each of these data elements can be captured by the EHR technology. Also included in the standard adopted at § 170.204(c) is a list of ''supplemental'' data elements required for CQM data submission to CMS. The list of supplemental data elements will be required for capture and transmission in each and every CQM report and includes (but is not limited to) race, ethnicity, sex, payer, Medicare HIC number, and where appropriate, NPI, CCN and TIN.

We selected this option for several reasons. First, as noted above, there was strong support for this option in response to the Proposed Rule. Second, this option provides flexibility for EHR technology developers because it allows them to clearly understand the necessary data elements required to be captured for their customers (based on the CQMs for which they intend to seek

[24] *http://www.nlm.nih.gov/healthit/dec/.*

certification) rather than the entirety of the QDM. This is a significant improvement from our 2011 Edition CQM certification criteria, and will, in combination with a publicly available value set repository that the National Library of Medicine will release, assist EHR technology developers in meeting the requirements of CQM reporting. We believe that many of the historical problems with CQM reporting were due to the absence of accurate and complete data capture. A provider cannot accurately report on data from EHR technology that was not captured by EHR technology. With specific guidance and defining of the data that will be required for each CQM, we are now providing the foundation on which more accurate and reliable CQM reporting can be based. The supplemental data elements mentioned above are required by CMS, and will be important for the accurate processing, stratification, and assignment of CQM reports.

EPs, EHs, and CAHs may employ many methods to capture the information required by CQMs and we do not intend for this criterion to imply that technology submitted for certification would be required to demonstrate manual data entry through a user interface (such as form fields or templates). Rather, the technology must be capable of capturing the information in some manner, and this includes information transferred from other systems (such as a practice management system, PHR, portal or kiosk).

We appreciate the comments on the CQM measure set from the Stage 1 Final Rule. Some EHR technology certified to the 2011 Edition EHR certification criteria do not capture all data elements of these CQMs as structured data, and we note that this was not explicitly required for 2011 certification. This will be required for 2014 certification, as described above.

CQM Exclusions

Comments. One commenter stated that only exclusions that are clinically meaningful to ongoing care of the patient, for example, an allergy or drug intolerance should be required for CQMs in order to reduce the burden on documentation. Other commenters stated that negation rationales, exclusions and exceptions, should be minimized and be clinically relevant. Multiple commenters also suggested that negation rationales should not allow any free text submissions by providers, because free text would be very difficult to codify, use for decision support, or normalize or perform analytics.

Many commenters expressed support for linking CQM and CDS to improve the quality of care and patient outcomes. Some commenters expressed concern that the linkage of CDS to CQM would lead to alert fatigue and if a 1:1 CQM:CDS intervention was required and that would be a burden to both developers and users of EHR technology. Commenters also expressed concern that our Proposed Rule does not include criteria for ''linking'' or ''relating'' CDS and CQM.

Response. We appreciate the comments on our proposal regarding CQM exclusions. We agree that all data elements needed for CQM calculation should be discrete and codified. We don't believe that exclusions and exceptions must be captured to the granular level of detail described by a CQM that was developed for manual chart abstraction, but agree that where this granular data is available in coded form, it can and should be employed. In light of these comments, we will not require free text, but will permit that free text be captured and made available in addition to a codified entry. Codified entries may include specific terms as defined by each CQM, or may include codified expressions of the three global concepts: ''patient reason,'' ''system reason'' or ''medical reason.'' In addition, we appreciate the comments regarding linkage of CDS to CQM, and agree that this should not be an explicit requirement for 2014 certification, as we have not formally defined how CDS and CQM should be ''linked'' or how this would be tested. We do not intend to require a 1:1 requirement of CDS interventions to CQM. Rather, we suggest that EHR technology developers incorporate CDS interventions for the clinical areas in which they have selected to submit CQMs for certification. For example, if an EHR technology developer has selected to seek certification for NQF 0028 ''Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention,'' then we would recommend that they incorporate CDS that would enable their customers to assess their patients' smoking status and facilitate the documentation of smoking cessation interventions.

Data Export

Comments. Several commenters supported standardized patient level data export capability as a certification criterion. A few commenters stated concern regarding the use of QRDA category I as an export standard noting that requiring a separate export format to support clinical quality measurement is an extra step in quality improvement with ''little value added'' that increases maintenance costs and represents an additional potential point of failure. One commenter also noted that many EHRs are, in fact, particularly highly modularized in the inpatient setting, noting that it is rare for a single module to include all the data necessary for calculation. Others noted that QRDA Category I standard is too narrow in focus to support calculation and analytics because not all of the data elements that would be required for calculation are included in a QRDA Category I report. A few commenters encouraged investigation to determine the feasibility of using the Consolidated CDA or other applicable standard to support the required export.

Several commenters stated they did not believe that ''complete EHRs,'' which can calculate CQMs, should be required to support data export and that patient-level data export, should be optional.

Other commenters argued in support of this requirement, and one noted that there would be value in a ''simple and standardized CQM data export format.'' One commenter expressed support for our approach to CQM export and believes that this approach ''will support both the development of certification standards for all CQMs and encourage interoperability among systems.''

Response. We appreciate the comments on export of clinical quality data, and after careful review of these comments, we have decided to require this functionality for certification at § 170.314(c)(1)(ii). As stated in our Proposed Rule, for many care delivery settings, CQM calculation and reporting may occur through the use of different EHR technologies from those used to capture data. For example, certified EHR Module #1 may be part of an EH's EHR technology that meets the Base EHR definition, but the EH may use certified EHR Module #2 to perform the analytics needed for CQM calculation and reporting. By requiring that all EHR technology presented for certification capture CQM data and also export the data, we believe EPs, EHs, and CAHs will be provided the flexibility to use separate EHR Modules for calculation and/or reporting, even if they have purchased or licensed an integrated solution.

We believe this approach preserves portability and flexibility and offers the EPs, EHs, and CAHs the option of using regional or national CQM calculation and/or reporting solutions, such as registries or other types of data intermediaries that could obtain modular certification for the services

that they offer. We requested comment regarding the appropriate data standard for this export functionality, and at the time of publication of our Proposed Rule, the HL7 QRDA Category I standard had not yet been successfully balloted. Several commenters noted that it was at that time too immature for inclusion in our regulation. QRDA Category I has now been successfully balloted through HL7, has been selected by CMS as an accepted form of quality data reporting, and will therefore be required for certification to § 170.314(c)(1)(ii). We disagree that this criterion or this standard format provide little ''value added.'' Indeed, this standard provides, for the first time—a method of moving a ''snapshot'' of patient data from one EHR technology to another without loss of semantic integrity. We anticipate that there may be opportunities for this model to be of value beyond quality measurement in the future—such as in the domain of clinical decision support services.

Import and Calculate

Comments. Many commenters supported certification of incorporation and calculation capabilities to each CQM. One commenter noted that some EHR technology developer products have been certified for CQMs with very light testing requirements and that the certification process for EHRs did not include testing the accuracy of the embedded measure calculations, nor did it examine whether the needed data were, in fact, available in the EHR. Several commenters described frustration with the lack of testing devoted to CQMs under the temporary certification program. One commenter expressed concern about errors encountered in measures that have been transcribed from paper abstraction to e-specification. This commenter noted that the original measure developer specified measures for non-EHR use and in many cases did not e-specify the measures for EHR-use and that subsequent changes in measures occur with e-specification. This commenter called for a process to ensure comparable data calculations across EHR technology developers and hospitals and a systematic process to ensure these changes are broadly communicated and systematically incorporated. Multiple commenters suggested methods for the field testing of new measures. One commenter noted that there was minimal feasibility testing of CQM measure specifications for the Stage 1 CQMs.

Response. We appreciate the comments on CQM calculation and testing. Through the rulemaking comment period and via additional channels, we have become aware of challenges that providers have faced in the use of technology certified under our 2011 Edition EHR certification criterion. Our proposed changes were intended to rectify these concerns. Notably, we have modified our proposal for § 170.314(c)(2) to finalize a more specific and clear certification requirement that EHR technology be able to import a QRDA category I file that has been generated by the ''export'' capability in § 170.314(c)(1)(ii) specified above. Unlike for the 2011 Edition EHR certification criteria for CQMs, EHR technology will be tested and certified for conformance with this capability. As we noted in the Proposed Rule, we now seek to provide express guidance to ONC–ACBs that when an EHR technology is presented for certification and includes capabilities to meet all three CQM certification criteria (i.e., the certification criteria adopted at § 170.314(c)(1), (2), and (3)) that the capability to ''import'' as specified in § 170.314(c)(2)(i) will not need to be assessed. Given that the CQM capabilities within the EHR technology are in essence ''self-contained,'' we believe that it is unnecessary to require EHR technology to be able to import data from itself. EHR technology that is eligible for this treatment would still have to meet all of the other specific capabilities required by all three of the CQM certification criteria. Finally, consistent with other terminology changes we have made, we changed the term ''incorporate'' to ''import'' in this certification criterion to provide more clarity regarding the action that is required to be demonstrated for certification. Note that in our discussion of § 170.314(c)(1) (Clinical quality measures—capture and export), we did not require that all data be directly entered through a user interface. Some data may flow into EHR technology through other means. These functions are not required for certification, nor will they be tested as part of the certification process.

We appreciate the comments on e-specification of chart-abstracted measures, but note that many comments about the selection, content, and management of the CQMs are beyond the scope of this final rule. We appreciate the value of reliability and validity testing for CQM technical specifications and support testing of CQMs prior to public release. CMS is responsible for CQM testing and we defer to their comments on this subject in their Final Rule that is published elsewhere in this issue of the **Federal Register**. We also appreciate the many comments in reference to feasibility testing. Feasibility testing in preparation for Stage 2 of MU has been enhanced in order to minimize variation and post-specification modifications to electronically specified CQMs.

Electronic Submission

Comments. Commenters were supportive of our proposal. One commenter suggested that the XML file format should be a valid standard that has been tested for accuracy and completeness. Another commenter expressed agreement with the use of aggregate XML and recommend that the technical structure align with 2011 Physician Quality Reporting System registry reporting. One commenter suggested that we employ the Core Measure XML and particularly The Joint Commission's ''HCD'' XML.

Response. We referred to this capability as ''reporting'' in the Proposed Rule, but now refer to this capability as ''electronic submission'' in this final rule and in regulation. This renaming more accurately reflects the required capability, which is the ability to create a file in a particular format and be capable of submitting that file to CMS in a manner that CMS is able to accept. We appreciate the supportive comments regarding a standard XML format and aggregate reporting methods. In order to provide CQM file submission flexibility for EPs, EHs and CAHs, CMS intends to offer several reporting methods from which providers will choose, as described in the Stage 2 final rule published elsewhere in this issue of the **Federal Register** and is considering other mechanisms/methods that could be implemented or relied upon in the future. In this regard, we believe that EHR technology should be capable of creating CQM data files that would support the forms of electronic submission that CMS makes available to EPs, EHs, and CAHs. Therefore, we have adopted both the HL7 QRDA Category I standard to support a patient level data submission approach and HL7 QRDA Category III to support an aggregate level data submission approach.

As noted above, we proposed that the electronic submission capability would require EHR technology to generate an (XML) data file with aggregate CQM calculation results in the format CMS would have the capacity to accept. CMS has since specified that the optimal XML format for aggregate reporting will be the HL7 QRDA Category III. CMS has also made a policy decision to provide an option for patient-level reporting. CMS has specified that the optimal XML format for patient-level reporting will be

the HL7 QRDA Category I. Although these standards were in development at the time of our Proposed Rule, QRDA Category I has now been balloted through HL7, and QRDA Category III is much more complete than it was at the time of the Proposed Rule, with balloting scheduled in the near future. We understand that the timing of the QRDA Category III balloting is suboptimal, but note that the alternative would have been for CMS to develop its own XML specification for a format that performs precisely the same functionality as QRDA Category III. This would have been redundant of the QRDA Category III effort and could have adversely affected its progress. We also note that the patient-level reporting standard (QRDA Category I) is the same standard as the standard we have adopted for the ''export'' capability in § 170.314(c)(1). Therefore, we anticipate that the burden on EHR technology developers that also submit EHR technology for certification to this certification criterion will be minimal.

In general, we expect that providers who choose to submit aggregate reports will use the standard specified at § 170.205(k) (HL7 QRDA Category III), and providers who choose to submit patient-level reports will use the standard specified at § 170.205(h) (HL7 QRDA Category I). We require that EHR technology, regardless of the setting (inpatient or ambulatory) for which it was designed, be certified to produce CQM data that could be submitted by an EP, EH, or CAH according to either standard. While the HL7 QRDA Category III standard has not yet been successfully balloted, we expect it to become a normative standard in the near future. Further, we agree with and support CMS's decision to select this format rather than developing its own CMS-defined XML template because QRDA Category III is a product of several years of industry consensus work. EHR technology presented for certification will therefore need to be certified as being capable of creating results for transmission to CMS according to both reporting standards (§ 170.205(h) (HL7 QRDA Category I)) and § 170.205(k) (HL7 QRDA Category III)).

We note for readers that we have modified this certification criterion to more explicitly address the fact that CMS must be able to receive an electronic data file created by EHR technology and submitted by an EP, EH, or CAH. If this could not occur then, arguably, the most important aspect of what certification was intended to support would go unmet. Accordingly, we have added to this certification criterion, not only that EHR technology be able generate both QRDA Category I and QRDA Category III data files, but that such files can also be electronically accepted by CMS. This explicit requirement creates two benefits while also reducing regulatory burden due to CMS' intended programmatic alignment efforts. It benefits providers and CMS in that each will know as a result of certification that when EHR technology is used to electronically submit a QRDA Category I or III that CMS will be able to receive it. With respect to testing, we expect to approve a test procedure for this certification criterion that will assess an EHR technology's ability to create data files conformant to the QRDA Category I and III standards, and upon a positive conformance assessment, verify that these data files could be accepted by CMS. If the data files were conformant and verified by the accredited testing laboratory in terms of their ability to be accepted by CMS, then the EHR technology would have fully demonstrated compliance with this certification criterion.

• *Auditable Events and Tamper-Resistance; and Audit Report(s)*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criteria
§ 170.314(d)(2) (Auditable events and tamper-resistance).
§ 170.314(d)(3) (Audit report(s)).

We proposed two revised certification criteria at § 170.314(d)(2) and (3)—one focused on the capability to record auditable events and another focused on the capability to create audit reports—in place of the single 2011 Edition EHR certification criterion for audit logs adopted at § 170.302(r). We also proposed to move the specific capability ''detection'' from the integrity certification criterion (§ 170.302(s)(3)) to the proposed auditable events and tamper-resistance certification criterion. We made these proposals based on HITSC recommendations as well as stakeholder feedback that indicated splitting the 2011 Edition certification criterion into two separate certification criteria would permit a wider variety of EHR technologies to be certified as EHR Modules. We also expanded upon the scope of the HITSC's recommendation to address input from the HHS Office of Inspector General (May 2011 report [25]) and to reflect our general belief that a more stringent certification policy for audit logs will ultimately assist EPs, EHs, and CAHs to better detect and investigate breaches. The proposed expansion included the specific capabilities that the audit log must be enabled by default (i.e., turned on), immutable (i.e., unable to be changed, overwritten, or deleted), and able to record not only which action(s) occurred, but more specifically the electronic health information to which the action applies. The proposed certification criterion would also require that the ability to enable and disable the recording of actions be limited to an identified set of users (e.g., system administrator). Further, to accommodate these changes, we proposed a revised standard at § 170.210(e) and proposed to require that: (1) When the audit log is enabled or disabled, the date and time (in accordance with the standard specified at § 170.210(g) (synchronized clocks)), user identification, and the action(s) that occurred must be recorded; and (2) as applicable, when encryption for end-user devices managed by EHR technology is enabled or disabled, the date and time (in accordance with the standard specified at § 170.210(g) (synchronized clocks)), user identification, and the actions that occurred must be recorded. Finally, we acknowledged, as recommended by the HITSC, that an example standard that could be followed in designing EHR technology to meet these certification criteria could include, but is not limited to ASTM E2147–01, Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems.

General Comment Summary. Many commenters generally supported the more detailed certification criteria and the standards we proposed. Comments on the two certification criteria and standards we proposed focused on a number of different dimensions. The following comment summaries and responses address each of these dimensions.

Comments. Many commenters requested clarifications related to the proposed certification criterion's first specific capability—that the auditable events capability be ''enabled by default.'' Many commenters noted that our proposal essentially skipped a step from an implementation perspective. They contended that the certification criterion should include, make reference to, or that we should make clear that the certification criterion did not prohibit the audit recording capability or service from being be subject to some type of initial configuration. Further they stated that once initial configuration was

[25] *http://oig.hhs.gov/oas/reports/other/180930160.pdf.*

complete the audit log could be ''enabled by default.'' Another commenter stated that audit logs should not be enabled by default by EHR technology developers because the decision of whether settings in the software are enabled or disabled are the responsibility of each organization, not the EHR technology developer. Additionally, this commenter and others indicated that EHR technology developers cannot enable the audit logs of organizations that already have this capability in use.

Response. We understand the concerns raised by commenters and seek to clarify this proposal as follows. It appears that by including the parenthetical ''(i.e., turned on)'' that we confused many commenters because, as they noted, steps needed to occur before the auditing service could actually be ''turned on.'' We acknowledge that 2014 Edition EHR technology will need to be setup and configured at each practice or hospital in which EHR technology with this capability is installed. This certification criterion is not meant to prohibit such configuration. Rather, what this certification criterion expresses (and what we have made clear in modifications to the certification criterion) is that in order for the EHR technology to be certified it must be set by default to record the actions and information specified in the standards referenced by the certification criterion. Thus, this part of the certification criterion is meant to ensure that at the point of installation or upgrade EHR technology certified to this 2014 Edition EHR certification criterion, the EHR technology will be set by default for an EP, EH, or CAH to record the actions and information specified in the standards referenced by the certification criterion.

Comments. Commenters also expressed a set of concerns with respect to another element included in the proposed certification criterion's first specific capability—that only a limited set of identified users be permitted to be disable (and re-enable) the capability to record auditable events. Some commenters, typically EHR technology developers, referenced that some EHR technologies do not include any capability at all for users to change (enable/disable) auditable event recording. As such, these commenters stated that the final rule should accommodate this approach with respect to certification. Further, commenters agreed that if auditable events can be disabled, that it only be able to be done so by a limited set of users. Echoing that this provided separation of duties, so that a user who is able to access or make changes to a patient's health information is not also able to modify the audit log to remove traces of suspicious activity. One commenter stated that since EHR technology cannot interpret the meaning of ''limited,'' that we should change the wording to '' * * * by authorized users.'' Another commenter noted that it may be necessary to turn off the auditable events capability for performance, patching, or other events.

Response. In response to comments, we have modified the certification criterion to make the accommodations requested. As noted by at least one commenter, the practice indicated by others to never permit anyone to be able to disable an audit log is not uniformly applied in EHR technology. Therefore, we have reframed and reordered the specific capabilities within the certification criterion. As a general rule, the certification criterion identifies the actions and statuses that EHR technology must be able to record. The actions related to electronic health information are listed first; the change in audit log status second; and the change in encryption status of electronic health information locally stored by EHR technology on end-user devices third. With respect to the latter two (the two status oriented requirements), we have included conditional statements as requested by commenters to permit EHR technology to meet this certification criterion if the EHR technology developer can demonstrate that no user has the ability to change those statuses. Further, we have reworded and moved to the third specific capability within this certification criterion the separation of duties aspect that many commenters endorsed. This modified requirement specifies that if EHR technology permits the recording of auditable actions or statuses to be disabled the ability to do so must be restricted to a limited set of identified users. We decline to modify this certification criterion in response to the commenter's suggestion to change the wording related to ''limited'' set of identified users because the commenter has misinterpreted the requirement that the certification criterion specifies. EHR technology does not have to interpret the meaning of ''limited.'' Rather, to meet this certification criterion, EHR technology would need to include a capability that allows only a limited set of identified users (by the EP, EH, or CAH) to be have the privileges necessary to change when auditing is enabled or disabled. In general, we do not expect and would discourage any general EHR technology user from being permitted to perform such actions.

Comments. Some commenters requested clarification on the meaning of ''as applicable'' in the ''auditable events'' certification criterion and accompanying standard with respect to auditing the encryption status of end-user devices managed by EHR technology. Consistent with other comments provided in terms of the capabilities within the scope of an EHR technology's control, commenters noted that ''as applicable'' in this context should be if an EHR technology developer supplied the end-user device and if the sole purpose of the device is to use the EHR technology. In other words, tracking the enabling and disabling of encryption on health care providers' personal devices (such as smart phones) should not apply.

Response. The phrase ''as applicable'' was originally intended (in this proposed certification criterion and standard) to accommodate situations where the EHR technology did not locally store electronic health information on any end-user devices. In general, we agree with commenters that tracking the enabling and disabling of encryption on health care providers personal devices would not apply, because the primary certification criterion implicated by this requirement (170.314(d)(7)) is not applicable to all end-user devices. However, we note for commenters that this situation is fact dependent and could apply to the health care provider's personal device if EHR technology is run on the device and locally stores electronic health information on the device after use has stopped. Consistent with the changes discussed in our responses above, we believe the certification criterion has been clarified. Further we have removed the phrase ''as applicable'' in the standard listed at 170.210(e) in favor of more plain language usage in the certification criterion itself.

Comments. Several comments applied to the standards we proposed to adopt and associate with the proposed ''auditable events'' certification criterion. Consistent with other comments summarized above, commenters asked that we accommodate situations where EHR technology does not allow for an audit log to be disabled or when it does not permit the encryption of electronic health information managed by EHR technology on end-user devices to be disabled. Other commenters suggested that we rely on SDO standards compared to the enumerated requirements we specified in the proposed standard at 170.210(e). They reasoned that an SDO standard has undergone much more extensive review

and socialization than the list of requirements embedded in the proposal and that an SDO standard is much more broadly adopted than a ''standard'' embedded in a regulation, and therefore more likely to take on uniform interpretation. Along those lines, they suggested that the ASTM E2147 standard we referenced in the proposed rule would be preferred over enumerating a list of requirements embedded in regulation. One commenter further suggested that a variety of HL7 and ASTM standards be referenced by this certification criterion to denote information objectives, actions, structural roles, participation function codes with security permissions, and data types to encode user identification. Another commenter asked that we clarify if the part of the ASTM E2147–01 standard that deals with disclosures has applicability to this certification criterion. One commenter suggested that we clarify that audit logging requires at a minimum date, time, and user id to determine who accessed certain electronic health information. With limited exceptions, commenters generally supported the adoption and application of the clock synchronization standards we had proposed.

Response. As discussed in the responses directly above related to changes already made to the certification criterion, we do not believe that it would be necessary or appropriate to include the conditional language suggested by commenters in the standards (and have since removed it from what we proposed). We agree with commenters that we should leverage SDO produced standards wherever possible and not embed an enumerated list in regulation. Accordingly, and as suggested by commenters, we analyzed ASTM E2147–01(2009) and believe that it includes an equivalent set of requirements as we proposed. Thus, the standards we express now refer to the appropriate sections of ASTM E2147–01(2009), rather than an enumerated list. For the first specific capability related to actions involving electronic health information, we have required that the data elements specified in sections 7.2 through 7.4, 7.6, and 7.7 of ASTM E2147–01(2009) be captured. For the other two specific capabilities related to the status of the audit log or the encryption status of electronic health information managed by EHR technology on end-user devices, we have required that the data elements specified in sections 7.2 and 7.4 of ASTM E2147–01(2009) be recorded. All three of these standards require that the user ID, date and time be recorded. We note that not all of the section 7.X parts of the ASTM E2147–01(2009) standard have been specified as they go beyond what we proposed to include. Thus, we seek to make clear that only those sections in section 7 that we have explicitly included in our standards are the minimum required for certification.

We decline to modify the certification criterion in response to the commenter's suggestion that we include a variety of standards to denote information objectives, actions, structural roles, participation function codes with security permissions, and data types to encode user identification. We did not propose such specificity, nor did the HITSC recommend that we include such specificity in the certification criterion. As we have noted in other responses, certification is a minimum. Thus, where additional standards exist and can be used to further improve capabilities for which certification is required, we encourage EHR technology developers to consider doing so. As requested by a commenter, we confirm that the ''disclosure log'' section (section 8) of ASTM E2147–01(2009) has no applicability to this particular requirement.

Last, we are finalizing the changes we discuss in this response as well as our proposal to adopt the clock synchronization standards we proposed.

Comments. Numerous commenters requested different clarifications related to the expected granularity of actions and information to be recorded. A commenter suggested that the granularity of electronic health information be limited to the metadata involved in identifying the patient whose record has been accessed, be sufficient for recording actions, and that it not require lower level clinical data objects to be logged if appropriate context of what kinds of information is logged is otherwise recorded. Another recommended that the certification criterion be more explicit in describing the level of how the ''action taken'' should be captured in terms of what was done, the data, and how it was changed. Yet another suggested that the information logged should be sufficient to enable a system administrator to identify, for example, that a specific patient's order that was modified, deleted, etc., or that a user accessed a patient's medication list. Other commenters raised concerns about the about the granularity of the information recorded in the audit log and its potential to include electronic health information. They contended that requiring this level of specificity would inappropriately duplicate clinical information in the audit log and could cause greater security issues. Instead, they suggested that the type of data acted upon should be the proper scope of this certification criterion and that implementing this approach would be more feasible and less costly. Further, these commenters expressed concern that the certification criterion could be interpreted to require very granular auditing which would adversely impact system performance and place undue burden on security auditors who may not be able to find the information they need. They argued that requiring this type of very granular auditing may introduce a burden on EHR adopters because of the amount of disk space required to store these audit logs. Other commenters stated that the scope of the data recorded should not be at the same level as a ''history table'' or ''action/event history table.'' Commenters indicated that the clinical level of detail included in those tables is appropriate to maintain the wholeness of clinical documents and data, but not for security audit trails. Instead, commenters suggested that HHS consider adopting a ''medical record history and completeness'' objective that is not related to security auditing.

Response. We appreciate the detail and thoughtfulness of the comments submitted on this certification criterion. In consideration of comments received, we agree that further explanation is necessary related to the scope and granularity of the information expected to be recorded. Given that we are now referencing relevant sections of ASTM E2147–01(2009), we believe that this standard reinforces what we would have said had we maintained our enumerated requirements. Section 7.7 of ASTM E2147–01(2009) discusses the ''identification of patient data that is accessed.'' It states that the ''granularity should be specific enough to clearly determine if data designated by federal or state law as requiring special confidentiality protection has been accessed.'' And, more to the point, Section 7.7 goes on to state that ''[s]pecific category of data content, such as demographics, pharmacy data, test results, and transcribed notes type, should be identified.'' We agree with commenters and understand the burden and security and privacy concerns issued as well as the disk space limitations referenced. Thus, we believe that it is appropriate for actions made to electronic health information and recorded in the audit log to be identified at a categorical (or type) level—this is also consistent with the guidance

included in ASTM E2147–01(2009). For instance, as noted by a commenter, we believe that the ability of the audit log to record that a user accessed a patient's medication list would be sufficient for certification and that the audit log would not have to also record the specific medication.

Comment. One commenter asked whether we intended for the certification criterion to require that relevant information be captured in a manner that supports the forensic reconstruction of the sequence of changes to a patient's chart or if we intended for the certification criterion to require that users be provided with on-demand snapshot views of the patient chart at any point in time with a highlighted comparison of data which is changed at any given moment. This commenter preferred the former because it stated that in order to implement the latter EHR technology developers would need to expend substantially more effort into the development of user interface capabilities, which would be used only in rare circumstances.

Response. We intend for the former, as stated by the commenter, that the actions and information can be captured in a manner that supports the forensic reconstruction of the sequence of changes to a patient's chart.

Comments. Commenters almost unanimously focused on the scope of the proposed certification criterion's third specific capability—that actions record must not be capable of being changed, overwritten, or deleted. Commenters' feedback included a range of different opinions. One commenter noted that this certification criterion should focus on access and alterations, while being cautious about pursuing attainment of immutable audit logs and detection of audit logs because the EHR technology can still be circumvented by select individuals with malicious intent. Another indicated that there were other techniques such as using separate hardened audit log technologies and suggested that this capability be met by proving separation of duty for security auditors and clinical EHR end users, detection of changes in audit system configuration to the extent it is allowed by the audit system for recording, and audit log abilities that may be present in the audit log solution itself for detecting accesses to the log. The majority of commenters noted that from a technological perspective there is only so much that is within the control of the EHR technology. These commenters sought clarifications in terms of the extent to which EHR technology is responsible for preventing changes, overwrites or deletions to the audit log. Several provided similar examples referencing the fact that users could access a file or database used by the EHR technology through the operating system on top of which the EHR technology may run or by directly accessing the database in which the audit information is stored. In general, all of these commenters requested that we should limit the scope of this specific capability to make clear that the audit log should not be able to be changed, overwritten or deleted through the EHR technology by its users.

Response. We appreciate the detailed responses and examples offered by commenters. As noted by many commenters, we acknowledge that there is only so much that is within the control of EHR technology and that nothing is ever 100% impenetrable. Thus, we have revised this specific capability within the certification criterion to state that the audit log must not be capable of being changed, overwritten, or deleted *by the EHR technology.* We believe this addition properly scopes the capability for which certification is required and will address commenters' concerns. As discussed in other responses, where the EHR technology permits the auditable actions and statuses to be disabled, we have required that some form of separation of duty be implemented in that only a limited set of identified users should be able to modify audit settings.

Comments. Several commenters expressed concern that the proposed certification criterion's third specific capability we proposed—that actions recorded must not be capable of being changed, overwritten, or deleted—did not permit the deletion of the audit log. Further commenters stated that this specific capability disallows the purging of audit logs after the required legal retention period has expired. They recommend adding ''except when disposing of log information after a legally defined retention period.'' Another commenter expressed a similar concern with the implications of an ''immutable'' audit log. They stated that data may not be kept on the same physical device as it ages and that data is ''added'' to another device and ''deleted,'' and thus cannot be ''immutable.'' They also stated that immediate storage of an audit log on ''write once read many'' (WORM) technology is not practical in all configurations.

Response. We are uncertain as to what in the Proposed Rule led commenters to make this interpretation since this certification criterion focuses on a capability that EHR technology would need to include. It was not our intention, nor did the certification criterion specify, that audit logs could not be deleted or purged after a legal retention period. Such a step would be an organizational policy decision and not within the scope of certification. Thus, we decline to make the more detailed suggested modifications. However, to make it clear that such steps are not prevented by the certification criterion, we have added to the specific capability related to the audit log's immutability that the audit log must not be capable of being changed, overwritten, or deleted *by the EHR technology.* We believe this addition properly scopes the capability for which certification is required and will address commenters' concerns.

Comments. A few commenters indicated that they believed an inconsistency existed between the proposed certification criterion's third and fourth specific capabilities. Commenters noted that if the certification criterion requires that an audit log not be capable of being changed, overwritten, or deleted that it was unclear why we would also require EHR technology to detect an alteration to the audit log. The commenters questioned whether the third specific capability rendered the fourth capability moot and if the fourth was still necessary. Last, a commenter requested clarification regarding what would constitute an alteration of an audit log.

Response. Given the reordering of the specific capabilities within this certification criterion and the clarification that we made above regarding the scope of the now finalized fourth specific capability ''(iv)'' (that requires that an audit log not be capable of being changed, overwritten, or deleted by the EHR technology), we believe that it is also necessary to clarify the scope of the specific capability we proposed regarding EHR technology's ability to detect an alteration to the audit log. This specific capability, which is now designated as the fifth specific capability ''(v),'' has been revised to state that ''EHR technology must be able to detect whether the audit log has been altered.'' We believe that this specific capability complements the other capability specified at (d)(2)(iv) from a defense-in-depth perspective. Further, we clarify that this specific capability requires EHR technology to be able to determine whether activity outside of its control has in some way altered the audit log (e.g., that the operating system was exploited to modify the EHR technology's database). In this respect, the EHR technology will be able to detect whether its audit log has been corrupted. While this may not

be the only approach EHR technology developers can use, we encourage the use of hashing algorithms specified in FIPS 180–4 (Secure Hash Standard) to determine whether the audit log has been altered.

Comments. Commenters strongly supported the two certification criteria we proposed from the single 2011 Edition EHR certification criterion. Further, a commenter encouraged that testing and certification for these two certification criteria should be done independently to allow for separate security audit log technologies to be presented for certification as EHR Modules. This commenter urged that there should not be a dependence for an EHR technology developer of a free standing audit log reporting technology to certify with each and every source EHR that may send it audit events and data as if a business partnership were required to do so. In essence the commenter sought clarification that it was possible for the certification criterion proposed at 170.314(d)(3) to be certified independently and on a standalone basis.

Response. Yes, it is possible for EHR technology to be independently certified to 170.314(d)(3). We proposed two separate certification criterion for exactly this reason. Previously the 2011 Edition EHR certification criterion required that EHR technology demonstrate both the recording of auditable events and the report generation in order to be certified. With this separation EHR technology can be separately certified to perform these two capabilities. A stand-alone EHR Module for audit log reporting would not need to certify with each and every source EHR technology that may send it auditable events. In order to meet the certification criterion the EHR technology would need to demonstrate that it could capture the required data.

Comments. We received only a few comments on the proposed audit reports certification criterion at 170.314(d)(3). They expressed support for the proposed certification criterion and one commenter requested clarification of the expectation for reports generation.

Response. We appreciate commenters' support. We are finalizing the certification criterion as proposed. This certification criterion expresses the capability that EHR technology must 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 elements specified in the standards at § 170.210(e). Anything beyond that requirement is beyond the scope of certification and likely depends upon organizational policy.

• *End-User Device Encryption*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion
§ 170.314(d)(7) (End-user device encryption).

In the Proposed Rule, we proposed to revise the ''general encryption'' certification criterion adopted at § 170.302(u) as part of the 2011 Edition EHR certification criteria in favor of a certification criterion focused on the capability of EHR technology to encrypt and decrypt electronic health information managed by EHR technology on end-user devices if such electronic health information would remain stored on the devices after use of EHR technology on that device has stopped. We proposed this revised approach because we thought it would be more practical, effective, and easier to implement than the otherwise general encryption requirement adopted at § 170.302(u). Further, we agreed with the HITSC that we should focus more attention on promoting EHR technology to be designed to secure electronic health information on end-user devices (which are often a contributing factor to a breach of protected health information [26]). The OIG provided similar rationale in its May 2011 report (previously cited under the discussion of the ''*auditable events and tamper-resistance'' and ''audit report(s)'' certification criteria*) in which it recommended that ONC address IT security controls for encrypting data on mobile devices. The proposed certification criterion was drafted to permit EHR technology developers to demonstrate in one of two ways that a Complete EHR or EHR Module is compliant.

The first proposed way, § 170.314(d)(7)(i), accounted for circumstances in which EHR technology was designed to manage electronic health information on end-user devices and on which electronic health information would remain stored on the end-user devices after use of the EHR technology on the devices has stopped. We clarified that we intended for the term ''stopped'' to mean that the session had been terminated, including the termination of the network connection. We stated that in these circumstances, EHR technology presented for certification must be able to encrypt the electronic health information that remains on end-user devices. And, to comply with paragraph (d)(7)(i), that this capability must be enabled (i.e., turned on) by default and only be permitted to be disabled (and re-enabled) by a limited set of identified users. We did not include ''decrypt'' in the proposed certification criterion because we determined it was best to focus certification on the most critical capability, the act of encryption after use of the EHR technology on the end-user device has stopped. Last, we explained that the phrase ''manages electronic health information'' in the certification criterion meant that the EHR technology was designed in a way that it could exert control over the electronic health information that remains on an end-user device after the use of EHR technology on that device has stopped. We stated, for example, that if an EHR technology was designed to manage a client application that can be executed on a laptop or tablet, and electronic health information would remain stored—even in temporary storage—on that end-user device when a user stops using the client application on the laptop or tablet, the EHR technology would need to meet the requirements specified at § 170.314(d)(7)(i) in order to be certified.

The second proposed way to demonstrate compliance with this certification criterion was for an EHR technology developer to demonstrate that its EHR technology could meet § 170.314(d)(7)(ii) and prove that electronic health information managed by EHR technology never remains on end-user devices after use of EHR technology on those devices has stopped. We explained that this alternative method was important to include because it: (1) Verifies as part of certification that the EHR technology was, in fact, designed in a way such that it does not enable electronic health information to remain on end-user devices after use of EHR technology on those devices has stopped; (2) provides EHR technology developers a way to demonstrate compliance with this certification criterion; and (3) it encourages an outcome that is more secure (i.e., when no electronic health information is permitted to remain, the potential for a breach is mitigated).

Comments. Many commenters offered their support for this certification criterion. One applauded the decision to allow the option to either encrypt end-user devices or make sure no data remains on end user devices managed by the EHR technology. Several noted that since a majority of breaches by

[26] *http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/breachrept.pdf.*

HIPAA covered entities or their business associates have been due to lost or stolen unencrypted portable media, requiring default encryption functionality for end-user devices managed by CEHRT should help reduce health data breaches. Another commenter indicated that this security measure has largely been ignored and agreed that making encryption a requirement for EHR certification should help spur industry to protect data security.

Response. We thank commenters for the positive feedback. As we have stated elsewhere in this final rule, we believe that certification can help to ensure that in adopting CEHRT EPs, EHs, and CAHs have technical capabilities that they can use to enhance their security practices and make compliance with other regulatory requirements more efficient.

Comments. A few commenters requested clarification of the term ''stopped.'' One suggested that we include ''in the prescribed manner.'' A second referenced ''prescribed manner'' and stated that they thought it would be difficult to test that an EHR technology never leaves electronic health information on an end-user device when it is terminated in the prescribed or non-prescribed manner. They encouraged that attestation be permitted for the test procedure. Another suggested that we consider whether ''stopped'' includes abnormal termination of a session and a network connection versus normal termination. They explained that routines that manage temporary storage may only be part of normal session termination whereas there may be processes to preserve images or caches for session resumption in the case of an abnormal termination that could pose risk by persisting health information in order to prevent data loss when an abnormal interruption such as battery failure or power outage to the device occurs.

Response. We decline to modify this certification criterion to add ''in a prescribed manner.'' We do not believe that this qualifying phrase is necessary or adds significant clarity to the proposed certification criterion. We continue to believe that our general description of ''stopped'' in the proposed rule (''that the session has been terminated, including the termination of the network connection'') is sufficient for this certification criterion. In other words, use of EHR technology is considered to be stopped when a user closes or exits the EHR technology application and would need to re-execute the EHR technology application to again engage in use. However, we acknowledge, as commenters pointed out, that there could be predictable/prescribed stops and unpredictable/abnormal stops (i.e., power or battery failure). For the purposes of certification to this 2014 Edition EHR certification criterion, we clarify that testing and certification will focus on normal terminations. We will consider whether more advanced and rigorous testing and certification requirements for future editions of certification criteria would be necessary. In the following responses when we refer to ''stop'' or ''stopped,'' we are referring to normal stops.

Comments. Numerous commenters requested clarification regarding the phrase ''managed by'' in the certification criterion. Along those lines many asked that we clarify the certification criterion's scope and applicability. Some stated that we should clarify that it only applies to storage capabilities that are designed for use with EHR technology developer provided or supported technologies for desktop, laptop, mobile, cellular based technologies or similar technologies, and not to capabilities that may be present in technology components such as operating systems, swap files, and memory management technologies that are embedded and non-configurable as to their use by the EHR system (since the EHR technology developer is unable to change those capabilities). These commenters suggested that this certification criterion be applied to the deliberate use of storage capabilities that are configurable or to the management of caching files that the EHR technology developer, by design, elects to use and manage on such devices. One commenter asked whether the EHR technology is expected to enforce encryption or if it must be capable of notifying the receiving device that the data being downloaded contains electronic health information and therefore such data must be encrypted.

A few sets of comments on the ''managed by'' concept included detailed information on two points. The first asked whether we had intended for the certification criterion to apply only in cases where the EHR technology *has control over* the ability of the user to store data on their device, installs a client application, etc. This commenter suggested that the language in the certification criterion may be unclear when it is read in isolation, outside of the preamble. Further, this commenter noted (as was echoed in a different comment) that the meaning of the term ''managed by'' was missed by many of its contributors and that many assumed that the certification criterion required the EHR technology to enforce encryption on *any* mobile or portable device. The second point addressed a technical concern and limitation. Commenters stated that the operating system or other technology on the end-user device may cache electronic health information and retain it after use of the EHR technology on an end user device has stopped. They indicated that, for example, swap and cache files, sleep and hibernate features, and application context switching in Windows 8 Metro apps or iOS may all cause electronic health information to be cached to disk. Similarly, they stated that some browsers do not respect ''no-cache'' headers, potentially leading to electronic health information being cached on the end-user device if users access the EHR with a non-vendor supported browser. Additionally, commenters indicated that these instances were beyond the control of the CEHRT and are subject to user configuration and control to achieve the desired objective. These commenters requested a reasonable clarification of the term ''manage'' and stated that it would be unreasonable to expect EHR technology to control how operating systems and other technologies perform memory management and that they did not consider this information to be managed by the EHR technology.

Last, a commenter asked who was responsible for encryption on end-user devices (e.g., EHR developer, covered entity/business associate, etc.). They stated that in practice this requirement will affect all desktops—even home computers—that cache content from web-based EHR systems. Further, they questioned how this requirement interacted with the proposal that the encryption capability must only be disabled by a limited set of identified users.

Response. We appreciate the detailed and thoughtful feedback provided by commenters. Because all of the comments revolved around the phrase ''managed by,'' we believe it will be most effective to respond to the general clarifications up front and then explain the revisions we have made to this proposed certification criterion. We believe this approach will be clearer and more efficient with respect to how we interpret this certification criterion than if we were to individually address each specific comment within this comment summary.

As noted in the Proposed Rule, we proposed this certification criterion to focus and encourage EHR technology developers to design secure implementations and equip EHR technology with the ability to assist users in keeping end-user devices

secure. End-user devices can pose a specific vulnerability, especially as they become more prevalent and computationally powerful.

Given the uniform confusion surrounding the phrase ''managed by,'' we have revised this certification criterion to functionally describe the event that we had intended to capture with the phrase—the local storage and persistence of electronic health information on end-user devices. The general policy we express in this certification criterion requires EHR technology designed to locally store electronic health information on end-user devices to encrypt such information after use of EHR technology on those devices stops. We clarify that in this context, locally stored electronic health information is intended to mean the storage actions that EHR technology 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. Similar to the changes we made to the auditable events certification criterion, we have clarified that in this scenario, the EHR technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users. While it may not ''enforce'' encryption per se, this certification criterion does require that EHR technology designed in this way be set by default to encrypt when electronic health information is locally stored on end-user devices.

We agree with commenters and clarify that this certification criterion focuses on, and only applies with respect to, the storage capabilities that are designed for use with EHR technology developer provided or supported technologies for desktop, laptop, or mobile technologies (and similar variations of such technologies) (i.e., it is generally not intended to apply to personally owned end-user devices, unless an EHR technology developer supported technology is loaded/installed on such a device). The certification criterion does not apply with respect to capabilities that may be present in the underlying technology on which EHR technology may run, but is unable to control through the EHR software, such as operating systems, swap files, and memory management technologies that are embedded and non-configurable by the EHR technology. Thus, these revisions are consistent with the sentiments issued by commenters that suggested this certification criterion be applied to the deliberate use of storage capabilities that are configurable or to the management of caching files that the EHR technology developer, by design, elects to use and manage on such end-user devices. We recognize that a spectrum of different implementations exist and that they may range from a ''thin client,'' [27] to a viewer that shows the screen of remote virtual server, to a web browser that accesses a remote web service, to more traditional client/server ''thick client'' [28] implementations, and to where EHR technology in its entirety could run entirely on single a device. On one end of the spectrum no electronic health information would persist when a user stops using EHR technology. Toward the other end of the spectrum electronic health information would always persist when a user stops using EHR technology. Ultimately, as expressed in the paragraph (d)(7)(i) of this certification criterion, if the EHR technology developer designs EHR technology that requires or utilizes locally stored electronic health information, it is the EHR technology developer's responsibility to ensure that such information is set to be encrypted by default in order to meet this certification criterion. We expect that this capability could be accomplished through a number of different technical mechanisms, including techniques to ''sandbox'' [29] and limit the extent to which data can be accessed and used to only be within a secure session.

With respect to paragraph (d)(7)(ii) of this certification criterion, we have revised the language to acknowledge that despite an EHR technology developer's best effort to design EHR technology in such a way (as suggested by our proposal) that electronic health information never remains, we understand from commenters that such absolutes cannot always be guaranteed (especially when an EHR technology developer is unable to modify the functionality a particular web browser or operating system employs). With this in mind, we have revised this portion of the certification criterion to state that an EHR technology developer would not have to demonstrate that its EHR technology can encrypt electronic health information locally stored on end-users devices if the EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops. We interpret ''prevent'' to include, for example, situations where EHR technology is designed to and would normally disallow electronic health information to be locally stored on end-user devices after use of EHR technology on those devices stops, but is run in a browser that does not respect ''no-cache'' headers. In this circumstance, and if shown under normal circumstances (i.e., running in a browser that does respect ''no-cache'' headers), the EHR technology could meet paragraph (d)(7)(ii) of this certification criterion.

Comment. A commenter stated that they considered information that has been sent to a print queue or downloaded by the user (such as downloading a PDF report) to no longer be managed by the EHR technology.

Response. We generally agree with this statement.

Comment. A commenter asked that we clarify whether data at rest on a server located at a secure data center must be encrypted and, if yes, to please reconsider this requirement because they believed it would slow down response times in large cloud-based EHR systems.

Response. As indicated above, this certification criterion does not focus on server-side or data center hosted EHR technology. We recognized 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 capabilities.

Comment. One commenter recommended that disk level encryption, which is implemented outside of CEHRT, be deemed an acceptable means through which to fulfill this criterion. They contended that EHR technology developers should not be forced to create their own proprietary encryption implementations, when this capability is already available through other means.

Response. We cannot deem this approach acceptable to fulfill this certification criterion because it would not be a capability that could be demonstrated by EHR technology. However, in situations where a user has implemented disk encryption hardware

[27] In some cases referred to as lean or slim, a thin-client typically does not perform/provide any computational assignments. Rather, it serves as a terminal through which a user can access computational resources on a server.

[28] Compared to thin-clients, thick-clients typically perform/provide for computational assignments to be completed on the thick-client rather than the server, but may also utilize certain features/resources that a server includes.

[29] ''Sandbox'' or ''sandboxing'' is typically used to describe an information security approach that allows programs to run in a separate and secure environment. Programs run within a sandbox typically have limited access to certain system resources and may be restricted from performing certain actions.

and would be using EHR technology that is designed to save electronic health information to local storage on end-user devices, the user may, through a risk analysis, determine that disabling the EHR technology's encryption capability is prudent since its data will be protected through the disk encryption hardware.

Comment. A commenter recommended that we discourage the use of or remove the allowance for 3DES because the algorithm is on track to be deprecated by NIST in the near future.

Response. We agree with this commenter and encourage EHR technology developers to use the other encryption algorithms, such as AES, that are included in FIPS 140–2 Annex A.

Comment. A commenter expressed concern that this certification criterion would cause financial hardship related to the additional involvement of copy machines, EKG machines, etc., and stated that health care practices need to be aware of the cost.

Response. Given our responses above, we do not believe that this concern is valid.

Comment. In the context of this certification criterion, a commenter encouraged ONC to evaluate the necessary steps to incorporate the ability to access a patient's health information during urgent or emergency situations.

Response. We have considered this comment and do not believe that any change to the certification criterion is warranted given the clarifications we have made above.

Comments. A commenter indicated that the proposed certification criterion could be interpreted to exceed the requirements set forth in the HIPAA Security Rule, which provides that encryption is addressable requirement (evaluated as part of a risk assessment), rather than a required control. They stated that one might infer that the implementing organization must use this capability if their EHR technology was required to be certified to it. The commenter suggested that we clarify any distinction between the HIPAA Security Rule and the proposed certification criterion. Last, they suggested that if the encryption of data on connecting devices is truly considered a best practice, that it seems that it is best first addressed by OCR as a new required control in the HIPAA Security Rule, which could then be incorporated into the MU requirements (compared to using the MU requirements to indicate best practice for a limited set of HIPAA regulated entities).

Response. This certification criterion applies to EHR technology and does not supersede or affect the HIPAA Security Rule's requirements or associated flexibilities. As we have stated in this preamble and prior rules, we believe that by requiring these capabilities to be part of an EP, EH, or CAH's CEHRT that it will assist and enable them to more efficiently comply with security requirements such as the HIPAA Security Rule. We note that HHS [30] has issued guidance around encryption as a possible risk management strategy to address storage of electronic protected health information.[31] In addition, HHS has issued guidance on how to render unsecured protected health information unusable, unreadable, or indecipherable to unauthorized individuals.[32]

• *Immunization Information; and Transmission to Immunization Registries*

MU Objective
Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.
2014 Edition EHR Certification Criteria
§ 170.314(f)(1) (Immunization information).
§ 170.314(f)(2) (Transmission to immunization registries).

We proposed two certification criteria for immunization registries that were essentially a split of the 2011 Edition EHR certification criterion for submission to immunization registries (§ 170.302(k)). We proposed one certification criterion that focused just on the capabilities to electronically record, change, and access immunization information (data capture) and another that focused on the capability to electronically create immunization information for electronic transmission in accordance with specified standards. We discussed these two proposed certification criteria together in the Proposed Rule for simplicity and to prevent confusion, but noted that we did not consider the certification criterion we proposed to focus on data capture to be a revised certification criterion. Rather, we stated that we believed that the certification criterion would constitute an unchanged certification criterion because all the capabilities included in the criterion were the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.302(k)). Additionally, for this certification criterion, we proposed to replace the terms ''retrieve'' and ''modify'' in the revised criterion with ''access'' and ''change,'' respectively.

For the certification criterion focused on electronically creating immunization information for electronic transmission, we clarified that this criterion focuses on the capability of EHR technology to properly create immunization information for electronic transmission in accordance with the applicable standards and implementation specifications. We further emphasized that the criterion does not address the ability to query and evaluate immunization history from the immunizations information systems (IIS) to determine a patient's vaccination need, nor does it address the specific connectivity requirements that an EP, EH, or CAH would need to establish or meet to successfully transmit immunization information, as such requirements are likely to vary from state to state and are outside the scope of certification. We proposed the use of only the HL7 2.5.1 standard for formatting immunization information because immunization registries are rapidly moving to this standard. We also proposed to adopt the HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.3 as the implementation specification which provides corrections and clarifications to Release 1.0 and contains new guidance on how to message vaccines for children (VFC) eligibility. Finally, we proposed to adopt the August 15, 2011 version of CVX code sets.

Comments. Commenters supported our proposed ''two certification criteria approach.'' One commenter noted strong support for ONC's change in terminology from ''retrieve and modify'' to ''access and change'' and the clarification that this criterion does not include in scope the retrieval of immunization data from an external source to the EHR.

Response. We appreciate the support for the proposed certification criteria and the change in terminology. We are adopting these certification criteria as proposed, but with the inclusion of an updated implementation guide as discussed below.

Comments. Commenters expressed support for moving to only HL7 2.5.1. Commenters stated that requiring all EHR technology developers to consistently adopt the same standards would promote the access and use of immunization data and further boost

[30] Please note that CMS originally issued HIPAA Security Rule guidance.

[31] *http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/remoteuse.pdf.*

[32] *http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brguidance.html.*

interoperability and exchange. A couple of commenters recommended that HL7 2.3.1 and HL7 2.5.1 both be accepted for certification as part of the 2014 Edition EHR certification criteria. These commenters also recommended that HL7 2.5.1 could be required and HL7 2.3.1 could be optional as a means of allowing a reasonable transition period.

Response. We appreciate the support for the moving solely to HL7 2.5.1. We do not believe that permitting EHR technology to continue to be certified to HL7 2.3.1 as a means of meeting this certification criterion promotes improved exchanged and interoperability. Therefore, we are adopting only HL7 2.5.1 for the ''transmission to immunization registries'' certification criterion.

Comments. Commenters generally agreed with our proposal to adopt the HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.3 as the implementation specifications. One commenter contended that the implementation guide is vague on several important points regarding requirements for specific types of data and the circumstances in which specific data should be sent. The commenter recommended using the HL7 2.3.1 standard for certification because the HL7 2.3.1 Implementation Guide for Immunization Messaging is more clear on these important points than the 2.5.1 guide.

Response. We appreciate the support for the implementation guide. The CDC has worked to clarify ambiguities in Release 1.3 of the implementation guide and has published a new version of the implementation guide, Release 1.4, which reflects these clarifications. In particular, Release 1.4 clarifies the separate usage responsibilities for senders and receivers, provides conformance statements identifying core data elements that must be supported based on the National Vaccine Advisory Committee (NVAC) core data elements, adds support for messaging Vaccine Information Statement (VIS) data based on a 3D barcode, and provides HL7 version 2.7.1 usage guidance that improves clarity for conformance criteria and the requirements for HL7 message elements. Overall, these revisions do not establish additional substantive requirements in comparison to Release 1.3. Rather, the revisions improve the ability to test and certify EHR technology to the implementation guide and make it easier for EHR technology developers to implement the guide's requirements based on the corrections and clarifications. Accordingly, in lieu of adopting Release 1.3 of the implementation guide as we had proposed, we have adopted Release 1.4 for the ''transmission to immunization registries'' certification criterion. For the reasons stated above, we are not adopting HL7 2.3.1.

Comments. One commenter recommended that EPs, EHs and CAHs comply with the public health agency's local HL7 specifications guide as these guides describe what data elements are required within the jurisdiction that may go beyond those described in the CDC HL7 implementation guide. Conversely, another commenter stated variances at the local public health agency level in the content and transmission specifications continue to add challenges and cost to the adoption of immunization reporting (e.g., additional requirements or proprietary specifications). The commenter stated these challenges are further exacerbated by the fact that there are no standard specifications for the transmission of immunization reports. The commenter urged ONC to work with the CDC to identify ways to improve the adoption of the CDC implementation guides (content and transmission specifications) by the state immunization registries.

Response. Release 1.4 of the implementation guide reduces variability and standardizes the required data elements across public health jurisdictions. Release 1.4 also notes a standard format for states to indicate any variability. The certification criteria do not address transport standards, as this is left to the receiving public health authority. However, an expert panel convened by CDC and American Immunization Registry Association (AIRA) has recommended a SOAP-based standard for transport of immunization data.

Comments. Commenters stated that at least several states have made recording a patient's consent decision relative to the disclosure of immunization data by the provider (or consent to its re-disclosure by the external agency collecting it) a de facto requirement for electronic submission of immunization data. Commenters noted that recording patient consent was not part of the testing and certification for the 2011 Edition EHR certification criterion, but asked whether recording a patient's consent will be part of certification to the 2014 Edition EHR certification criteria. Some commenters more specifically asked whether patient consent would not to be recorded per the PD1–12 Protection Indicator of the referenced implementation guide.

Response. We believe that Release 1.4 of the implementation guide reduces the variability and standardized the required data elements across public health jurisdictions, including requirements for consent.

Comments. Commenters expressed support of the continued use of the CVX code sets and the August 15, 2011 version. Commenters requested that we specify that the vaccine administered be coded by the CVX and MVX (where known) as the combination would allow a specific vaccine to be identified accurately. One commenter recommended that a detailed review be conducted between ONC, the AIRA, CDC, and selected public and commercial stakeholders, for the purpose of revising the current CVX immunization code set to account for a small but significant number of remaining common discrepancies between data necessary to comprise an accurate and minimally complete immunization record which remains unaccounted for in current certified EHR systems. A few commenters recommended the inclusion of the National Vaccine Advisory Committee (NVAC) approved Immunization Information System Core Data Elements as required elements. One commenter noted that these are currently under review and revision but expected to be in place for 2013. One commenter requested clarification on what data should be included in immunization history.

Response. As we required for the 2011 Edition EHR certification criterion for immunization reporting, we continue to believe that the adoption of CVX is appropriate and that no other vocabulary standard need to be expressly adopted for the purposes of certification. We do, however, appreciate the points raised by commenters and will discuss them with our colleagues at CDC for consideration in proposals for the next edition of EHR certification criteria we propose.

Comments. One commenter noted a challenge facing transitioning data entry immunization registry challenges relating to replacing the ''Vaccines for Children'' inventory tracking and ordering functionality with EHR functionality.

Response. It is not clear exactly what the commenter was specifically addressing. The Implementation Guide defines a standardized way to record and track VFC eligibility. However, it does not address issues of inventory tracking.

Comments. A commenter expressed concern about specifying a particular CVX code set in regulation, particularly as the code set has been updated since the August 15, 2011 version. Commenters recommended the

following wording change: ''HL7 2.5.1 and Implementation Guide for Immunization Messaging Release 1.3, or the most recent version as published by CDC'' for adoption of the implementation guide in regulation.

Response. We have established a process for adopting certain vocabulary standards, including CVX, which permits the use of newer versions of those standards than the one adopted in regulation. We refer readers to section IV.B for a discussion of ''minimum standards'' code sets and our new more flexible approach for their use in certification and upgrading certified Complete EHRs and certified EHR Modules. Readers should also review § 170.555, which specifies the certification processes for ''minimum standards'' code sets. In response to the commenters' suggestion that we permit the use of the ''most recent version'' of the implementation guide for certification, we refer the commenters to section III.A.5 found earlier in this preamble. This section explains why we cannot take such an approach. To note, as discussed above, in lieu of adopting Release 1.3 of the implementation guide as we had proposed, we have adopted Release 1.4.

Comments. A commenter noted concerns about the meaning of the language regarding reporting immunizations after receipt of a CCDA. It should be the responsibility of the EHR transmitting the CCDA to report the original immunization information. Requiring EHRs to report immunizations not administered within the context of the EHR may lead to duplicate results and require additional reconciliation at state immunization registry level.

Response. We cannot locate the exact language in the Proposed Rule that would have led this commenter to raise these concerns. The triggering event for reporting of an immunization is not part of the certification criteria. Certification focuses on the ability of EHR technology to properly create immunization information for electronic transmission according to the adopted standard and implementation specification.

Comments. One commenter disagreed with the requirement to transmit data to an immunization registry. The commenter stated that a process where data is directly entered into a state's certified application that is provided by the state immunization registry should be acceptable. The commenter noted that this information is stored directly in the state's immunization database and then the commenter's EHR technology hosts the state's immunization application. The commenter argued that this obviates the need for an interface and does not put the data at risk. The commenter stated that because of the inflexibility of the certification requirements, it has had to create a costly and inefficient interface to send data from its EHR technology to the state's registry. Therefore, the commenter recommended that § 170.314(f)(2) be made optional for those institutions that use a certified module provided by a state registry to directly enter immunization information as part of their EHR technology.

Response. The purpose of this certification criterion is to support interoperability between EHR technology and public health. Thus, any EHR technology that meets the certification requirements can be utilized to submit data to an Immunization Registry. Again, to meet this certification criterion, EHR technology must be able to properly create immunization information for electronic transmission according to the adopted standard and implementation specification. How this standardized data created by CEHRT gets to public health is not within the scope of certification. Additionally, we are aware that some states are considering modular certification of the state immunization registry to accomplish this function.

Comments. Commenters noted that the HITSC commented that it would be useful to have a standard for updating registries with groups or lists of patients instead of only individual patient transactions. The commenters stated that we should consult standards development organizations (i.e., HL7 for the v.2.5.1 message) to determine the most appropriate standard to achieve this goal.

Response. It is our understanding that most state immunization registries can accept batch reporting via the HL7 2.5.1 message standard and we previously indicated this approach was acceptable in FAQ 9–10–002–1.

Comments. Commenters expressed confusion over whether EHR technology must be certified to a transport standard to meet this certification criterion and whether EPs, EHs, and CAHs must use certain transport standards for submitting immunization information to immunization registries. Several commenters supported the requirement that eligible professionals utilize the transport method or methods supported by the public health agency to achieve meaningful use. Conversely, commenters requested that ONC require EHRs be certified in SOAP web services as well as Direct. These commenters also recommended that SOAP web services requirements should include the Centers for Disease Control and Prevention (CDC)'s Transport Layer Expert Panel WSDL specifications.

Response. We want to make clear that we do not require EHR technology to be certified to any transport standard, including Direct, to meet this certification criterion. There is no consensus transport standard that states and public health agencies use for the reporting of immunization information. Therefore, we believe that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies.

Comments. Several commenters suggested using the preferred term ''Immunization Information Systems'' for the ''transmission'' certification criterion rather than ''Immunization Registries.''

Response. We appreciate this suggestion, but are retaining the same naming convention for the certification criterion to prevent confusion with the associated MU objective and measure. The associated MU objective specifically references immunization registries.

Comments. Commenters stated that EPs, EHs, and CAHs that are currently successfully submitting immunization data in an ongoing manner using the HL7 2.3.1 and its implementation guide should continue to be able to do so for MU. One commenter suggested we explore offering additional incentives to early-adopting EPs, EHs, and CAHs that upgrade to the HL7 2.5.1 standard. A few commenters stated that, although bi-directional communication is not proposed for MU Stage 2, we should indicate that it will likely be required for MU Stage 3.

Response. We appreciate the submission of these comments, but they are outside the scope of this rulemaking. We direct commenters to the Stage 2 final rule found elsewhere in this issue of the **Federal Register** for a discussion of the MU objective and measure and a response to these comments.

Comments. A commenter stated that patients should be able to have access to immunization records and receive an accounting of all disclosures for public health surveillance. Another commenter requested that interoperable immunization registries which require all registries to accept the proposed standards without requiring additional data.

Response. We thank commenters for these comments, but they are outside the scope of this rulemaking.

Comments. One commenter requested that Federal sources build a common portal for connectivity to immunization registries and other external data sources (e.g., HIEs, public health agencies, cancer registries, and non-cancer registries) so that the financial burden on EHR technology developers and end users is reduced.

Response. We appreciate this feedback, but it is outside the scope of certification and this rulemaking. We note that while no proposal for a single interface to all immunization registry exists, an expert panel convened by CDC and AIRA recommended standards for transport that include a standard WSDL which should help reduce the financial burden on EHRs to interface with immunization registries.

• *Transmission to Public Health Agencies—Syndromic Surveillance*

MU Objective
Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.
2014 Edition EHR Certification Criteria
§ 170.314(f)(3) (Transmission to public health agencies—syndromic surveillance).

We proposed two certification criteria for reportable laboratory tests and values/results that were essentially a split of the 2011 Edition EHR certification criterion for reportable lab results (§ 170.302(l)). We proposed one certification criterion that focused just on the capabilities to electronically record, change, and access syndrome-based public health surveillance information (data capture) and another that focused on the capability to electronically create syndrome-based public health surveillance information for transmission in accordance with specified standards. We discussed these two proposed certification criteria together in the Proposed Rule for simplicity and to prevent confusion, but noted that we did not consider the certification criterion we proposed to focus on data capture to be a revised certification criterion. Rather, we stated that we believed that the certification criterion would constitute an unchanged certification criterion because all the capabilities included in the criterion were the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.302(1)).

For the certification criterion focused on creating syndrome-based public health surveillance information for transmission, we proposed the use of only the HL7 2.5.1 standard for formatting syndrome-based public health surveillance. We stated that we proposed only the HL7 2.5.1 standard because public health agencies are rapidly moving to this standard and all stakeholders would benefit from focusing on a single standard for public health surveillance. We also proposed to constrain the standard for hospitals with the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1 (Release 1.0). We further proposed that certification to this guide be optional for the ambulatory setting because certification of ambulatory EHR technology to this guide could be useful for EHR developers that provide EHR technology to EPs that practice in urgent care settings.

Comments. Commenters supported our proposed ''two certification criteria approach.'' Commenter also stated that proposing the certification criteria in the manner that we had would permit HIEs to be certified to the certification criterion that includes the capability to create syndrome-based public health surveillance for transmission in accordance with specified standards and then serve as intermediaries for the transport of syndromic information to public health agencies. Another commenter noted that there should be no certification requirement required of the HIE to support this MU measure.

Response. We appreciate the support expressed by commenters for our approach. We are adopting as part of the 2014 Edition EHR certification criteria the certification criterion focused on the capability to create syndrome-based public health surveillance in accordance with the standards we have specified (§ 170.314(f)(3)). We are not, however, adopting the certification criterion we proposed that focused on data capture. We have chosen to drop this proposed certification criterion because we do not believe that it is essential to focus on from a testing and certification perspective. It is our understanding that EPs, EHs, and CAHs will not necessarily be recording, accessing, and capturing separate kinds of ''syndromic surveillance'' information to facilitate the transmission of syndrome-based public health surveillance information to public health agencies. Rather, they will simply be ''passing on'' or reporting the information that already exists in their CEHRT to public health agencies. Thus, upon further reflection, this ''data capture'' certification criterion is unnecessary for certification.

We agree with commenters regarding HIEs and noted in the Proposed Rule that our approach to the public health certification criteria could enable additional EHR technologies (likely in the form of EHR Modules) to be certified and provides additional pathways and flexibility to EPs, EHs, and CAHs to have EHR technology that can be used to satisfy the proposed revised definition of CEHRT. In regard to the commenters assertion that HIE should not be required to be certified, we note that there is no such requirement. However, if an HIE performs a capability for which certification is required and an EP, EH, or CAH uses that capability for MU, then that capability must be certified.

Comments. Many commenters supported the use of the HL7 2.5.1 standard and moving to a single standard. Some commenters asserted that imposing new standards, like a move from HL7 2.3.1 or HL7 2.5.1 to a requirement for HL7 2.5.1 only, on all systems will penalize early-adopting providers. One commenter suggested that newer data formats supported through the consolidated CDA be acceptable alternatives for transmission to public health agencies for medical research and public health.

Response. We appreciate the support for the HL 2.5.1 standard we proposed and have now adopted this standard as the sole standard for this certification criterion. We are adopting only the 2.5.1 standard because, as noted above and in the Proposed Rule, public health agencies are rapidly moving to this standard and all stakeholders would benefit from focusing on a single standard for public health surveillance. In regard to the concern expressed by commenters that our approach would punish early adopters using HL7 2.3.1, we direct commenters to the Stage 2 final rule found elsewhere in this issue of the **Federal Register** for a response to this comment. Last, we do not believe that the Consolidated CDA is appropriate for this certification criterion at the present time.

Comments. A commenter believed that it would be sufficient to simply adopt the implementation guide itself for this certification criterion because it incorporates the HL7 2.5.1 standard.

Response. We believe it is appropriate to specifically adopt this standard and not just the implementation guide that references this standard to provide clarity around the certification requirements for this certification criterion. In particular, the implementation guide is optional for the ambulatory setting. Therefore, clearly specifying the standard will ensure that

EHR technology designed for the ambulatory setting will be certified to the HL7 2.5.1 standard.

Comments. Commenters supported the adoption of the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1 (Release 1.0). Commenters also supported having certification to the implementation guide optional for the ambulatory setting, while one commenter requested that it be mandatory and another commenter stating that it was unnecessary to have for the ambulatory setting.

Response. We appreciate the support expressed for the implementation guide. The CDC has recently published Release 1.1 of the implementation guide. Release 1.1 reflects the work of the CDC to correct errors and clarify ambiguities that were present in Release 1.0 as well as provide information that was missing in Release 1.0. The CDC also recently published an addendum to the implementation guide, titled ''Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance.'' The addendum consolidates Release 1.1 information and clarifies existing conformance requirements of the implementation guide. For example, it specifies conformance statements and conditional predicates that clarify message requirements. It also specifies value set requirements and provides general clarifications and PHIN MG corrections. Overall, Release 1.1 and the addendum do not create additional substantive requirements in comparison to Release 1.0. Therefore, we believe the adoption of Release 1.1 and the addendum is appropriate as they will improve the ability to test and certify EHR technology to the implementation guide, as well as make it easier for EHR technology developers to implement the guide's requirements.

EHR technology designed for the inpatient setting seeking certification to this certification criterion must be certified to the implementation guide, while EHR technology designed for the ambulatory setting will have the option of being certified to the implementation guide. We believe that the guide can provide necessary clarity for ambulatory EHR developers that provide EHR technology to EPs that practice in urgent care settings.

Comments. Several commenters recommended replacing ''Inpatient'' with ''Hospital or urgent care.'' The commenters asserted that such a change more appropriately reflects the clinical settings that transmit syndromic surveillance data to health departments.

Response. While we appreciate the commenters' recommendation, the designation ''inpatient'' is a general designation that we use to distinguish certification criteria and capabilities that apply to a particular setting for certification. We currently designate only two settings for certification, the inpatient setting and the ambulatory setting without variation. EHs use ''inpatient-certified'' EHR technology for their inpatient department and emergency departments. For urgent care settings that are not the emergency department, the providers would be non-hospital-based EPs and would require ''ambulatory-certified'' EHR technology. Therefore, we are retaining the ''inpatient'' designation.

Comment. Commenters recommended adding in regulation after the implementation guide the following statement ''or the most recent version as published by CDC.''

Response. We refer the commenters to section III.A.5 found earlier in this preamble. This section explains why we cannot take such an approach.

Comments. Commenters expressed confusion over whether EHR technology must be certified to a transport standard to meet this certification criterion and whether EPs, EHs, and CAHS must use certain transport standards for submitting syndrome-based public health surveillance information to public health agencies. Some commenters requested that we require EHR technology to be certified in SOAP web services as well as Direct. One commenter encouraged us to expand the required transport standards to include commonly used transports, such as MLLP (HL7) and IHE XDS, or define specific data types and transactions for each transport type.

Response. We want to make clear that we do not require EHR technology to be certified to any transport standard, including Direct, to meet this certification criterion. There is no consensus transport standard that states and public health agencies use for the reporting of syndrome-based public health surveillance information. Therefore, we believe that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies.

Comment. One commenter suggested that this certification criterion include the capability to capture adverse drug events for reporting to public health agencies. Another commenter recommended that we should require the capture of occupational exposure and industry worker health information.

Response. The certification criterion does not preclude other types of reportable events from being captured and reported by EHR technology. We do not believe, however, that it is appropriate to modify the certification criterion to explicitly reference adverse drug events or any other specific syndrome-based surveillance information for the purposes of EHR technology certification.

Comments. A commenter recommended that the ONC tighten the message structures within the HL7 message, such that one single message works with all registries of the same type. Specifically, there should not be 50 different flavors of the HL7 2.51 format for 50 different states for each transmission type. In addition, to make transmission simple, the registries captioned above should be required to accept messages via the Direct Project messaging system only as this will reduce the burden on providers for making dozens of point-to-point connections with registries.

Response. We acknowledge this commenter's recommendation, but do not believe that the recommended outcome can be effectively reached through certification. While certification can ensure that EHR technology can create a single, standardized message it cannot affect the additional data states may also require be submitted or the IT system differences across states.

Comments. One commenter stated that in consideration of the challenges for many public health agencies to receive this data electronically, the objective and associated criterion should be removed.

Response. We appreciate the submission of this comment, but it is outside the scope of this rulemaking. We direct the commenter to the Stage 2 final rule found elsewhere in this issue of the **Federal Register** for a discussion of the MU objective and measure and a response to this comment.

- *Automated Measure Calculation*

MU Objective
N/A.
2014 Edition EHR Certification Criterion
§ 170.314(g)(2) (Automated measure calculation).

We proposed to adopt a revised ''automated measure calculation'' certification criterion for the 2014 Edition EHR certification criteria. We revised the certification criterion to clearly identify that the recording, calculating, and reporting capabilities

required by this certification criterion apply to the numerator and denominator associated with the capabilities that support an MU objective with a percentage-based measure. We clarified that the capabilities are the capabilities included in the certification criteria to which a Complete EHR or EHR Module is presented for certification.

We emphasized that testing to this certification criterion would not only include verification of the ability of EHR technology to generate numerators and denominators, but would also verify the accuracy of the numerators and denominators generated by the EHR technology. We stated testing to ensure the accuracy of these calculations would significantly reduce the reporting burden for MU attestation. Additionally, we stated that testing and certification to this revised certification criterion would include testing and certifying the ability to electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable MU measure that is supported by a capability in the new certification criteria proposed and adopted in a final rule.

Comments. Commenters supported this certification criterion and emphasized the value of automated measure calculation for EPs, EHs, and CAHs. Commenters noted that it is important to ensure that EHR technology can accurately calculate these measures and stated that accurate measure calculations are critical to reducing the burden of reporting and for promoting adoption. One commenter noted that although ''automated measure calculation'' suggests a simple process is required for physicians to calculate their data for meeting MU measures, they recommended that ONC explicitly require that EHR technology enable the automatic creation of reports.

Response. We thank commenters for supporting this certification criterion and agree that the improved accuracy of measure calculations will reduce reporting burdens for EPs, EHs, and CAHs. We have adopted this certification criterion as proposed. This certification criterion requires EHR technology to demonstrate the capability to automatically create reports based on the numerator and denominator for MU objectives with percentage-based measures.

Comments. A commenter stated that this certification criterion does not fall into patient-centric care and while a necessary component of reporting, the functionality it includes could be performed by another technical component outside the EHR.

Response. As stated in the S&CC July 2010 final rule (75 FR 44642), we adopted this certification criterion to reduce the reporting burden associated with participating in MU. This certification criterion is required in order for EHR technology presented for certification to meet the Complete EHR definition. We permit, but do not require, EHR technology presented as an EHR Module for certification to also be certified to this certification criterion. In instances where an EHR Module is not presented for certification to this certification criterion, it would need to be certified to the ''automated numerator calculation'' certification criterion adopted in this final rule. We also note that CMS permits reporting outside certified EHR technology per FAQ 3063, which can be found at *https://questions.cms.gov/faq.php?id=5005&faqId=3063.*

Comments. A commenter recommended that EHR technology developers be required to provide not only the numerator, denominator, and percentage for the selected reporting period, but also offer the capability to display a detail level that includes patient identifiers and data elements and if the patient record assessed met or did not meet the objective.

Response. While we realize such detailed information may have value for an EP, EH, and CAH, but we do not believe that we need to require such level of detail be displayed to the user for purposes of certification and to support the calculation and reporting of objectives with percentage-based measures. We note, however, that this level of detail may be useful to demonstrate an EHR technology's compliance with this certification criterion during testing.

Comments. Commenters requested clarification on the testing procedures that will be used for this certification criterion. Commenters also provided many recommendations for testing EHR technology to this certification criterion. One commenter suggested not moving forward with this criterion unless a test data set is provided from ONC that validates the ability of EHR technology to generate these accurate calculations and reports. Other commenters requested clarification on whether test data would be provided and EHR technology would be expected to match some predetermined calculations by the tester. These commenters stated if EHR technology developers are expected to demonstrate each measure calculation on the report, then they are concerned about the time that could be required to validate such accuracy and thus added to the time it takes to certify EHR technology. Another commenter suggested providing specifications on how the numerators and denominators for these measures should be calculated. The commenter also requested that in giving EHR technology developers a test data set, they are also given multiple ways to accommodate the different approaches that exist to importing practical data sets.

Some commenters expressed concerns that testing tools similar to Cypress are not accurate. For an accuracy test, commenters recommended that test scripts be developed that can be used by EHR developers. The commenters further recommended that the test scripts be based on real-world clinical workflows where a patient should be included or excluded from the numerators and denominators of an objective in an expected manner. The commenters noted that the test would determine the accuracy of the EHR technology based on whether the patient is included or excluded from the numerators and denominators according to expectations. Commenters also recommended that testing include time-based elements to simulate an EHR reporting period.

Response. We appreciate the many comments on testing to this certification criterion. Consistent with the process we outlined in the Permanent Certification Program final rule (76 FR 1280), we anticipate approving a test procedure for this certification criterion that, at minimum, is clearly traceable to the capabilities included in the certification criterion, sufficiently comprehensive (i.e., assesses all required capabilities) for NVLAP-accredited testing laboratories to use in testing a Complete EHR's or EHR Module's compliance with the certification criterion, and was developed using an appropriate public comment process. With CMS, we intend to be more proactive about explaining numerator and denominator requirements so that misinterpretations are reduced to a minimum. To that end, we will work with CMS to provide education materials and any additional guidance necessary to help EHR technology developers better understand the numerator and denominator requirements for MU objectives and measures. Finally, we wish to make clear that for MU objectives which CMS has provided flexibility in its final rule for EPs, EHs, and CAHs to pursue alternative approaches to measuring a numerator and denominator, the EHR technology must be able to support all CMS-

acceptable approaches in order to meet this certification criterion. For example, there are two options for counting emergency department admissions. If an EHR technology developer only included one option in its EHR technology for certification, the EHR technology developer would take away the flexibility granted to the EP, EH or CAH by CMS. We believe that this flexibility should be available to all EPs, EHs, and CAHs regardless of what Certified EHR Technology they utilize.

b. Ambulatory Setting

We propose to adopt the following revised certification criteria for the ambulatory setting.

• *Electronic Prescribing*

MU Objectives
Generate and transmit permissible prescriptions electronically (eRx).
2014 Edition EHR Certification Criterion
§ 170.314(b)(3) (Electronic prescribing).

We proposed to adopt a revised certification criterion for the ambulatory setting that requires the use of RxNorm as the vocabulary standard. We proposed to continue to permit the use of NCPDP SCRIPT version 10.6 to meet this certification criterion, but also to no longer include the use of NCPDP SCRIPT version 8.1 as a way to meet the 2014 Edition EHR certification criterion. We stated that we made this proposal because we understood CMS was planning to propose the retirement of NCPDP SCRIPT version 8.1 (adopted as a Medicare Part D e-prescribing standard) in a proposed rule that was scheduled to be issued soon after the Proposed Rule was published. We noted that if we received information indicating a change in CMS' plans prior to the issuance of our final rule, we may, based also on public comment, reinstate this standard in a final revised certification criterion. We stated that we were proposing to adopt this certification criterion for both the ambulatory and inpatient settings because it supports our desired policy and interoperability outcome for content exchange standards to be used when information is exchanged between different legal entities.

In the interest of providing readers with a clear, cohesive, and consistent recitation of comments and our response and to also avoid redundancy, we direct readers to our discussion of the adopted ''electronic prescribing'' certification criterion (§ 170.314(b)(3)) under section III.A.8.c.

• *Clinical Summary*

MU Objective
Provide clinical summaries for patients for each office visit.
2014 Edition EHR Certification Criterion
§ 170.314(e)(2) (Ambulatory setting only—clinical summary).

We proposed to revise the ''clinical summaries'' certification criterion for the 2014 Edition EHR certification criteria to reflect the proposed new and revised standards for problem lists and other vocabulary standards. We noted in the Proposed Rule that we made several refinements to the HITSC recommended certification criterion to ensure that EHR technology meets the appropriate standards and is capable of making available the information CMS is proposing be provided to a patient after an office visit.

We proposed that when information is provided electronically, the information should be provided according to the Consolidated CDA standard. We stated in the Proposed Rule that adopting the Consolidated CDA for this certification criterion is advantageous since its template structure can accommodate the formatting of a summary of care record that includes all of the data elements that CMS proposed be provided to a patient after an office visit. We requested public comment on whether we should adopt separate certification criteria to explicitly require the capture of unique data elements included in clinical summaries, such as care plans and future scheduled tests. For certain other data elements in § 170.314(e)(2), we proposed to require that the capability to provide the information be demonstrated in accordance with the specified vocabulary standard. We noted that these vocabulary standards had been previously adopted or were proposed for adoption in the Proposed Rule.

Comments. Many commenters expressed agreement with this certification criterion and the use of the Consolidated CDA. Commenters noted that the use of the Consolidated CDA would be beneficial for interoperability purposes.

Response. We appreciate the support for this certification criterion and the use of the Consolidated CDA for the clinical summary. We are adopting this certification criterion as proposed with Release 2.0 (July 2012) of the Consolidated CDA standard as discussed earlier in the preamble under the ''view, download, and transmit to a 3rd party'' certification criterion, which fully supports the clinical summary as defined by CMS in the Stage 2 final rule for the MU objective and measure associated with this certification criterion. To note, we have revised the certification criteria heading to the singular form (''clinical summary'').

Comments. We received numerous comments regarding what should and should not be included in a clinical summary, including requests for clarification of data in the clinical summary and care plan. We also received requests for alignment of the data in a clinical summary used for this certification criterion and with the data included in the clinical summary used for other certification criteria. We also received requests for alignment with the use of the clinical summary by CMS for MU.

Some commenters stated that the inclusion of names and contact information of any additional care team members provides no clinical benefit and will likely distract the patient and degrade the effectiveness of the clinical summary. A few commenters stated that we postpone the adoption of standards and certification criteria for care plans and future scheduled tests as part of the clinical summaries. Other commenters stated that EHR technology should offer EPs the capability to customize the clinical summary, where omitting some information is in the best interest of the patient.

Response. As noted in the Proposed Rule, this certification criterion specifies the capabilities that EHR technology would need to include in order for an EP to provide the information identified by CMS to a patient after an office visit. A clinical summary and the data it includes such as a care plan are defined or described by CMS. We direct commenters to the Stage 2 final rule found elsewhere in this issue of the **Federal Register** for a complete discussion of the ''clinical summaries'' MU objective and measure, including the clinical summary data that are required to be provided after an office visit. We have adopted the Consolidated CDA standard, which supports all of the data that CMS has included for the MU objective and measure to which this certification criterion correlates.

Further to make this certification criterion easier to read and to clearly express the capabilities that EHR technology must include in order to support MU, we have broken the certification criterion into three separate specific capabilities. The first echoes the requirement that EHR technology must be able to create a clinical summary in both human readable format and according to the Consolidated CDA. The second would require EHR technology

to enable a user to customize (e.g., be able to edit) the data they include in the clinical summary. This capability supports CMS's policy for this MU objective and measure that permits EPs excluding certain data from a clinical summary and clarifies as well as makes explicit the customization capability other commenters mentioned should be present. And, overall we believe this capability will assist EPs in determining how to best structure the clinical summary they want to provide their patients based on the data their CEHRT is able to produce. The third specific capability identifies the minimum data EHR technology must permit a user to select for inclusion in a clinical summary.

Comments. A commenter stated that future appointments could be a part of scheduling system and not readily available to the EHR to include in the summary. The commenter noted that this could perhaps require that another application be included in the ''process for certification.''

Response. We interpret EHR technology broadly for the purposes of certification in that any technology that meets a certification criterion is defined as an EHR Module.

To meet this certification criterion, EHR technology must demonstrate all the capabilities included in the certification criterion. These capabilities support the associated MU objective and measure, which includes providing any future appointments in a clinical summary.

Comments. Commenters stated that it was unnecessary to adopt separate certification criteria to explicitly require the capture of unique data elements included in clinical summaries such as care plans and future scheduled tests, while a few commenters suggested we pursue such an approach.

Response. We agree with those commenters that stated it was unnecessary to adopt separate certification criteria. We made this similar response in the transitions of care certification criterion where we also posed this question.

Comments. Commenters stated that they support the increased focus on supporting patients' access to their information through various means, but were concerned that the proposed certification criterion for clinical summaries included requirements to share information with unknown third parties. A commenter suggested that patients as well as their designated agent(s) be registered on the EP's CEHRT to enable transmission of their clinical data to them.

Response. We are unclear as to what language in the Proposed Rule prompted commenters to raise this concern. This certification criterion does not require the sharing of patient health information with third parties. We encourage commenters to review our responses to comments on the view, download, and transmit to a 3rd party certification criterion.

Comments. A commenter noted that patients should be able to access, download, and use clinical summaries which are a matter of patient safety so errors and omissions can be detected.

Response. This certification criterion requires EHR technology to be capable of enabling a user to electronically create a clinical summary in human readable format and formatted according to the Consolidated CDA.

Comment. A commenter stated that EHR technology should support integration with HIEs to enable the export of clinical summaries, making the information available to any authorized provider involved in the patient's care.

Response. This certification criterion focuses on capabilities that EHR technology would have to demonstrate for certification that would support an EP's ability to provide a clinical summary to a patient, including electronically. It is not focused on the exchange of a patient's health information. Therefore, we decline to modify this certification criterion in response to this recommendation. We note, however, that the ''transitions of care–create and transmit transition of care/referral summaries'' certification criterion (§ 170.314(b)(2)) requires EHR technology to be capable of formatting a patient's transition of care/referral summary in accordance with the Consolidated CDA and capable of using transport standards.

c. Inpatient Setting

We are adopting the following revised certification criterion for the inpatient setting.

• *Transmission of Reportable Laboratory Tests and Values/Results*

MU Objective
Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.
2014 Edition EHR Certification Criteria
§ 170.314(f)(4) (Inpatient setting only—transmission of reportable laboratory tests and values/results).

We proposed two certification criteria for reportable laboratory tests and values/results that were essentially a split of the 2011 Edition EHR certification criterion for reportable lab results (§ 170.306(g)). We proposed one certification criterion that focused just on the capabilities to electronically record, change, and access laboratory rests and values/results (data capture) and another that focused on the capability to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with specified standards. We discussed these two proposed certification criteria together in the Proposed Rule for simplicity and to prevent confusion, but noted that we do not consider the certification criterion we proposed to focus on data capture to be a revised certification criterion. Rather, we stated that we believed that the certification criterion would constitute an unchanged certification criterion because all the capabilities included in the criterion were the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.306(g)).

For the certification criterion focused on creating reportable laboratory rests and values/results for transmission, we proposed the use of only the HL7 2.5.1 standard and LOINC® version 2.38 as the vocabulary standard. Following consultation with the Centers for Disease Control and Prevention, we also proposed to adopt the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications and SNOMED CT® International Release January 2012 version—which, we noted, contains corrections and will require minor changes to conformance testing and certification to account for newly assigned OIDs (object identifiers) identifying the message profiles in the implementation guide.

Comments. Commenters supported our proposed ''two certification criteria approach.'' Commenter also stated that proposing the certification criteria in the manner that we had would permit HIEs to be certified to the certification criterion that includes the capability to create reportable laboratory tests and values/results for transmission in accordance with specified standards and then serve as intermediaries for the transport of laboratory tests and values/results to public health agencies.

Response. We appreciate the support expressed by commenters for our approach. We are adopting as part of the 2014 Edition EHR certification criteria the certification criterion focused on the capability to electronically create reportable laboratory rests and values/

results for electronic transmission in accordance with the standards we have specified (§ 170.314(f)(4)). We are not, however, adopting the certification criterion we proposed that focused on data capture. For similar reasons as expressed in the syndromic surveillance certification criterion, we have dropped this requirement because we believe it is not necessary to focus on for the purposes of EHR technology certification.

We agree with commenters regarding HIEs and noted in the Proposed Rule that our approach to the public health certification criteria could enable additional EHR technologies (likely in the form of EHR Modules) to be certified and provides additional pathways and flexibility to EPs, EHs, and CAHs to have EHR technology that can be used to satisfy the proposed revised definition of CEHRT.

Comments. Commenters supported maintaining the use of the HL7 2.5.1 standard and adopting the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata, as well as the latest versions of SNOMED CT® and LOINC®. Commenters suggested that we simply state in regulation that EHR technology can be certified to the most recent versions of the vocabulary standards (SNOMED CT® and LOINC®) and the implementation guide for certification.

Response. We appreciate the commenters' support for the standards and implementation guide we proposed. We have adopted the proposed certification criterion, including the proposed standards and implementation guide with errata and clarifications and a recently published supplement to the implementation guide, titled ''''ELR 2.5.1 Clarification Document for EHR Technology Certification.'' The supplement was not available when the Proposed Rule was published. It does not specify additional substantive requirements. Rather, it clarifies conformance requirements and other aspects of Release 1 with errata and clarifications that will improve testing and certification to the implementation guide. Accordingly, we are adopting the supplement and the proposed Release 1 with errata and clarifications.

We have established a process for adopting certain vocabulary standards, including SNOMED CT® and LOINC®, which permits the use of newer versions of those standards than the one adopted in regulation. We refer readers to section IV.B for a discussion of ''minimum standards'' code sets and our new more flexible approach for their use in certification and upgrading certified Complete EHRs and certified EHR Modules. Readers should also review § 170.555, which specifies the certification processes for ''minimum standards'' code sets. In response to the commenters' suggestion that we permit the use of the ''most recent version'' of the implementation guide for certification, we refer the commenters to section III.A.5 found earlier in this preamble. This section explains why we cannot take such an approach.

Comments. A commenter expressed concern about the ongoing volatility of the LOINC® and SNOMED CT® code sets and the burden that will be placed on laboratory staff. The commenter further stated that the failure to adopt national standards for that coding may result in less than optimal interstate sharing of laboratory results. Another commenter noted that the mapping of local codes to our standard codes is needed but little guidance is provided.

Response. We are not familiar with the ''volatility'' that the commenter references and believe that LOINC® and SNOMED CT® constitute consensus-based national standards. The CDC has published the Reportable Condition Mapping Table (RCMT) that provides a subset of LOINC® and SNOMED CT® codes associated with reportable conditions. RCMT can be obtained from CDC vocabulary server PHIN VADS (*http://phinvads.cdc.gov*). The CDC vocabulary team provides guidance to implementers regarding the implementation of RCMT and mapping of LOINC® and SNOMED CT® codes to local lab tests. CDC vocabulary team can be reached directly via email at *phinvs@cdc.gov* or through the CDC Meaningful Use technical assistance team (*meaningfuluse@cdc.gov*). In addition, the LOINC® SDO has created a tool known as ''RELMA,'' which helps to map the local tests to standard LOINC® laboratory tests. LOINC® SDO provides RELMA training twice a year and, through a partnership with LOINC® SDO, the CDC provides RELMA training to the public health community at least twice a year with a special focus on microbiology lab tests.

Comments. Commenters pointed to what they believed to be an inconsistency between the Proposed Rule and the Stage 2 proposed rule. Commenters stated that the Stage 2 proposed rule stated that ''Public Health Agencies may specify the means of transport as long as it does not go above and beyond what is required in ONC's certification criteria.'' These commenters further stated that we only required the Direct Protocol for transport.

One commenter strongly recommended the inclusion of PHIN–MS as a required transport mechanism for hospital EHR systems and further noted that leaving ''other transport mechanisms'' undefined or defined by state will likely result in EHR vendor implementation variance. Another commenter suggested the use of the NwHIN query-and-response protocol to share reportable laboratory tests and values/results. Conversely, other commenters strongly supported the requirement that transport method or methods supported by the public health agency should be used for MU.

Response. We want to make clear that we do not require EHR technology to be certified to any transport standard, including Direct, to meet this certification criterion. There is no consensus transport standard that states and public health agencies use for the reporting of laboratory test and values/results. Therefore, we believe that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies.

Comments. Some commenters stated that the MU objective related to these certification criteria describes a function of a laboratory information system rather than EHRs. A commenter stated that if standards we propose for this certification criterion are mandated, then state-level programs must also be amended to support the standards. Other commenters stated that early adopters that support only HL7 2.3.1, common among public health systems, should not be penalized in MU Stage 2. One commenter requested clarification that ongoing submission means that all relevant data is transmitted in a timely fashion as required by the agency. Another commenter suggested that we clarify that ''reportable laboratory tests'' means only those whose transmission is required under state and local law.

Response. We appreciate the submission of these comments, but they are outside the scope of this rulemaking. We direct commenters to the Stage 2 final rule found elsewhere in this issue of the **Federal Register** for a discussion of the MU objective and measure and responses to these comments.

Comments. A commenter stated that is important that public health authorities have the prerogative to prioritize which submitters are moved in to production first.

Response. This certification criterion and certification in general does not

address or regulate these decisions made by public health agencies.

11. Unchanged Certification Criteria

In the Proposed Rule, we described the certification criteria that we considered ''unchanged.'' We noted the following factors in determining whether a certification criterion would be ''unchanged:''

- The certification criterion includes only the same capabilities that were specified in previously adopted certification criteria;
- The certification criterion's capabilities apply to the same setting as they did in previously adopted certification criteria; and
- The certification criterion remains designated as ''mandatory,'' or it is re-designated as ''optional,'' for the same setting for which it was previously adopted certification criterion.

For clarity, we explained that an unchanged certification criterion could be a certification criterion that includes capabilities that were merged from multiple previously adopted certification criteria as long as the capabilities specified by the merged certification criterion remain the same. The ''authentication, access control, and authorization'' certification criterion discussed below and adopted at § 170.314(d)(1) meets this description. Additionally, as we specified in the Proposed Rule, an unchanged certification criterion could be a certification criterion that has fewer capabilities than a previously adopted certification criterion as long as the capabilities that remain stay the same. The ''integrity'' certification criterion discussed below and adopted at § 170.314(d)(8) meets this description. We discussed in the Proposed Rule and in the description of revised certification criteria in this final rule that a certification criterion could be characterized differently based on the setting to which it applies or the designation it is given (''mandatory'' or ''optional''). For example, a certification criterion that includes the same capabilities that were specified in a previously adopted certification criterion would be considered unchanged for the ambulatory setting if the previously adopted certification criterion only applied to the ambulatory setting and certification to the criterion was ''mandatory.'' However, this same certification criterion would be considered new for the inpatient setting if it were subsequently adopted for both settings.

Comments. We did not receive comments questioning our description of unchanged certification criteria.

Response. Therefore, we continue to use this description of unchanged certification criteria to categorize the following certification criteria we have adopted as part of the 2014 Edition EHR certification criteria. For clarity, we have adopted these unchanged certification criteria in addition to the unchanged certification criteria previously discussed in this preamble (''immunization information'' § 170.314(f)(1) and ''receive laboratory test and values/results'' § 170.314(b)(5)—inpatient setting only).

a. Refinements to Unchanged Certification Criteria

In the Proposed Rule, we proposed refinements to the following unchanged certification criteria. We received public comments on all of the certification criteria. We discuss the public comments received and the adoption of these unchanged certification criteria as part of the 2014 Edition EHR certification criteria below.

- *Computerized provider order entry*

MU Objective
Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.
2014 Edition EHR Certification Criterion
§ 170.314(a)(1) (Computerized provider order entry).

We proposed a CPOE certification criterion that merged the separate ambulatory and inpatient CPOE certification criteria in the 2011 Edition EHR certification criteria into one criterion because they those certification criteria are identical. We proposed to replace the terms ''modify'' and ''retrieve'' with ''change'' and ''access,'' respectively. We also proposed to remove the term ''store'' from the criterion because it is redundant with our interpretation of the term ''record.'' Finally, we proposed to move the phrase ''at a minimum'' in the certification criterion to eliminate any possible ambiguity as to what the phrase modifies. As proposed, the certification criterion made clear that the phrase modifies the order types and not the terms ''record,'' ''change,'' and ''access.''

Comments. Many commenters expressed general support for this certification criterion as proposed. We also received many comments requesting further clarification of the CPOE denominator, including clarifying what orders count, what providers may enter the orders, and how current MU EHR users should report measures when transitioning to EHR technology certified to the 2014 Edition EHR certification criteria during an EHR reporting period in 2013. One commenter requested clarification as to whether the change in the CMS measure definition would require ''re-certification'' to this certification criterion or if it would only affect certification to the automated measure calculation certification criterion.

A commenter recommended that this certification criterion include the capability to send the order information in an electronic format consistent with the content exchange standard identified in the Proposed Rule at section 170.205(k) (HL7 2.5.1 and the HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm)). Another commenter recommended that this certification criterion should be amended to require some notation about a patient's predominant race when multiple races are identified.

One commenter recommended that CPOE of radiology be separated into its own certification criterion. The commenter stated that the new ''radiology'' certification criterion should require that CPOE of radiology have integrated CDS tied to national physician association-developed appropriateness criteria guidelines. The commenter reasoned that appropriateness criteria-guided CDS at the point-of-order will inform referring physicians and their patients as to the most clinically appropriate imaging examinations for the given indications.

Response. We appreciate the support for the certification criterion as proposed and are adopting this certification criterion as an unchanged certification criterion for the 2014 Edition EHR certification criterion at § 170.314(a)(1). The comments requesting clarification related to the denominator and the reporting of the CPOE measure during 2013 are outside the scope of this rulemaking. We direct commenters to the Stage 2 final rule for a discussion of these issues. However, we do clarify that the change in the CPOE denominator affects the ''automated measure calculation'' certification criterion (§ 170.314(g)(2)), which is a revised certification criterion for the 2014 Edition EHR certification criteria.

This certification criterion focuses on enabling a user to electronically record, change, and access, at a minimum, medication, laboratory and radiology/imaging orders. It does not focus on the transmission of these orders.

Additionally, the standard recommended by the commenter is incorrect because it focuses on the receipt of laboratory tests results, not the outbound transmission of laboratory orders. Therefore, we decline, as recommended by the commenter, to include the standard. We also do not believe that the recording of race should be associated with this certification criterion as recommended by a commenter because such an action would dictate workflow and the recording of race is already required by the ''demographics'' certification criterion (§ 170.313(a)(3)). Last, we decline to separate out radiology orders into a separate certification criterion. While we appreciate the enhanced clinical functionality presented in the commenter's recommendation, this certification criterion is focused on the general CPOE capability for various types of orders and supporting the associated MU objective and measure. Additionally, as structured, this certification criterion contemplates the general functionality applying to more than just radiology or the other two types of orders specified.

• *Authentication, access control, and authorization*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion
§ 170.314(d)(1) (Authentication, access control, and authorization).

We proposed to merge the ''access control'' certification criterion at § 170.302(o) and the ''authentication'' certification criterion at § 170.302(t) into one certification criterion for the 2014 Edition EHR certification criteria. We reasoned that since the two test procedures developed for these certification criteria were similar and that the capabilities included in the certification criteria go hand-in-hand, it was best to merge the two certification criteria into one certification criteria. We stated that this would allow for more efficient testing and was consistent with EHR technology development.

In combination with this proposal, we proposed to adopt part of the HITSC's recommendation related to person/user authentication, which was reflected in the proposed certification criterion. We also expressed the HITSC's authentication recommendation as additional guidance for this certification criterion in that the capability to authenticate human users would consist of the assertion of an identity and presentation of at least one proof of that identity. We stated that it is most appropriate for this certification criterion to focus on users that would be able to access electronic health information in EHR technology within an EP, EH, or CAH's organization and not to focus on external users that may make requests for access to health information contained in the EHR technology for the purpose of electronic health information exchange. We further stated that the latter purpose would likely require a different/additional security approach(es) and rely on a health care provider's overall infrastructure beyond its EHR technology.

We acknowledged in the Proposed Rule's preamble, as recommended by the HITSC, example standards and implementation specifications which could be followed in designing EHR technology to meet this certification criterion. In particular, we specified that these example standards and implementation specifications could include, but were not limited to: NIST Special Publication 800–63, Level 2 (single-factor authentication) and ASTM, E1986–09 (Information Access Privileges to Health Information).

Comments. A majority of comments on the proposed certification criterion supported it as proposed and without any changes for the final rule. One commenter voiced its appreciation for the consolidation of the two prior 2011 Edition EHR certification criteria. Another commenter requested that we clarify whether the certification criterion applies to: internal system and/or human users; external system and/or human users that are recipients of ''push'' type health information exchanges such as those required for in the Stage 2 proposed rule; or excludes all external system and/or human users. The commenter went on to note that this certification criterion does not include standards to consistently specify electronic health information as distinguishable security objects; specify whether the access is at a coarse or fine grain level as would likely be required for data segmentation for privacy; encode the ''actions'' in a consistent and meaningful manner using standard data operations vocabulary; and specify an interoperable value set of standard structural and functional roles. Further, commenters noted that we should clarify the users to which the certification criteria apply; and require adoption of the privacy and security standard vocabularies such as those established by HL7 and ASTM. Other commenters noted that the test procedure would need to be updated for this certification criterion. Last, a commenter stated that we should revise the requirement for single factor level of assurance (LOA) 2 authentication and increase it to LOA 3, 2-factor authentication. The commenter reasoned that by the time the final rule goes into effect, additional LOA 3, 2-factor credential form factors will be available to the general public and that these credentials will be readily available from multiple commercial sources.

Response. We appreciate commenters support for this certification criterion and have adopted it in this final rule as proposed. As we stated in the Proposed Rule, we intend and believe that it is most appropriate for this certification criterion to focus on users that would be able to access electronic health information in EHR technology within an EP, EH, or CAH's organization and not to focus on external users that may make requests for access to health information contained in the EHR technology for the purpose of electronic health information exchange. The latter purpose would likely require a different/additional security approach(es) and rely on a health care provider's overall infrastructure beyond its EHR technology. With respect to the other points raised in comments, we have purposefully left this certification criterion flexible to accommodate for different implementations, deployments, and organizational policy decisions. Ultimately, this certification criterion sets a minimum requirement and provides assurance that an EP, EH, and CAH's CEHRT includes capabilities that can perform authentication, access control, and authorization. Contrary to a commenter's suggestion, the certification criterion does not specify an LOA, which in turn permits EHR technology developers to satisfy it in a number of different ways. Practically speaking, however, one-factor authentication would, at a minimum, be needed to satisfy the certification criterion. Finally, we appreciate the commenters' suggestions about specific security vocabulary standards. We did not propose to include any of these standards and believe that it would be prudent to first have the HITSC consider their inclusion and whether it would be necessary to specify them in a certification criterion or in guidance or some other type of educational material.

• *Automatic log-off*

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion § 170.314(d)(5) (Automatic log-off).

In the Proposed Rule, we proposed to adopt the automatic log-off certification criterion from the 2011 Edition EHR certification criteria (i.e., as unchanged). We did, however, seek to clarify what ''terminate'' in the certification criterion conveyed. We stated that terminating a session should not be confused with locking a session, where access to an active session is permitted after re-authentication. We then indicated that EHR technology must have the capability to terminate the session, including terminating the network connection.

Comments. Many commenters supported our proposal and agreed that the certification criterion should remain unchanged for the 2014 Edition EHR certification criteria. Several commenters, though, took issue with our clarification. One commenter noted that our proposal does not describe what impact termination has on documentation in progress at the time termination occurs. The commenter stated that this would create the potential for information loss and give clinicians a false sense that information entered into the patient's medical record had been saved. Another commenter disagreed with our clarification because it would draw a distinction between a session ''termination'' and a session ''lock.'' The commenter contended that any attempt to draw such a distinction is purely subjective. The commenter stated that, for example, an application's session state may persist in local memory or in a centralized data store and that both of these could be used to reconstitute a session which has been suspended by various means. In the latter case, where a centralized data store is used for the persistence of session state, the user may terminate the application, reboot the workstation, restart the application and pick up where they left off during their previous session. In the end, the commenter proposed that any application state which: (a) Renders application information completely inaccessible; (b) requires login authentication to access the application; and (c) requires the same credentials to access previous session state should qualify as a termination. Further, they stated that this definition should apply regardless of whether the application is physically terminated or not, and regardless of whether the ability to reconstitute a previous session is implemented through a centralized data store, or through in-memory persistence of session state. Another comment sought clarification that automatic log-off of an application does not lead to automatically terminated network connections of other applications active on, e.g., the desktop or server. Similarly, another commenter stated that multiple applications may be running and concurrently using the network connection on the same device. The commenter stated that the proposed language implies that all network connections from the end-user device are terminated automatically when the application shuts down. They suggested that the termination of network connections be limited to those used by the application being shut down. Once commenter believed that we should clarify that it is the user's session within the EHR that should be terminated.

Response. We appreciate the thoughtful and detailed responses provided by commenters. In considering the prior response we issued in the S&CC July 2010 Final Rule (75 FR 44617–618), our clarification in the Proposed Rule, and the comments received on the Proposed Rule, we believe that additional clarity is necessary regarding the capability expressed by this certification criterion. Given the scenarios identified by commenters, we believe that EHR technology developers should interpret this certification criterion to require (as one commenter described) that after a period of inactivity the EHR technology must make a user's session inaccessible and subsequently require the user to re-authenticate using the same credentials used to begin or resume the session. To make the capability expressed by this certification criterion clearer to EHR technology developers, we have replaced ''Terminate'' with ''Prevent a user from gaining further access to * * *.'' Although this may be longer phrasing toward the same meaning, we believe it less ambiguous than ''terminate,'' is more plain language, and that it is also consistent with the language used for the ''session lock'' security control specified in NIST 800–53 rev3. Additionally, we clarify that this certification criterion is not meant to result in the termination of network connections, especially network connections that are not in use by the EHR technology, but by other applications.

- *Emergency access*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion § 170.314(d)(6) (Emergency access).

In the Proposed Rule, we proposed to include in the 2014 Edition EHR certification criteria a refined version of the 2011 Edition EHR certification criterion for emergency access codified at § 170.302(p). We proposed to remove the parenthetical ''who are authorized for emergency situations'' from the certification criterion and include the phrase ''identified set of users.'' We stated that these refinements would more clearly convey the capabilities included in this certification criterion and align with our consistent use of the phrase ''identified set of users'' in every certification criterion where we intend for the same capability to be available. We explained that the purpose of this certification criterion is to provide certain users (''identified set of users'') with the ability to override normal access controls in the case of an emergency.

Comments. Almost all commenters that commented on this certification criterion expressed their support for the certification criterion as an unchanged certification criterion. One commenter recommended that organizations be afforded the opportunity to define their solution for emergency access based on their organizational security policy, which may differ from the certification criterion and testing procedures for emergency access. Another commenter suggested that we create a more specific requirement because the current requirements are ambiguous and do not provide enough guidance to EHR technology developers.

Response. We appreciate the support expressed by many commenters and are finalizing this certification criterion as proposed. With respect to the two comments expressing alternative options for certification, we believe these comments represent the opposite ends of the continuum we seek to balance and manage when we adopt a certification criterion. If the certification criterion was too specific, the capability provided by a Complete EHR or EHR Module may not be able to accommodate various organizational implementations. If not specific enough, EHR technology developers could include significantly different capabilities. The clarifying language provided in the Proposed Rule and recited above as well as our prior responses to comments included in the

S&CC July 2010 Final Rule (75 FR 44617) for the 2011 Edition version of this certification criterion provide ample specificity for EHR technology developers. They also include for the benefit of commenters the citation to the HIPAA Security Rule requirement on which this certification criterion is modeled (68 FR 8355).

• *Integrity*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion
§ 170.314(d)(8) (Integrity).

We proposed an ''integrity'' certification criterion at § 170.314(d)(8) that was consistent with the HITSC's recommendation. We also proposed to remove the capability to detect changes to an audit log because we proposed to add that capability to the proposed certification criterion for ''auditable events and tamper resistance'' at § 170.314(d)(2). The 2011 Edition EHR certification criterion adopted at § 170.304(b) specifies that EHR technology must be able to create a message digest in accordance with the standard specified at § 170.210(c). The adopted standard is: ''A hashing algorithm with a security strength equal to or greater than SHA–1 (Secure Hash Algorithm (SHA–1)) * * * must be used to verify that electronic health information has not been altered.'' We stated in the Proposed Rule that, after consultation with NIST, we understood that the strength of a hash function in digital signature applications is limited by the length of the message digest and that in a growing number of circumstances the message digest for SHA–1 is too short for secure digital signatures (SHA–2 produces a 256-bit message digest that is expected to remain secure for a long period of time). We also stated that certain operating systems and applications upon which EHR technology may rely use SHA–1 and do not or cannot support SHA–2 at the present time. Therefore, we requested public comment on whether we should leave the standard as SHA–1 or replaces it with SHA–2.

Comments. Many commenters expressed support for the certification criterion as proposed. These commenters also recommended retaining the SHA–1 standard as a baseline because it is still relied upon in many instances. One commenter noted that the use of SHA–1 and its security strength is sufficient until digital signatures are broadly required in the industry. Other commenters supported moving to SHA–2 as a better long-term alternative.

One commenter did not support the use of ''message logs'' as the only method of protecting health information during transmission. The commenter contended that this certification criterion accounts for a single-vendor system and does not address self-developed systems that may use multiple platforms and internally-developed systems that are interfaced together. The commenter further contended that there are available methods to provide for secure and accurate exchange without limiting the solution to message logs. As such, the commenter suggested that this certification criterion should be modified to account for internal versus external transmissions.

Response. We thank commenters for their support. We are finalizing this certification criterion and its associated standard as proposed. We agree with commenters that EHR technology developers should migrate towards the use of SHA–2 because of its increased security strength, but only where possible and voluntarily. The SHA–1 standard included in this certification criterion serves as a floor and permits EHR technology to be certified if it includes hashing algorithms with security strengths equal to or greater than SHA–1. As expressed by many commenters, the use of SHA–1 is still relied upon in many instances. For example, the Applicability Statement for Secure Health Transport standard that we have adopted in other certification criteria requires that SHA–1 must be supported in addition to SAH–256. We decline to accept the commenter's recommendation to have the certification criterion differentiate between internal and external transmissions as that distinction is not necessary for the purposes of certification and determining whether EHR technology can perform this capability according to the adopted standard. The capability's subsequent use for internal and/or external transmissions, as the commenter advocates, is up to the EP, EH, and CAH to determine in accordance with its organizational policies. As a final note, we seek to call to readers' attention that NIST has superseded FIPS 180–3 with FIPS 180–4. The changes in FIPS 180–4 are limited in scope and do not affect the approach we have expressed in the standard we adopted for this certification. Therefore, in order keep the regulation current with this recent publication we have modified the regulation text to refer to FIPS 180–4 instead of 180–3.

b. Unchanged Certification Criteria Without Refinements

We proposed to include the following unchanged certification criteria in the 2014 Edition EHR certification criteria without any substantial refinements, except, where appropriate, replacing the terms ''generate,'' ''modify,'' and ''retrieve'' with ''create,'' ''change,'' and ''access,'' respectively. For the ''accounting of disclosures'' certification criterion, we specifically requested comments whether we should revise the criterion. We received public comments on all of the certification criteria. We discuss the public comments received and the adoption of these certification criteria as part of the 2014 Edition EHR certification criteria below.

• *Accounting of Disclosures*

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion
§ 170.314(d)(9) (optional—accounting of disclosures).

We proposed to adopt the same optional ''accounting of disclosures'' certification criterion included in the 2011 Edition EHR certification criteria (§ 170.302(w)) as an optional certification criterion for the 2014 Edition EHR certification criteria (§ 170.314(d)(9)). We did, however, specifically request public comment on whether we should adopt a revised certification criterion. We noted that since publication of the S&CC July 2010 final rule, the HHS Office for Civil Rights (OCR) issued a proposed rule (76 FR 31426) addressing the changes required by section 13405(c) of the HITECH Act, including changes to the accounting of disclosure requirements under the HIPAA Privacy Rule.[33] We expressed interest in knowing whether commenters believed that the 2014 Edition EHR certification criterion for ''accounting of disclosures'' should be revised to be a mandatory certification criterion. We also expressed interest in knowing whether commenters thought that the 2014 Edition EHR certification criterion should be revised to include capabilities that would more fully support an EP's, EH's, and CAH's ability to comply with the current HIPAA Privacy Rule accounting for disclosure requirements at 45 CFR 164.528.

[33] *http://www.gpo.gov/fdsys/pkg/FR-2011-05-31/pdf/2011-13297.pdf.*

Additionally, we expressed interest in receiving input on whether, and what additional, changes to the certification criterion would be needed to support compliance with the proposed HIPAA Privacy Rule accounting for disclosure provisions, if they were to be adopted by final rule in substantially the same form as they were proposed. For those commenters that believed revisions were appropriate, we asked that their comments identify whether the certification criterion should be changed from optional to mandatory and identify the specific capabilities that the certification criterion should include and the rationale for including those capabilities.

Comments. Commenters overwhelmingly supported keeping this certification criterion as optional and without revision. Many commenters pointed to the significant amount of comments that were submitted on the ''accounting of disclosures'' proposed rule (76 FR 31426) issued by OCR, particularly the comments they characterized as expressing significant concern with the proposals in the proposed rule. Most commenters stated that this certification criterion must be fully aligned with the specifics of the ''accounting of disclosures'' final rule and suggested that ONC and OCR work together in this regard. A few commenters even suggested that we remove the certification criterion until a ''accounting of disclosures'' final rule is issued. A few commenters recommended that this certification criterion become mandatory and generally stated that it should be revised to include capabilities that would more fully support an EP's, EH's, and CAH's ability to comply with the current HIPAA Privacy Rule accounting for disclosure requirements. One commenter recommended that the specific capabilities that the ''accounting of disclosures'' certification criterion should be revised to include are: (1) The access report capability set forth in the proposed rule proposing to modify the HIPAA Privacy Rule's accounting for disclosures requirements; and (2) the universal accessibility of accounting of disclosures. Another commenter recommended that the certification criterion include a requirement to account for disclosures of protected health information, including release of information to third parties for care coordination, data-sharing and research purposes. Along these lines, a commenter recommended that EHR technology have the capability to document whether a patient has accepted or denied a disclosure agreement (e.g., for research purposes).

A commenter requested clarification regarding whether the data elements required to be recorded for accounting of disclosures be in structured format or free text. One commenter asked whether the part of the ASTM E2147–01 standard that deals with disclosures has applicability to this certification criterion and suggested that it should be applicable to this certification criterion.

Response. We thank commenters for their feedback. We are adopting this certification criterion as an unchanged certification criterion for the 2014 Edition EHR certification criterion at § 170.314(d)(9) and have continued to designate it as ''optional.'' After consideration of the comments received, we agree with those commenters that recommended we wait and consider how best to align this certification criterion with the provisions of an ''accounting of disclosures'' final rule issued by OCR. We appreciate the suggested revisions offered by commenters, but believe that alignment with an ''accounting of disclosures'' final rule will provide the most certainty and useful functionality for EPs, EHs, and CAHs, while also mitigating any EHR technology development and implementation burdens that may accrue through compliance with potential multiple adopted versions of this certification criterion.

We clarify for commenters that each disclosure that has been recorded must be done so in accordance with the standard at § 170.210(d) and must include the date, time, patient identification, user identification and the description of each disclosure. As to the commenter's question about whether this information could be captured in free text, we expect that date, time, patient identification, and user identification would be automatically recorded only by EHR technology. With respect to the description of each disclosure, we reiterate what we stated in the S&CC July 2010 Final Rule in response to this question (75 FR 44624). ''As we discussed in the Interim Final Rule, we intended to leave Complete EHR and EHR Module developers with the flexibility to innovate in this area and to develop new solutions to address the needs of their customers. We anticipated that a 'description of the disclosure' would, at the present time, be a free text field that would have included any information that could be readily and electronically associated with the disclosure. For example, we envisioned that some descriptive information could be included such as the words 'treatment,' 'payment,' or 'health care operations' separately or together as a general category.''

The ASTM E2147–01 standard has not been adopted in whole or in part for this certification criterion and we decline to adopt any part of the ASTM E2147–01 standard for this certification criterion at this time. Consistent with our rationale above, 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.

- *Advance Directives*

MU Objective
Record whether a patient 65 years old or older has an advance directive.
2014 Edition EHR Certification Criterion
§ 170.314(a)(17) (Inpatient setting only—advance directives).

Comments. The majority of commenters expressed support for this certification criterion as an unchanged certification criterion. More specifically, commenters stated that this certification criterion should include the capability to record whether a patient has an advance directive, but not require the EHR technology to demonstrate that the actual advance directive document is recorded as an electronic document in the EHR technology. A commenter recommended that this requirement be included for the ambulatory setting as well so that this data could be easily exchanged between EPs, EHs, and CAHs. One commenter suggested that EHR technology be required to provide user access to the advance directive. Another commenter suggested that EHR technology should provide patients with access to their advance directives and provide patients the capability to change the advance directive.

Some commenters recommended that the certification criterion be modified to accommodate scanned copies of advance directives as well as reconciliation and version control capabilities. Other commenters suggested that standard vocabulary was needed to describe and capture an advance directive, including in the Consolidated CDA. A few commenters suggested that we consider requiring EHR technology be capable of recording the type of advance directive (e.g., Intubation, Tube Feedings, Life Support) and the effective date/time periods for the advance directive. The commenters reasoned that, while the indication of an advance directive is not part of the summary of care record for

MU, the Consolidated CDA that will be used for the 2014 Edition EHR certification criteria calls for an indication of the type of advance directive. Therefore, these commenters suggested this was an opportunity to encourage EHR technology developers to implement such functionality in conjunction with the Consolidated CDA functionality. Conversely, some commenters stated that it is not necessary to require specific codes for ''types'' of advance directives because they are not often collected and may vary from state to state.

A few commenters requested clarification on whether ''yes'' and ''no'' data fields constituted ''structured'' data. Another commenter requested clarification on whether structured data implied a Boolean indicator.

Response. We appreciate the support for the certification criterion as proposed and are adopting this certification criterion as an unchanged certification criterion for the 2014 Edition EHR certification criterion at § 170.314(a)(17). This certification criterion's scope focuses on the capabilities necessary to support MU, which requires the recording of whether a patient 65 years old or older has an advance directive. A patient's advance directive is not required to be available or accessible with EHR technology. Under MU, advance directive information is also not included in the summary care record, required to be provided after a patient's office visit, or required to be available for online viewing or downloading by a patient. Accordingly, while we appreciate the commenters' suggested modifications and inclusion of additional capabilities for this certification criterion (i.e., requiring this capability for the ambulatory setting, making the actual advance directive available in scanned or structured format, noting the type of advance directive, providing user or patient access to the advance directive and the ability to change the advance directive), we decline to make any revisions to this certification criterion at this time since such additional capabilities would be beyond those needed to support MU.

We clarify that EHR technology would only need to demonstrate that it can include an advance directive indicator and that the indicator is stored in the patient's record. The use of ''yes'' and ''no'' data fields may be one method for EHR technology to meet this certification criterion. A Boolean search capability based on patients with advance directives is not a requirement to meet this certification criterion.

- *Medication List*

MU Objective
Maintain active medication list.
2014 Edition EHR Certification Criterion
§ 170.314(a)(6) (Medication list).

Comments. The majority of commenters recommended that this certification criterion remain unchanged. Commenters reasoned that it is appropriate to be non-prescriptive related to standards for internal EHR functionality, while requiring the use of standards for health information exchange. Conversely, a few commenters suggested that we evaluate the applicability of standards for this certification criterion with one commenter suggesting the use of the RxNorm standard. These commenters suggested that this would lead to EPs, EHs, and CAHs having the capability of providing this information as structured data in an interoperable format. One commenter suggested that this certification criterion be modified to require that EHR technology be capable of providing a description of each medication's class and intended purpose. One commenter stated that EHR technology should support the import of medication lists from external sources, such as an HIE, for true longitudinal care across providers.

Response. We appreciate the support for the certification criterion as proposed and are adopting this certification criterion as an unchanged certification criterion for the 2014 Edition EHR certification criterion at § 170.314(a)(6). We believe that this certification criterion as adopted supports MU. Therefore, requiring EHR technology to be capable of providing a description of each medication's class and intended purpose is not necessary for certification. However, as we state elsewhere, EHR technology developers are free to include capabilities that go beyond certification requirements.

As discussed in other certification criteria, we have required the use of RxNorm in instances where EHR technology would be used to perform external transmissions (e.g., for a transition of care (§ 170.314(b)(2)). Additionally, we require the capability to reconcile a patient's medication list as part of the adopted ''clinical information reconciliation'' certification criterion at § 170.314(b)(4) and the receipt of RxNorm codes in a transition of care/referral summary should greatly facilitate this process. Thus, at this juncture, we do not believe it is necessary to require as a condition of certification that EHR technology natively record medications directly into RxNorm although such an approach may be more efficient and expeditious for some. We continue to remain cognizant of the potential burden that requiring a standard for this certification criterion could cause and continue to believe it is appropriate to provide EPs, EHs, and CAHs with the flexibility to internally record such information in a manner that includes the medication vocabularies with which they are familiar.

We note that in response to comments received on our use of the term ''longitudinal care'' in this certification criterion and in other certification criteria, we have replaced the term with the meaning we gave the term for the ambulatory and inpatient settings in the Proposed Rule. We refer readers to our discussion of the revised ''problem list'' certification criterion earlier in this preamble.

- *Medication Allergy List*

MU Objective
Maintain active medication allergy list.
2014 Edition EHR Certification Criterion
§ 170.314(a)(7) (Medication allergy list).

Comments. The majority of commenters recommended that this certification criterion remain unchanged. A couple of commenters suggested expanding to include all allergies, including food and substance allergies. The commenters reasoned that it was important to maintain lists of these allergies to prevent adverse reactions and other patient-safety events. These commenters also suggested referencing a standard such as RxNorm or UNII as applicable for these additional types of allergens. Another commenter specifically suggested that we require the use of RxNorm for this certification criterion. One commenter stated that EHR technology should support the import of medication allergy lists from external sources, such as an HIE, for true longitudinal care across providers.

Response. We appreciate the support for the certification criterion as proposed and are adopting this certification criterion as an unchanged certification criterion for the 2014 Edition EHR certification criterion at § 170.314(a)(7). While we appreciate the commenters' suggestion to expand the capabilities included in this certification criterion to cover additional types of allergens and patient safety is one our utmost concerns, such additional capabilities would be beyond those needed to support MU. Therefore, although we decline to adopt this recommendation, we continue to encourage EHR technology developers

to include capabilities that may go beyond certification requirements, particularly where that may improve patient safety. Similar to the rationale provided in our response above regarding the ''medication list'' certification criterion, we decline to require as a condition of certification that EHR technology natively record medication allergies directly into RxNorm. We have however, in response to these comments and other comments received on the other certification criteria that reference medication allergies, adopted RxNorm for instances where this data would be included in a CCDA formatted document.

We note that in response to comments received on our use of the term ''longitudinal care'' in this certification criterion and in other certification criteria, we have replaced the term with the meaning we gave the term for the ambulatory and inpatient settings in the Proposed Rule. We refer readers to our discussion of the revised ''problem list'' certification criterion earlier in this preamble.

12. Gap Certification

''Gap certification'' is ''the certification of a previously certified Complete EHR or EHR Module(s) to: (1) [a]ll applicable new and/or revised certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results of a NVLAP-accredited testing laboratory; and (2) [a]ll other applicable certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results used to previously certify the Complete EHR or EHR Module(s).'' We stated in the Permanent Certification Program final rule (76 FR 1307) and reiterated in the Proposed Rule that gap certification will focus on the difference between certification criteria that are adopted through rulemaking at different points in time. We discuss in section III.A of this preamble, as we did in the Proposed Rule, the factors we would consider in determining whether a 2014 Edition EHR certification criterion is ''new'' or ''revised.'' Examples of new certification criteria are the ''secure messaging'' certification criterion at § 170.314(e)(3) and the ''electronic medication administration record'' certification criterion at § 170.314(a)(17). An example of a revised certification criterion is the ''CDS'' certification criterion at § 170.314(a)(8). This certification criterion is ''revised'' because it add capabilities to the certification criteria for CDS that were previously adopted at §§ 170.304(e) and 170.306(c). An example of a certification criterion that we would consider both new and revised is the ''e-prescribing'' certification criterion at § 170.314(b)(3). This certification criterion is a revised certification criterion for the ambulatory setting, but would be considered a new certification criterion for the inpatient setting.

We stated in the Proposed Rule that for a Complete EHR or EHR Module that was previously certified to the 2011 Edition EHR certification criteria to be certified to the 2014 Edition EHR certification criteria, test results from a NVLAP-accredited testing laboratory would be required for all of the applicable new and revised certification criteria that are adopted. For the certification criteria that we identified as unchanged in the Proposed Rule, we stated that test results that were used previously to certify a Complete EHR or EHR Module to the 2011 Edition EHR certification criteria could be used to certify the Complete EHR or EHR Module to the corresponding 2014 Edition EHR certification criteria that we identified. We provided an illustration of how gap certification would work with our proposed 2014 Edition EHR certification criteria. An EHR Module that was previously certified to the ''CPOE'' and ''drug-drug, drug-allergy interaction checks'' certification criteria (i.e., previously tested and certified to § 170.304(a) or § 170.306(a) and § 170.302(a)) would not need to be retested to the ''CPOE'' certification criterion at § 170.314(a)(1) because this criterion has been identified as an unchanged certification criterion. However, the previously certified EHR Module *would need* to be retested for ''drug-drug, drug-allergy interaction checks'' because the ''drug-drug, drug-allergy interaction checks'' certification criterion at § 170.314(a)(2) has been identified as a revised certification criterion as part of the 2014 Edition of EHR certification criteria.

Comments. Multiple comments expressed support for our gap certification policy and the identification of unchanged certification criteria for the purposes of gap certification. Commenters noted that gap certification would increase the efficiency of the certification process and reduce costs for EHR technology developers and EPs, EHs and CAHs. A commenter requested clarification about whether a Complete EHR or EHR Module previously certified to the 2011 Edition EHR certification criteria would need to maintain the same scope of certification to be able to be ''gap-certified'' to the 2014 Edition EHR certification criteria, and whether pursuing a different scope of certification would require a ''new'' certification even if the same criteria are part of the scope of the 2014 Edition certification. This same commenter also noted that for some Complete EHRs and EHR Modules certified to unchanged certification criteria, they would still need to be tested to § 170.314(g)(2). Another commenter requested that ONC provide ONC–ACBs with gap certification guidance so that there is consistency in the implementation of the policy.

Response. We appreciate commenters support for gap certification. We agree with commenters that gap certification would be a less costly and more efficient certification option for EHR technology developers. We assume that by ''same scope of certification,'' the commenter meant whether a Complete EHR or EHR Module previously certified to the 2011 Edition EHR certification criteria could only be certified to the corresponding 2014 Edition EHR certification criteria. We clarify that a previously certified Complete EHR or EHR Module would not need to maintain the same scope of certification to be gap certified. For example, it would be impossible for a Complete EHR designed for the ambulatory setting presented for certification to the 2014 Edition EHR certification criteria to be the same in scope as a Complete EHR previously certified to the 2011 Edition EHR certification criteria because the 2014 Edition EHR certification criteria applicable to the ambulatory setting include new certification criteria adopted by the Secretary. Similarly, an EHR Module presented for certification to the 2014 Edition EHR certification criteria may be certified to more certification criteria than it was previously certified to the 2011 Edition EHR certification criteria and still be gap certified to the unchanged certification criteria it includes. Along these lines, as referenced by a commenter, EHR Modules certified to the 2014 Edition EHR certification criteria that include a capability that supports a MU percentage-based measure will need to be certified to either the new certification criterion at § 170.314(g)(1) or the revised certification criterion at § 170.314(g)(2) independent of the designation (i.e., new, revised, or unchanged) of the certification criterion that includes the capability that supports a MU percentage-based measure (to note, Complete EHRs would need to be certified to § 170.314(g)(2)). As stated in the Permanent Certification Program final rule (76 FR 1308), in all of these

examples, an ONC–ACB would issue a certification to the entire Complete EHR or EHR Module it certifies to the 2014 Edition EHR certification criteria. We also provided a detailed explanation of gap certification and initial guidance in the Permanent Certification Program final rule (76 FR 1307–08) and intend to provide additional guidance as necessary to facilitate a consistent implementation of gap certification by ONC–ACBs.

For the purposes of gap certification, table 3 below provides a crosswalk of unchanged 2014 Edition EHR certification criteria to the corresponding 2011 Edition EHR certification criteria. This table has been revised compared to the table included in the Proposed Rule (77 FR 13860–61). We have removed from the table both the certification criteria that have now been adopted as revised certification criteria and those that were not adopted as part of the 2014 Edition EHR certification criteria. The proposed unchanged certification criteria that have been adopted as revised certification criteria are: ''drug-formulary checks'' (§ 170.314(a)(10)); ''vital signs, body mass index, and growth charts'' (§ 170.314(a)(4)); ''smoking status'' (§ 170.314(a)(11)); ''patient lists'' (§ 170.314(a)(14)); and ''patient reminders'' (§ 170.314(a)(15))[now combined and collectively referred to as ''patient list creation'' (§ 170.314(a)(14)) in this final rule]. The certification criteria that were proposed as part of the 2014 Edition EHR certification criteria, but were not adopted are ''public health surveillance'' (§ 170.314(f)(3)) and ''reportable laboratory tests and values/results'' (§ 170.314(f)(5)). We also note, as identified in table 3, that for the certification criterion at § 170.314(b)(5) (Incorporate laboratory tests and values/results), EHR technology designed for an ambulatory setting would need to be tested by a NVLAP-accredited testing laboratory because such EHR technology must meet new standards and implementation specifications, while the capabilities required for the inpatient setting are unchanged.

TABLE 3—GAP CERTIFICATION: CROSSWALK OF UNCHANGED 2014 EDITION EHR CERTIFICATION CRITERIA TO THE CORRESPONDING 2011 EDITION EHR CERTIFICATION CRITERIA

2014 Edition		2011 Edition	
Regulation section	Title of regulation paragraph	Regulation section	Title of regulation paragraph
170.314(a)(6)	Medication list	170.302(d)	Maintain active medication list.
170.314(a)(7)	Medication allergy list	170.302(e)	Maintain active medication allergy list.
170.314(b)(5)	Incorporate laboratory tests and values/results (inpatient setting only).	170.302(h)	Incorporate laboratory test results.
170.314(f)(1)	Immunization information	170.302(k)	Submission to immunization registries.
170.314(d)(1)	Authentication, access control, and authorization.	170.302(o)	Access control.
170.314(d)(6)	Emergency access	170.302(p)	Emergency access.
170.314(d)(5)	Automatic log-off	170.302(q)	Automatic log-off.
170.314(d)(8)	Integrity	170.302(s)	Integrity.
170.314(d)(1)	Authentication, access control, and authorization.	170.302(t)	Authentication.
170.314(d)(9)	Optional–accounting of disclosures	170.302(w)	Accounting of disclosures.
170.314(a)(1)	Computerized provider order entry	170. 304(a) 170. 306(a)	Computerized provider order entry.
170.314(a)(17)	Inpatient setting only–advance directives	170.306(h)	Advance directives.

13. Disability Status

In the Proposed Rule, we solicited comments on whether EHR technology certified to the 2014 Edition EHR certification criteria should be capable of recording the functional, behavioral, cognitive, and/or disability status of patients (collectively referred to as ''disability status''). We stated that the recording of disability status could have many benefits. It could facilitate provider identification of patients with disabilities and the subsequent provision of appropriate auxiliary aids and services for those patients by providers. It could promote and facilitate the exchange of this type of patient information between providers of care, which could lead to better quality of care for those with disabilities. The recording of disability status could also help monitor disparities between the ''disabled'' and ''nondisabled'' population.

We asked commenters whether there exists a standard(s) that would be appropriate for recording disability status in EHR technology. We pointed commenters to the standard for disability status approved by the Secretary for use in population health surveys sponsored by HHS [34] and standards under development as part of the Standards and Interoperability Framework and the Continuity Assessment Record and Evaluation (CARE) assessment tool.[35] We asked commenters whether these standards or any other standards would be appropriate for recording disability status in EHR technology.

We requested that commenters consider whether the recording of disability status should be a required or optional capability that EHR technology would include for certification to the 2014 Edition EHR certification criteria. We also requested that commenters consider whether the recording of disability status should be part of a Base EHR definition and included in a separate certification criterion or possibly the ''demographics'' certification criterion (§ 170.314(a)(3)). Last, we requested that commenters consider whether disability status recorded according to the standard should also be included in other certification criteria such as ''transitions of care—incorporate summary care record'' (§ 170.314(b)(1)), ''transitions of care—create and transmit summary care record'' (§ 170.314(b)(2)), ''view, download and transmit to 3rd party'' (§ 170.314(e)(1)), and ''clinical summaries'' (§ 170.314(e)(2)).

Comments. Commenters stated that there could be many benefits from the recording of disability status, such as

[34] *http://www.minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlid=208.*

[35] *http://wiki.siframework.org/file/detail/CARE+Tool+Functional%2C+Cognitive+and+Skin+Status.xls.*

the ones we described in the Proposed Rule. Commenters, however, expressed a significant lack of consensus on how to define disability status. Some commenters stated that ''functional status,'' is a more precise, comprehensive, and objective measure for describing the patient's clinical status. Other commenters stated that functional, cognitive, and disability status were distinct. One commenter suggested that we use the definition for ''disability'' identified in the Americans with Disabilities Act Amendments Act. A couple of commenters stated that there is no commonly accepted definition that could be used for our purposes.

Commenters also expressed concern over disability status being improperly defined, accurately recorded for a patient, and shared with others. A few commenters stated that there may be legal ramifications for patients or providers if the term ''disability'' is erroneously applied to a patient record as benefit determinations, entitlement to protected class status, and/or reimbursement could be affected. Another commenter noted concerns that the accuracy of the data could differ if the definition has subjective components and information is entered by multiple providers. A couple of commenters noted that disability status is not required for all patients or all specialties and should not be required in any reports (they noted that when needed, it will be sent as part of existing information). A couple of other commenters noted privacy and security concerns with sharing and reporting patient disabilities.

Commenters made a variety of recommendations regarding how ''disability status'' should be incorporated into the 2014 Edition EHR certification criteria. Commenters suggested including it as its own certification criterion, in and not in the ''demographics'' certification criterion, in all the certification criteria we mentioned in the Proposed Rule, and in the Base EHR definition. A few commenters also suggested that disability status could be captured in patient problem lists. One commenter suggested that if the recording of disability status is part of certification, then its recording should be optional.

Commenters gave varying views on the availability of appropriate standards and tools for capturing disability standards. Many commenters also expressed views that standards were not mature enough. Commenters suggested the Consolidated CDA be used for capturing cognitive and functional status, but noted that it was not yet mature enough for capturing other kinds of disabilities in a structured way. Some of these commenters suggested that the Consolidate CDA could serve as a ''stepping stone.'' A commenter suggested the collection of disability status data using the American Community Survey (ACS) questions on disability (these constitute the 6-question data collection disability standard used for population health surveys sponsored by HHS). Another commenter noted that the World Health Organization created an entire framework and vocabulary standard—the International Classification of Functioning, Health and Disability (ICF)—to capture and record functional and disability status. A commenter also suggested SNOMED CT® (used in the SSA CCD) or ICD–10–CM/PCS could have potential for use in recording disability status. Multiple commenters suggested that the CARE assessment tool should be used. However, one commenter stated that the CARE tool in its current form will not accurately document medical severity, functional status, and other factors related to outcomes as the questions lack sensitivity and, therefore, the type of information about the patient needed to measure outcomes and severity is not being collected by this instrument. A few other commenters stated that there is no current standard(s) appropriate for recording disability status in EHR technology at this time. These comments suggested a new standard be developed using the CARE assessment tool and ICF Core Sets to help guide the development of the standard. Another commenter suggested that new standards could be developed for including this as a separate section such as ''disability history'' (alongside ''social history'').

Response. We appreciate the responses and various recommendations from commenters. Although commenters did not express consensus around a single definition or standard for recording or transmitting ''disability status,'' commenters generally provided a framework from which forward progress on this topic can be made. Commenters noted that benefits could be realized when such information is captured. Commenters were also clear that we should not use a single term, such as ''disability status,'' to capture both demographics (i.e., impairments that are generally permanent and do not change over time) and clinical information (i.e., clinically assessed impairments that may improve, worsen, or go away over time). Commenters did suggest that functional and cognitive status be used for clinical information and that standards were available to use for both capture and transmission.

We acknowledge that the Proposed Rule's use of a single term, ''disability status,'' was too imprecise to represent at least the two different concepts expressed by commenters. As shown by the diversity in commenters' views and considering that, in most cases, a standard *defines* the information that must be recorded, we believe that further stakeholder input is necessary before EHR technology is required as a condition of certification to be capable of recording a patient's disability(ies) in a specific standard. As a starting point, we ask that stakeholders consider whether the recently developed 6-question ''data standard for disability status'' adopted for population health surveys sponsored by HHS or any other standard would be appropriate for requiring the recording of the types of impairments identified in the 6-question survey standard (e.g., ''are you deaf or do you have serious difficulty hearing''). Unlike clinical cognitive or functional status assessments, this information can be used by health care providers to better accommodate and respond to individual patient needs. In turn, we will ask the HITPC and HITSC to consider during their deliberations on recommendations for MU Stage 3 that they review the 6-question ''data standard for disability status'' and any other relevant standard for the recording of disabilities.

As a current means of moving forward, we believe we can build on commenters' recommendations for transmitting cognitive and functional status. We agree with commenters that we should consider ''disability status,'' at minimum, in terms of functional and cognitive status. We also agree with commenters that the Consolidated CDA can serve as a ''stepping stone.'' The Consolidated CDA can capture functional and cognitive status as well as other ''disability statuses.'' Therefore, considering that the ''transitions of care'' certification criteria already require that EHR technology be capable of using the Consolidated CDA, we are also requiring that EHR technology be capable of including patient data on functional and cognitive status in order to align with inclusion of this information by CMS for transitions of care/referrals in the Stage 2 final rule.

Overall, we believe these initial steps will put us on a path forward using EHR technology to improve the quality of care for those patients with disabilities.

B. Redefining Certified EHR Technology and Related Terms

1. Proposed Revisions to the Definition of Certified EHR Technology

Based on feedback ONC and CMS received on the CEHRT definition from numerous stakeholders, including EPs, EHs, CAHs, EHR technology developers, and multiple associations representing these and other stakeholders and the recommendations [36] of the HITSC, we proposed a more flexible CEHRT definition. Overall, a majority of stakeholders and the HITSC recommended a definition that would provide EPs, EHs, and CAHs the flexibility to have or possess only the EHR technology certified to adopted certification criteria that they would need/use to demonstrate MU. Accordingly, consistent with the instruction of the President's Executive Order (EO) 13563 to identify and consider regulatory approaches that reduce burden and maintain flexibility for the public, we proposed to revise the CEHRT definition at § 170.102. The proposed revised CEHRT definition was broken into two parts based on years of applicability.

For FYs/CYs Up to and Including 2013

For the first part of the revised definition of CEHRT that would apply for the FYs/CYs up to and including 2013, we proposed two specific changes. The first was to include a reference to ''the 2011 Edition EHR certification criteria'' in order to make clear that these are the certification criteria previously adopted by the Secretary at §§ 170.302, 170.304, and 170.306. We stated that this clarification was necessary because with the adoption of the 2014 Edition EHR certification criteria in this final rule at § 170.314, there would be two ''editions'' of adopted certification criteria in the CFR. Both the 2011 Edition and the 2014 Edition EHR certification criteria must be effective at the same time for EHR technology to continue to be tested and certified to the 2011 Edition EHR certification criteria and so EHR technology developers may begin to have their EHR technology tested and certified to the 2014 Edition EHR certification criteria.

The second change we proposed would allow EPs, EHs, and CAHs to satisfy the definition by having EHR technology certified to the 2014 Edition EHR certification criteria that are ''equivalent'' to the 2011 Edition EHR certification criteria. We stated that we would consider ''equivalent'' certification criteria to be those proposed 2014 Edition EHR certification criteria that include capabilities that are at least equal to the capabilities included in certification criteria that were previously adopted as part of the 2011 Edition EHR certification criteria. For further clarity, we provided a cross-walk between 2011 Edition EHR certification criteria and what we considered equivalent proposed 2014 Edition EHR certification criteria (77 FR 13863). We stated that this revision was necessary to permit EPs, EHs, and CAHs with the flexibility to adopt or upgrade to EHR technology certified to the 2014 Edition EHR certification criteria without adversely affecting the certified status of previously adopted EHR technology or their ability to meet the definition of CEHRT. With respect to CQMs, however, we noted that EPs, EHs, and CAHs who adopt or upgrade to EHR technology certified to the 2014 Edition EHR certification criteria during FY/CY 2012 or FY/CY 2013 must ensure that their CEHRT will enable them to report on the CQMs required for the 2012 and 2013 EHR reporting periods. More specifically, the EHR technology required to electronically capture, calculate, and report CQMs during those years will be different than the EHR technology needed to do the same in FY/CY 2014 and subsequent years because CMS did not propose to change the set of CQMs on which EPs, EHs, and CAHs would need to report until FY/CY 2014. Therefore, we clarified that EPs, EHs, and CAHs will need to have EHR technology certified to the CQM certification criteria included in the 2011 Edition EHR certification criteria to be able to report on the CQMs required for the 2012 and 2013 EHR reporting periods. For further guidance, we encouraged EPs, EHs, and CAHs to read CMS' Stage 2 proposed rule to understand the CQMs that would need to be reported for a given EHR reporting period.

For FY and CY 2014 and Subsequent Years

We stated that the second part of the revised definition of CEHRT that would apply beginning with FY/CY 2014 would accomplish four main policy goals:

1. It defines CEHRT in plain language and makes the definition and its requirements readily understandable to EPs, EHs, CAHs, EHR technology developers, and other stakeholders.

2. It continues the progress towards increased interoperability requirements for EHR technology by requiring all CEHRT to have, at a minimum, the capabilities included the Base EHR definition.

3. It accounts for stakeholder feedback, which expressed that the definition should align more closely with MU requirements under the EHR Incentive Programs.

4. It follows the tenets expressed in EO 13563 by reducing regulatory burden, providing more flexibility to the regulated community, and making regulatory text more understandable.

We reminded stakeholders in the Proposed Rule that the definition of CEHRT does not speak to just one audience. EPs, EHs, and CAHs may view the definition of CEHRT in a way that informs them of the EHR technology that they must possess to accomplish MU. Alternatively, EHR technology developers may see the definition differently and in a way that informs them of the potential market demand for certain EHR technologies and, more specifically, the EHR technology that their customers will need to achieve MU.

We affirmed in the Proposed Rule that only two types of EHR technology, Complete EHRs and EHR Modules, can be certified under the ''ONC HIT Certification Program.'' However, we pointed out that under the revised definition of CEHRT that we proposed for FY/CY 2014 and subsequent years, an EP, EH, or CAH could meet the definition with a certified Complete EHR, a single certified EHR Module, a combination of separately certified EHR Modules, or any combination of the three. For example, an EHR technology developer could get an EHR Module certified that would subsequently enable an EP, EH, or CAH to have EHR technology that would satisfy the proposed revised definition of CEHRT. Alternatively, an EP, EH, or CAH could use a certified Complete EHR and a certified EHR Module to meet the proposed revised definition of CEHRT.

We provided the following scenarios in the Proposed Rule to demonstrate the added flexibility the proposed revised CEHRT definition could provide EPs, EHs, and CAHs. One scenario of added flexibility would be where an EP, EH, or CAH qualifies for an exclusion for a MU objective and associated measure. With respect to this scenario, we expect that this new flexibility would apply in situations where the MU objective and associated measure would not be applicable to the EP, EH, or CAH. In most cases, we expect this would occur for EPs based on their scope of practice

[36] HITSC recommendations dated November 16, 2011 and transmitted to ONC on January 17, 2012. *http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_0_6014_1818_17828_43/http%3B/wci-pubcontent/publish/onc/public_communities/_content/files/011712_iwg_transmittalmemo.pdf.*

and would be significantly less likely to occur for most EHs and CAHs. For example, a dentist will never give immunizations and, thus, would not need EHR technology with the capability to submit immunization information to immunization registries in order to satisfy the proposed revised definition of CEHRT. As another example, and as noted earlier, an EP may not have any office visits during an EHR reporting period and thus may qualify for the exclusion for the MU objective and associated measure requiring clinical summaries to be provided to patients for each office visit. Under the proposed revised definition of CEHRT, the EP would not need to have EHR technology that supports this capability. The second scenario would be where an EP, EH, or CAH is able to and has chosen to defer a MU ''menu set'' objective and associated measure for a particular stage of MU. In such a case, the EP, EH, or CAH would not necessarily need to have EHR technology with the capability to meet the menu set objective and associated measure in order to have EHR technology that satisfies the proposed revised definition of CEHRT. Ultimately, under the proposed revised definition of CEHRT for FY/CY 2014 and subsequent years, the EP, EH, and CAH would be responsible for ensuring that they have the necessary EHR technology to meet the Base EHR definition and support the MU objectives and measures that they seek to achieve under the EHR Incentive Programs. This means that EPs, EHs, and CAHs could run the risk of not having sufficient CEHRT to support their achievement of MU if, for example, they turn out not to be able to exclude a MU objective and measure as anticipated or they end up needing to satisfy a menu objective and measure that they originally expected to defer.

Having offered these examples of the added flexibility the proposed revised definition of CEHRT for FY/CY 2014 and subsequent years could provide, we also emphasized that under the proposed revised definition, all EPs, EHs, and CAHs must have EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that meets the Base EHR definition as defined in the Proposed Rule. For example, even if an EP could claim an exclusion from the MU objective and associated measure for CPOE, he or she would still need to have EHR technology that has been certified to the CPOE certification criterion adopted by the Secretary because this capability would be included in the Base EHR definition.

After consultation with CMS, we determined that it would be least confusing and burdensome for EPs, EHs, CAHs, and EHR technology developers if our revised definition would apply beginning with the EHR reporting periods that will occur in FY/CY 2014. We stated that this approach would account for the proposed start of MU Stage 2 in FY/CY 2014; the policy change we have made related to the Base EHR definition; the time it would take EHR developers to update their EHR technology to meet the proposed new and revised certification criteria and have the EHR technology tested and certified to those criteria; and the time it would take EPs, EHs, and CAHs to subsequently implement EHR technology certified to the 2014 Edition EHR certification criteria. We requested public comment on alternative approaches that would provide equivalent simplicity and flexibility for EPs, EHs, and CAHs, as well as EHR technology developers, but that would still meet our programmatic goals and timelines.

We clarified and emphasized in the Proposed Rule that the revised definition of CEHRT would apply for all EPs, EHs, and CAHs, regardless of whether they are in Stage 1 or Stage 2 of MU. For example, EPs, EHs, and CAHs that are in Stage 1 or Stage 2 of MU for the EHR reporting periods in FY/CY 2014 would need to meet the revised definition of CEHRT (which includes the Base EHR definition).

Comments. Commenters expressed appreciation and agreement with the added flexibility the proposed revised CEHRT definition provided EPs, EHs, and CAHs. The majority of commenters, however, expressed concern that the time available between the publication of this final rule and the proposed compliance dates (October 1, 2013 for EHs and CAHs and January 1, 2014 for EPs) for the revised CEHRT definition that would apply beginning with FY/CY 2014 would be insufficient. Commenters stated that there would not be sufficient time for developing, testing, and certifying EHR technologies to the 2014 Edition EHR certification criteria and subsequently implementing these EHR technologies in the healthcare environments of all EPs, EHs, and CAHs that intend to participate in the EHR Incentive Programs in FY/CY 2014. EHR technology developers suggested a minimum of 15 months is necessary from the availability of testing and certification for EHR technology to the 2014 Edition EHR certification criteria if all EHs must have CEHRT that meets the CEHRT definition for FY/CY 2014 on October 1, 2013.

Commenters suggested various alternatives to our proposed revised CEHRT definition and the CMS proposed EHR reporting periods in FY/CY 2014. These alternative proposals suggested ways to provide additional flexibility and reduce burden for EHR technology developers, EPs, EHs, and CAHs in complying with the proposed revised CEHRT and meaningful use requirements. Some commenters suggested permitting EPs, EHs, and CAHs to meet the revised CEHRT definition for FY/CY 2014 at any time during their Stage 2 EHR reporting period in 2014. This would essentially give EHs and CAHs until September 30, 2014, and EPs until December 31, 2014. Other commenters suggested a shorter EHR reporting period for EPs, EHs, and CAHs in their first year of MU Stage 2, such as a 90-day or 180-day EHR reporting period. Commenters stated this would be similar to how MU Stage 1 was implemented. Some commenters suggested permitting EPs, EHs, and CAHs to use EHR technology certified to the 2011 Edition EHR certification criteria until at least FY/CY 2015. A few commenters suggested that we directly correlate the definition of CEHRT with the MU stage. The commenters suggested that an EP, EH, or CAH would only need to have EHR technology that could support the MU stage they were attempting to achieve, such as EHR technology certified to the 2011 Edition if they were attempting to achieve MU Stage 1. The commenters also suggested that it should be optional for EPs, EHs, and CAHs to use EHR technology certified to the 2014 Edition in Stage 1.

A few commenters suggested an approach within the framework of our proposed revised CEHRT definition. These commenters suggested making the flexibility provided by our proposed revised CEHRT definition for FY/CY 2014 and subsequent years available during FY/CY 2012 and 2013. In particular, one commenter suggested that we revise the first part of the proposed CEHRT definition (applicable through FY/CY 2013) to provide EPs, EHs, and CAHs with the option of meeting a CEHRT definition similar to the definition for FY/CY 2014 and subsequent years. The commenter suggested this could be achieved by revising the CEHRT definition for FY/CY 2013 to include a Base EHR definition based on the 2011 Edition EHR certification criteria or by permitting the use of EHR technology in FY/CY 2013 that meets the CEHRT definition for FY/CY 2014 and subsequent years. The commenter stated

that we could add flexibility by permitting an EP, EH, or CAH to use either option in lieu of our proposal that would limit them to only being able to use EHR technology certified to all of the applicable 2011 Edition EHR certification criteria or equivalent 2014 Edition EHR certification criteria. The commenter identified, however, that if we adopt an approach allowing EPs, EHs, and CAHs to meet the proposed revised CEHRT definition for FY/CY 2014 and subsequent years in FY/CY 2013, it would create a potential inconsistency with respect to CQMs. More specifically, the commenter stated that such an approach would require an EP, EH, or CAH who wanted to adopt only 2014 Edition EHR technology to still have 2011 Edition EHR technology that could calculate the CQMs required for the EHR reporting periods in 2013. To address this alignment issue, the commenter recommended that EPs, EHs, and CAHs be permitted to use 2014 Edition EHR technology and attest in FY/CY 2013 using the CQMs designated for the 2014 EHR reporting period (and that would be part of their 2014 Edition EHR technology) in lieu of the other CQM reporting requirements for FY/CY 2013.

Response. We appreciate commenters' support for our proposed revised CEHRT definition. We understand the concerns expressed by commenters regarding time constraints and the steps needed for EPs, EHs, and CAHs to achieve compliance with the proposed revised CEHRT definition for FY/CY 2014. We believe with the timely publication of this final rule and the steps taken by CMS to add flexibility to the EHR reporting periods in FY/CY 2014, there will be sufficient time for all EPs, EHs, and CAHs that intend to participate in the EHR Incentive Programs in FY/CY 2014 to adopt and implement EHR technology that meets the CEHRT definition. The recommendations commenters made related to MU Stage 2 timing fall within the purview of CMS and the EHR Incentive Programs (i.e., length of EHR reporting periods and when EPs, EHs, and CAHs must possess CEHRT in relation to the EHR reporting periods). However, we have discussed the recommendations related to the length of EHR reporting periods with CMS, and CMS has determined to adopt three-month quarter EHR reporting periods in FY/CY 2014. This will provide additional time for EHR technology developers as well as give EPs, EHs, and CAHs up to an additional 9 months to adopt EHR technology that meets the revised CEHRT definition for FY/CY 2014.

We decline to accept commenters' suggestions about correlating ''editions'' of certification criteria with MU stages (i.e., 2011 Edition with Stage 1 and 2014 Edition with Stage 2), permitting the use of EHR technology certified to the 2011 Edition EHR technology through FY/CY 2015, or making the use of EHR technology certified to the 2014 Edition EHR certification criteria optional for those EPs, EHs, or CAHs participating in MU Stage 1. While these approaches could assuage commenters' timing concerns, they do not account for the fact that such a policy decision would have significant long-term consequences with respect to accelerating electronic health information exchange and interoperability. For example, as CMS illustrated in the Stage 2 proposed rule (77 FR 13703) and again in the Stage 2 final rule published elsewhere in this issue of the **Federal Register**, its policy remains that an EP, EH, and CAH will begin demonstrating meaningful use according to the Stage 1 criteria. Thus, if we implemented an approach of certifying EHR technology to MU stages (without a cutoff date), an EP, EH, and CAH could participate in MU Stage 1 well into the future with EHR technology certified to the 2011 Edition EHR certification criteria. Similarly, in a scenario where all three anticipated MU stages are in effect at the same time, EPs, EHs, and CAHs would all have different EHR technologies certified to different functional and interoperability capabilities. Such an outcome could potentially create a disparity among meaningful EHR users just because of the EHR technology they used to demonstrate MU and would serve as a limiting step for the adoption of more advanced capabilities for patient care, engagement, and safety. Moreover, this suggestion does not account for how confusing or challenging it could potentially be in the scenario where different EPs in a group practice are meeting different MU stages during an EHR reporting period nor does it appear to account for how feasible it would be for EHR technology developers to simultaneously support EHR technologies certified to different functional and interoperability capabilities for the time spans necessary. Alternatively, we believe, as we have finalized, that it is simpler for EPs, EHs, and CAHs, as well as their EHR technology developers, to have a single EHR technology edition upon which to reference and rely that can support any MU stage an EP, EH, or CAH seeks to achieve.

We agree with the commenter's detailed suggestion that we provide EPs, EHs, and CAHs with the option of using EHR technology that meets the proposed revised definition of CEHRT for FY/CY 2014 and subsequent years as soon as practicable. We are therefore modifying the first part of the proposed revised CEHRT definition to include this flexibility. In other words, for the EHR reporting periods in CY/FY 2012 and 2013, EPs, EHs, and CAHs may use technology that satisfies the CEHRT definition that will apply in FY/CY 2014 and subsequent years. We believe this is a better approach than retrospectively creating a CEHRT definition for FY/CY 2012 and 2013 based on the 2011 Edition EHR certification criteria, which would include a ''2011 Edition'' Base EHR definition. A revised CEHRT definition based on 2011 Edition EHR certification criteria for FY/CY 2012 and 2013 would only be effective for about a year and during a period of time when most EHR technology developers will be focused on designing and upgrading their EHR technology to meet the 2014 Edition EHR certification criteria and not on meeting a new ''2011 Edition'' Base EHR definition. More importantly, providing such flexibility earlier will support continued forward momentum towards increased electronic health information exchange and interoperability, as well as avoid the potentially unnecessary and duplicative adoption of 2011 Edition and 2014 Edition CEHRT in the same year. To this last point and to emphasize, if an EP, EH, or CAH does not take advantage of this new flexibility, then to meet the CEHRT definition for FY/CY 2012 and 2013, the EP, EH, or CAH will need to have EHR technology certified to *all* of the mandatory 2011 Edition EHR certification criteria (or equivalent 2014 Edition EHR certification criteria) for either the ambulatory or inpatient setting, as applicable. Last, with respect to the potential CQM misalignment the commenter raised, we understand CMS is adopting a policy to accommodate EPs, EHs, and CAHs that choose to use only 2014 Edition CEHRT in FY/CY 2013. For further explanation, we refer readers to CMS's final rule published elsewhere in this issue of the **Federal Register**.

Consistent with EO 13563, this additional flexibility and the original flexibility we proposed in the revised CEHRT definition should create additional regulatory efficiencies for EPs, EHs, and CAHs. Accordingly, the CEHRT definition will be revised at § 170.102 to reflect our proposal in the

Proposed Rule with the additional modification to the first part of the definition discussed above. Table 4 below provides a crosswalk between the 2011 Edition EHR certification criteria and the 2014 Edition EHR certification criteria that we consider equivalent for the purposes of revised CEHRT definition for any Federal FY or CY up to and including 2013. Table 5 below provides a general overview of the revised CEHRT definition in relation to the stages of MU and the EHR reporting periods in FY/CY 2011 through 2014.

Table 4. Equivalent Certification Criteria

2011 Edition		2014 Edition		2014 Edition
Ambulatory	**Inpatient**	**Ambulatory**	**Inpatient**	**Certification Criterion**
§ 170.304(a)	§ 170.306(a)	§ 170.314(a)(1)		Computerized provider order entry
§ 170.302(a)		§ 170.314(a)(2)		Drug-drug, drug-allergy interaction checks
§ 170.304(c)	§ 170.306(b)	§ 170.314(a)(3)		Demographics
§ 170.302(f)		§ 170.314(a)(4)		Vital signs, body mass index, and growth charts
§ 170.302(c)		§ 170.314(a)(5)		Problem list
§ 170.302(d)		§ 170.314(a)(6)		Medication list
§ 170.302(e)		§ 170.314(a)(7)		Medication allergy list
§ 170.304(e)	§ 170.306(c)	§ 170.314(a)(8)		Clinical decision support
§ 170.302(b)		§ 170.314(a)(10)		Drug-formulary checks
§ 170.302(g)		§ 170.314(a)(11)		Smoking status
§ 170.302(i)		§ 170.314(a)(14)		Patient list creation
§ 170.304(d)		§ 170.314(a)(14)		Patient list creation
§ 170.302(m)		§ 170.314(a)(15)		Patient-specific education resources
	§ 170.306(h)		§ 170.314(a)(17)	Advance directives
§ 170.304(i)	§ 170.306(f)	§ 170.314(b)(1) and § 170.314(b)(2)		Transitions of care – receive, display, and incorporate transition of care/referral summaries and Transitions of care – create and transmit transition of care/referral summaries
§ 170.304(b)		§ 170.314(b)(3)		Electronic prescribing
§ 170.302(j)		§ 170.314(b)(4)		Clinical information reconciliation
§ 170.302(h)		§ 170.314(b)(5)		Incorporate lab tests and values/results
§ 170.302(o)		§ 170.314(d)(1)		Authentication, access control, and authorization
§ 170.302(t)		§ 170.314(d)(1)		Authentication, access control and authorization
§ 170.302(r)		§ 170.314(d)(2) and § 170.314(d)(3)		Auditable events and tamper-resistance and Audit report(s)
§ 170.302(q)		§ 170.314(d)(5)		Automatic log-off
§ 170.302(p)		§ 170.314(d)(6)		Emergency access
§ 170.302(u)		§ 170.314(d)(7)		End-user device encryption
§ 170.302(s)		§ 170.314(d)(8)		Integrity
§ 170.302(w)		§ 170.314(d)(9)		Accounting of disclosures
§ 170.304(g)		§ 170.314(e)(1)		View, download, and transmit to 3rd party
§ 170.304(f)	§ 170.306(d)	§ 170.314(e)(1)		View, download, and transmit to 3rd party
	§ 170.306(e)	§ 170.314(e)(1)		View, download, and transmit to 3rd party
§ 170.304(h)		§ 170.314(e)(2)		Clinical summaries
§ 170.302(k)		§ 170.314(f)(1) and § 170.314(f)(2)		Immunization information and Transmission to immunization registries
§ 170.302(l)		§ 170.314(f)(3)		Transmission to public health agencies – syndromic surveillance
	§ 170.306(g)		§ 170.314(f)(4)	Transmission of reportable laboratory tests and values/results
§ 170.302(n)		§ 170.314(g)(2)		Automated measure calculation

TABLE 5—REVISED DEFINITION OF CEHRT

EHR Reporting Periods			
FY/CY 2011	FY/CY 2012	FY/CY 2013	FY/CY 2014
MU Stage 1	MU Stage 1	MU Stage 1	MU Stage 1 *or* MU Stage 2
All EPs, EHs, and CAHs must have: (1) EHR technology that has been certified to all applicable 2011 Edition EHR certification criteria or equivalent 2014 Edition EHR certification criteria adopted by the Secretary; *or* (2) EHR technology that has been certified to the 2014 Edition EHR certification criteria that meets the Base EHR definition and would support the objectives, measures, and their ability to successfully report CQMs, for MU Stage 1.			All EPs, EHs, and CAHs must have EHR technology certified to the 2014 Edition EHR certification criteria that meets the Base EHR definition and would support the objectives, measures, and their ability to successfully report the CQMs, for the MU stage that they seek to achieve.

Comments. Some commenters expressed confusion about the impact of our proposed revised CEHRT definition on our ''possession'' policy.

Response. In FAQs 9–10–017–2 [37] and 12–10–021–1,[38] we describe our ''possession'' policy. We consider ''possessing'' (or ''having'') Certified EHR Technology to include either the physical possession of medium on which a certified Complete EHR or combination of certified EHR Modules resides, or a legally enforceable right by an eligible health care provider to access and use, at its discretion, the capabilities a certified Complete EHR or combination of certified EHR Modules includes. An eligible health care provider may determine the extent to which it will implement or use these capabilities, which will not affect the provider's ''possession'' of Certified EHR Technology. In sum, prior to our revised CEHRT definition, an EP would need to possess EHR technology certified to all mandatory certification criteria for an ambulatory setting, and an EH or CAH would need to possess EHR technology certified to all mandatory certification criteria for an inpatient setting. As discussed above, this would still hold true for FY/CY 2012 and 2013, unless an EP, EH, or CAH chooses to use EHR technology that satisfies the FY/CY 2014 revised CEHRT definition for those years. As also noted in our discussion above, our revised CEHRT definition for FY/CY 2014 and subsequent years does limit the potential quantity of EHR technology EPs, EHs, and CAHs would need to ''possess'' to meet the CEHRT definition by requiring EPs, EHs, and CAHs to have only EHR technology that meets the Base EHR definition and would support the objectives and measures, and their ability to successfully submit the CQMs, for the MU stage that they seek to achieve.

We reiterate that an EP, EH, or CAH must continue to possess all of a certified Complete EHR or certified EHR Module (i.e., the capabilities for which certification is required) in order to receive the benefit of such certification. An EP, EH, or CAH cannot purchase or possess only ''components'' of a certified Complete EHR or certified EHR Module for the purposes of meeting the CEHRT definition. That is, unless independently certified, those ''components'' could not be used to meet the CEHRT definition. We refer commenters to our discussion in section III.B.4 of this preamble for further discussion related to certifications issued to Complete EHRs and EHR Modules. Also, we seek to make clear that the possession policy *does not apply to those capabilities* that an EHR technology developer may include with those that constitute a certified Complete EHR or certified EHR Module but *for which certification is not required.* In those instances, because these other included capabilities are not required for certification, an EP, EH, or CAH, would not necessarily need to possess them if the EHR technology developer would separately sell them. For more on this point, we refer commenters to our ''EHR Technology Price Transparency'' discussion in section IV.F of this preamble.

2. Base EHR Definition

In the Proposed Rule, we proposed to add to § 170.102 a new defined term, ''Base EHR,'' which would essentially serve as a substitute for the term ''Qualified EHR'' in the definition of CEHRT. We stated that the Base EHR definition would reflect all of the capabilities specified in the Qualified EHR statutory definition (that is, in section 3000(13) of the PHSA) plus the additional capabilities we proposed. We stated our intention to use the term ''Qualified EHR'' only as necessary and that its use would refer to the statutory definition unless otherwise indicated. We stated that the term ''Base EHR'' is more intuitive and conveys a plain language meaning. Moreover, we noted that the term ''Qualified EHR'' does not inherently convey the kinds of capabilities it includes. The term ''Base EHR,'' though, conveys that EHR technology includes certain fundamental capabilities. We also noted that the terms ''qualified EHR'' and ''qualified EHR products'' have been used by CMS in other programs and with a different meaning. Therefore, we concluded that the term ''Base EHR'' would be more easily understood and readily accepted by stakeholders.

We proposed that the Base EHR definition would include all the capabilities specified in the definition of a ''Qualified EHR'' under section 3000(13) of the PHSA. We also proposed that it would include an ''extra'' privacy and security capacity beyond what the Qualified EHR statutory definition required. Last, for clarity, we expressly listed the certification criteria to which an EP, EH, or CAH would need to make sure they had EHR technology certified in order to meet the Base EHR definition.

With respect to CQMs, we proposed that the Base EHR definition would include the certification criteria proposed at § 170.314(c)(1) and (2). We stated that the inclusion of § 170.314(c)(2) in a Base EHR ensures that EPs, EHs, and CAHs have the capability to incorporate all the data elements of, and calculate, at least one CQM. We stated that we anticipate that EHR technology developers will design EHR technology to incorporate the data elements for, and calculate, those CQMs

[37] *http://healthit.hhs.gov/portal/server.pt/community/onc_regulations_faqs/3163/faq_17/20779.*

[38] *http://healthit.hhs.gov/portal/server.pt/community/onc_regulations_faqs/3163/faq_21/21597.*

they believe their EHR technology would need to include in order to support the providers to which they market their EHR technology. We acknowledged, however, that this approach could leave a void in the market for EHR technology that would support certain CQMs that EPs, EHs, and CAHs would need to report beginning in 2014. Accordingly, we sought comments on whether we should require certification to a set number of CQMs as part of certification to § 170.314(c)(2) and provided potential options for such as an approach.

For one option, we stated that we could require EHR technology designed for the ambulatory setting to be able to incorporate data elements and calculate a specific number of CQMs for each of the CQM ''domains'' proposed by CMS for EPs in the Stage 2 proposed rule. For EHR technology designed for the inpatient setting, we stated that we could require that the EHR technology be able to incorporate data elements and calculate a minimum threshold number of CQMs proposed by CMS for EHs and CAHs (e.g., 24 or 36). Conversely, we noted a potential challenge with this more explicit approach. In order for EPs, EHs, and CAHs to have EHR technology that would meet the definition of a Base EHR, their EHR technology developers could be required to demonstrate that their EHR technology can incorporate and calculate data for certain CQMs that may ultimately be irrelevant their customers, but nonetheless are necessary for the EHR technology to be certified.

We also requested comment on whether a Base EHR should include, in addition to § 170.314(c)(1) and (2), the CQM reporting certification criteria proposed at § 170.314(c)(3), which would enable a user to electronically create a data file for transmission of clinical quality measurement results to CMS.

With respect to the ''privacy and security'' certification criteria associated with the Base EHR definition's proposed capacity to protect the confidentiality, integrity, and availability of health information stored and exchanged, we proposed that the certification criteria should apply equally to both the ambulatory and inpatient settings. We specifically requested public comment on whether there should be a distinction between the ambulatory and inpatient settings for EHR technology certification to the privacy and security certification criteria.

Comments. Commenters expressed support for the Base EHR definition and how it serves as the foundation of the CEHRT definition. However, it was also evident from comments that many commenters misunderstood the proposed Base EHR concept. That is, they interpreted the Base EHR as a singular, independent *type* of EHR technology that could or would be separately certified.

One commenter suggested adding a capacity to the Base EHR definition, including the ability to produce a health record for legal, business, and disclosure purposes. Other commenters suggested including additional certification criteria in the Base EHR definition, such as new certification criteria addressing nutrition, diet, and allergies, or proposed certification criteria such as family health history, electronic notes, and automated measure calculation. Conversely, other commenters suggested removing certification criteria from the Base EHR definition. One of these commenters suggested limiting the certification criteria included in the Base EHR definition to the minimum number of certification criteria that would still be consistent and compliant with the HITECH Act. Multiple commenters suggested not including certification criteria with capabilities that would not be needed by all EPs, EHs, and CAHs to attempt to achieve MU. These commenters contended that this would increase flexibility for EPs, EHs, and CAHs as well as prevent them from incurring unnecessary costs by being required to purchase unwanted and unwarranted EHR technology. More specifically, commenters suggested removing the ''vital signs'' certification criterion (§ 170.314(a)(4)), the ''drug-drug, drug-allergy interaction check'' certification criterion (§ 170.314(a)(2)), and the ''view, download, and transmit to 3rd party'' certification criterion (§ 170.314(e)(1)). Commenters did, however, express support for keeping the privacy and security certification criteria in the Base EHR definition.

Commenters suggested that certification for privacy and security should be consistent across both ambulatory and inpatient settings. Commenters did, however, express confusion over how privacy and security certification criteria correlated with other certification criteria included in the Base EHR definition as well as other certification criteria in general. In particular, commenters asked whether the privacy and security capabilities needed to integrate with the capabilities included in the other certification criteria that are part of the Base EHR definition. If such integration is not required, commenters suggested that we consider requiring integration certification, particularly where the capabilities do not share a common security architecture. One commenter asked for confirmation as to whether EPs, EHs, and CAHs bear the responsibility for appropriately implementing the privacy and security capabilities included in the Base EHR definition, including with other capabilities of their CEHRT they use to attempt to achieve MU.

Commenters expressed concern about the proposed CQM certification criteria included, or considered for inclusion, in the Base EHR definition. In response to our specific request for comment, many commenters strongly recommended that, as part of the Base EHR definition, we require certification to all CQMs by the setting the EHR technology is designed to meet. As an alternative approach, commenters suggested establishing a list of CQMs for certification by practice setting (e.g., cardiology, pediatrics, etc.) and that the list(s) be part of the Base EHR definition. One commenter suggested that the ''CQM reporting'' certification criterion (§ 170.314(c)(3)) be included in the Base EHR definition as a means of providing additional flexibility for those wishing to contain the measures within their local data warehouse infrastructure. Conversely, another commenter stated that not all EPs, EHs, and CAHs will need the CQM reporting capability and that it should not be a certification criterion that is part of the Base EHR definition.

Response. We appreciate the support expressed for the Base EHR definition. First, we would like to make clear that the Base EHR definition must be satisfied in order to meet the CEHRT definition. Stated another way, EPs, EHs, and CAHs should treat the Base EHR definition like a checklist. In order to ultimately have EHR technology that meets the CEHRT definition, an EP, EH, or CAH must ensure that the EHR technology it has first meets the Base EHR definition. We also want to make clear that the Base EHR definition is not meant to convey our expectation that EHR technology must be separately certified as ''a Base EHR.'' Nor should it be interpreted to mean that EHR technology presented for certification *must* include all the certification criteria included in the Base EHR definition. Rather, similar to the revised CEHRT definition, the Base EHR definition can be satisfied through a number of ways: (1) A certified Complete EHR; (2) a single certified EHR Module; (3) a combination of separately certified EHR Modules; or (4) a combination of 1 through 3.

As stated above and in the Proposed Rule, we believe that the Base EHR

definition should include the fundamental capabilities that any EP, EH, or CAH must have to demonstrate MU. Therefore, we are revising the proposed Base EHR definition to be more consistent with this approach.

First, we agree with commenters that certain certification criteria should be removed from the Base EHR definition. In particular, we have removed the certification criteria for ''vital signs'' (§ 170.314(a)(4)), ''drug-drug, drug-allergy interaction check'' (§ 170.314(a)(2)), and ''view, download, and transmit to 3rd party'' (§ 170.314(e)(1)). The capabilities specified by these three certification criteria are not necessarily needed by all EPs, EHs, and CAHs to support their achievement of MU.

Second, based on public comments, we have added one new certification criterion to the Base EHR definition. In response to our request for comments in the Proposed Rule and as discussed in section III.A.8 of this preamble, we received overwhelming feedback from EPs, EHs, and CAHs recommending that steps be taken to improve data portability. In response, we have adopted an initial data portability certification criterion and have included it in the Base EHR definition. We believe this initial data portability certification criterion directly aligns with the statutory capacity specified in the PHSA ''Qualified EHR'' definition ''to exchange electronic health information with, and integrate such information from other sources.'' We believe that by including this certification criterion in the Base EHR definition it will provide EPs, EHs, and CAHs with a mechanism to potentially expedite and enhance the migration of data from one EHR technology to another.

As noted above, the capabilities to capture (§ 170.314(c)(1)) and calculate (§ 170.314(c)(2)) CQMs remain part of the Base EHR definition. The ability to capture information relevant to health care quality aligns with statutory requirements for the Base EHR definition and we believe the ability to calculate CQMs through EHR technology is a fundamental capability all EPs, EHs, and CAHs should have to support their achievement of MU and their own continuous quality improvement. We have also amended our proposed Base EHR definition to require certification to no fewer than the minimum number of CQMs that an EP, EH, or CAH must report under the EHR Incentive Programs beginning in FY/CY 2014. Additionally, in light of the fact that CMS identified for EPs a subset of CQMs as a ''recommended core,'' we are separately requiring that to meet the Base EHR definition EPs must have EHR technology that has been certified to § 170.314(c)(1) and § 170.314(c)(2) for at least 6 CQMs from the ''recommended core.'' This final rule provision is meant to complement CMS' reporting requirements. We included this additional provision to support and highlight the ''recommended core'' CQMs prioritized by CMS. Further, we believe that by including this requirement in the Base EHR definition, EHR technology developers will seek to be certified to those ''recommended core'' CQMs that are most relevant to their customer base. As a result, EPs will then have the ability to report on some portion of the ''recommended core'' CQMs in support of CMS' CQM policy priorities.

In order for an EP to have EHR technology that meets the Base EHR definition, he or she would need to have EHR technology certified to § 170.314(c)(1) and § 170.314(c)(2) for no fewer than 9 CQMs that in total cover at least 3 domains and include at least 6 CQMs from the recommended ''core set'' for adult and pediatric populations as identified in the Stage 2 final rule published elsewhere in this issue of the **Federal Register**. In other words, of the minimum of 9 CQMs necessary to meet the Base EHR definition, at least 6 CQMs must be from the recommended core set identified by CMS, and altogether the 9 CQMs must cover at least 3 domains. In support of the Million Hearts [39] initiative, we strongly urge EHR technology developers that serve customers for which NQF 0018 (Controlling High Blood Pressure) and NQF 0028 (Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention) would be applicable to include these two CQMs as part of the 6 recommended core set CQMs selected for certification. These two CQMs support this HHS priority and will be broadly leveraged through many Federal quality measurement programs.

Similarly, in order for an EH or CAH to have EHR technology that meets the Base EHR definition, it would need to have EHR technology certified to § 170.314(c)(1) and § 170.314(c)(2) for no fewer than 16 CQMs that cover at least 3 domains as identified in the Stage 2 final rule published elsewhere in this issue of the **Federal Register**. Additionally, by setting this minimum requirement, EHR technology developers will now need to ensure that their EHR technology includes the appropriate amount of CQMs if they seek to market their EHR technology as meeting the Base EHR definition.

We decline to establish a list of CQMs by practice specialty for certification. Considering the evolving nature of CQM specification and development, the applicability and availability of CQMs for different scopes of practice, and the varied customer bases of EHR technology developers, we believe that this option would be both infeasible and impractical at the present time. We also decline to include as part of the Base EHR definition, even for the inpatient setting, a requirement that EHR technology must be certified to all of the CQMs selected by CMS for the EHR Incentive Programs because of instances where this type of policy approach would require EPs (because of scope of practice) and EHs and CAHs (e.g., children's hospitals and hospitals without an emergency department) to have EHR technology certified for CQMs on which they would have no information relevant to health quality to report. We believe the policy we have established minimizes this type of situation from occurring. It also seeks to balance the potential burden faced by EHR technology developers to include and get their EHR technology certified to CQMs on which their customers would not necessarily have information relevant to health quality to report. We acknowledge that EHR technology developers get to choose the CQMs to which their EHR technology is certified and that those CQMs may not necessarily meet the needs of every EP, EH or CAH. We continue to believe, however, that EHR technology developers will be cognizant of their customers' needs and will in most cases select CQMs for certification that can broadly support their customer base. EPs, EHs, and CAHs can also consult the CMS MU Stage 2 final rule to determine whether the EHR technology they intend to purchase has the necessary CQM capabilities. Last, we have included in the Base EHR definition the capability to electronically submit CQMs as specified by the certification criterion at § 170.314(c)(3). As noted under the discussion of CQM submission earlier in this preamble, EHR technology certified to § 170.314(c)(3) is required to enable the electronic submission of CQM data to CMS according to adopted standards. We believe that this capability will be useful to all EPs, EHs, and CAHs because it is now structured to support the electronic submission of CQMs for MU or as applicable under PQRS. Accordingly, we believe that it is appropriate and beneficial to include

[39] *http://millionhearts.hhs.gov/index.html.*

this capability and certification criterion in the Base EHR definition.

Last, we decline to expand the Base EHR definition beyond those capabilities already proposed and the one addition we discuss above because requiring the additional capabilities and certification criteria suggested by some commenters would be inconsistent with our stated approach of only requiring in the Base EHR definition capabilities that are as universally applicable as possible.

With these revisions to the proposed Base EHR definition, we now limit the definition to those certification criteria that most closely align with the capacities specified in the definition of a ''Qualified EHR'' under section 3000(13) of the PHSA and, as supported by commenters, improve data portability and protect the confidentiality, integrity and availability of patient health information. We see this as the most appropriate starting point from which to potentially expand (as necessary) the Base EHR definition in future rulemakings. Furthermore, this modified Base EHR definition gives EPs, EHs, and CAHs even more flexibility than we had proposed and could potentially further reduce CEHRT adoption costs.

We agree with commenters that, as proposed, certification for privacy and security should be consistent across both ambulatory and inpatient settings. The privacy and security certification criteria included in the Base EHR definition are designed to provide EPs, EHs, and CAHs with basic technical capabilities that can support compliance with parts of the HIPAA Privacy and Security Rules. As we stated in the Proposed Rule, EPs, EHs, and CAHs are responsible for implementing their CEHRT in ways that meet applicable privacy and security requirements under Federal law (such as the HIPAA Privacy Rule and Security Rule and 42 CFR Part 2) and applicable state law. The Base EHR definition gives EPs, EHs, and CAHs the flexibility to implement and combine EHR technology capabilities (particularly those capabilities used for MU) in their healthcare environment in ways that they determine are the most functional (e.g., with various different certified EHR Modules), efficient, and cost effective.

''Integration certification'' is not currently part of the temporary certification program nor is it included in the ONC HIT Certification Program. We responded to similar comments in a prior rulemaking (76 FR 1273) that integration certification was impractical because of technical and logistical concerns (e.g., the integrated healthcare environment of a hospital) as well as financial costs (e.g., bringing certified EHR Modules from different EHR technology developers together for additional certification after being separately certified). For these reasons, we continue to believe that such certification should not be part of the ONC HIT Certification Program at this time, even for only privacy and security. We reiterate, however, our position stated in the Permanent Certification Program final rule (76 FR 1273) that nothing precludes an ONC–ACB or other entity from offering a service to certify EHR Module-to-EHR Module integration. To be clear, although we do not require or specifically preclude an ONC–ACB from certifying EHR Module-to-EHR Module integration, any EHR Module-to-EHR Module certification performed by an ONC–ACB or other entity will be done without specific authorization from the National Coordinator and will not be considered part of the ONC HIT Certification Program.

The Base EHR definition is included at § 170.102 and has been revised to remove the certification criteria referenced in the discussion above, to add in a minimum number of CQMs for the ambulatory and inpatient settings, and to add the certification criterion at § 170.314(c)(3). Table 6 below specifies the 2014 Edition EHR certification criteria included in the Base EHR definition and the Base EHR capacities they support. To note, as mentioned under section III.B.1 ''Revisions to the Definition of Certified EHR Technology,'' the Base EHR definition will now be one part of an optional means for meeting the definition of CEHRT for any FY or CY up to and including 2013.

TABLE 6—CERTIFICATION CRITERIA REQUIRED TO SATISFY THE BASE EHR DEFINITION

EHR technology that:	Certification criteria
Includes patient demographic and clinical health information, such as medical history and problem lists.	Demographics § 170.314(a)(3). Problem List § 170.314(a)(5). Medication List § 170.314(a)(6). Medication Allergy List § 170.314(a)(7)
Has the capacity to provide clinical decision support	Clinical Decision Support § 170.314(a)(8).
Has the capacity to support physician order entry	Computerized Provider Order Entry § 170.314(a)(1).
Has the capacity to capture and query information relevant to health care quality.	Clinical Quality Measures § 170.314(c)(1) through (3).
Has the capacity to exchange electronic health information with, and integrate such information from other sources.	Transitions of Care § 170.314(b)(1) and (2) Data Portability § 170.314(b)(7).
Has the capacity to protect the confidentiality, integrity, and availability of health information stored and exchanged.	Privacy and Security § 170.314(d)(1) through (8).

3. Complete EHR Definition

We stated in the Proposed Rule that we intended to maintain the concept of a Complete EHR and permit EHR technology developers to seek Complete EHR certifications for their EHR technology. We proposed, however, to revise the Complete EHR definition for clarity to mean ''EHR technology that has been developed to meet, at a minimum, all mandatory certification criteria of an edition of certification criteria adopted by the Secretary for either an ambulatory setting or inpatient setting.''

Comments. We received a few comments expressing support for our proposed revised Complete EHR definition.

Response. We are revising our approach to the Complete EHR definition based on modifications we have made to the Base EHR definition and to clarify the applicability of the revised CEHRT definition for any FY or CY up to and including 2013 to a Complete EHR. In our proposal, a Complete EHR would have inherently met the Base EHR definition because it would have required certification to all the certification criteria included in the proposed Base EHR definition. We have, however, modified the Base EHR definition to require that EHR technology be certified to a minimum

number of CQMs per the ambulatory or inpatient setting in order to meet the Base EHR definition, which will require certification to § 170.314(c)(1) and (2) for more than one CQM. To ensure that a Complete EHR encompasses the Base EHR definition, we are establishing two separate Complete EHR definitions, one for the 2011 Edition EHR certification criteria and one for the 2014 Edition EHR certification criteria. As stated in the Proposed Rule, for certification to the 2011 Edition EHR certification criteria, a Complete EHR designed for an ambulatory setting must meet the mandatory certification criteria adopted at §§ 170.302 and 170.304, while a Complete EHR designed for an inpatient setting must meet the mandatory certification criteria adopted under §§ 170.302 and 170.306. For certification of a Complete EHR to the 2014 Edition EHR certification criteria, EHR technology must meet the Base EHR definition and all mandatory certification criteria for either the ambulatory or inpatient setting. Our addition of paragraph (d) to § 170.300 and the use of ''ambulatory setting only'' and ''inpatient setting only'' headings within § 170.314 clarifies which certification criteria have general applicability (apply to both ambulatory and inpatient settings) or apply only to an inpatient setting or an ambulatory setting. Additionally, we have made a guidance document available on our Web site that clearly specifies the 2014 Edition EHR certification criteria that apply to a Complete EHR designed for the ambulatory setting and a Complete EHR designed for an inpatient setting.

Our revised CEHRT definition for any FY or CY up to and including 2013 states that a Complete EHR meets the definition if it ''meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria *or* the equivalent 2014 Edition EHR certification criteria.'' We want to make clear that, although the ''equivalency option'' permits EPs, EHs, and CAHs to use a combination of EHR technology certified to the 2011 Edition and 2014 Edition EHR certification criteria to meet the revised CEHRT definition, a certification *cannot* be issued for a Complete EHR based on a combination of 2011 Edition and 2014 Edition EHR certification criteria. This would be inconsistent with how we described a Complete EHR in the Proposed Rule and with our ''representation requirement'' for Complete EHRs and EHR Modules certified under the ONC HIT Certification Program at § 170.523(k)(1)(i) (i.e., 2011 Edition or 2014 Edition compliant). Further, we believe a Complete EHR certified to a combination of 2011 Edition and 2014 Edition EHR certification criteria would cause confusion for EPs, EHs, and CAHs, particularly when transitioning to meet the CEHRT definition for FY/CY 2014 and subsequent years, which only permits EPs, EHs, and CAHs to use of EHR technology certified to the 2014 Edition EHR certification criteria to meet the definition. Accordingly, we are replacing the Complete EHR definition at § 170.102 with the 2011 Edition Complete EHR definition described above and adding the 2014 Edition Complete EHR definition also as described above.

4. Certifications Issued for Complete EHRs and EHR Modules

We restated frequently asked question (FAQ) 9–10–005–1 [40] and its supporting policy rationale in the Proposed Rule. FAQ 9–10–005–1 clarifies that a stand-alone, separate component of a certified Complete EHR cannot derive ''certified'' status based solely on it having been included as part of the Complete EHR when the Complete EHR was certified. We noted that this same principle applies to certified EHR Modules with multiple capabilities in that the components of the EHR Modules cannot be separately sold or purchased as certified EHR technology unless they have been separately certified.

Comments. We received two comments that supported our policy and a comment that criticized it. The commenter that offered criticism stated that EHR technology developers have been inclined to only get their EHR technology certified as Complete EHRs and have not obtained certification for their EHR technologies in the form of EHR Modules that would best benefit EPs, EHs, and CAHs. The commenter stated that as a consequence, EPs, EHs, and CAHs must possess more EHR technology than they need or want from a particular EHR technology developer. The commenter further stated that the option of EHR technology self-developer certification to address such situations was not a viable option because of the costs and complexity to pursue such an approach was too daunting for most EPs, EHs, and CAHs. The commenter suggested that as an alternative that we require that every Complete EHR presented for certification also be certified as individual EHR Modules.

Response. After consideration of the comments received, we reaffirm our policy incorporated in FAQ 9–10–005–1. We believe that allowing separate components of a certified Complete EHR or certified EHR Module to derive ''certified'' status from the certification of the entire certified Complete EHR or certified EHR Module would undermine the purpose of the ONC HIT Certification Program. As stated in the Proposed Rule, it would permit EHR technology developers to ''*self-declare*'' certifications for components of a certified Complete EHR or certified EHR Module that have never been independently reviewed by an ONC–ACB as actually being able to work as separate, independent technologies. This approach could result in inaccurate, deceptive, or false representations about an EHR technology's capabilities. Furthermore, it is important for all stakeholders to recognize that a certification is assigned to a Complete EHR or EHR Module, not to a capability. And, as we look forward towards the development and introduction of combined and/or workflow-based test procedures, one would be unable to infer that a specific component of a certified Complete EHR or certified EHR Module was compliant with a particular certification criterion unless the component had been separately certified as performing the required capability.

In regard to the commenter's specific suggestion that we require Complete EHR technology developers to have their Complete EHR also certified as EHR Modules, we reiterate that, in accordance with PHSA section 3001(c)(5), the act of seeking certification is voluntary. More importantly, in some cases it may not be practicable (from an EHR technology design and functionality perspective or financially or otherwise) for an EHR technology developer to seek separate certifications for its EHR technology (Complete EHR or EHR Module) as a more limited EHR Module or even in a manner that meets the needs of a particular EP, EH, or CAH. Further, we question whether such an approach could be equitably operationalized. There does not readily appear to be an objective, non-arbitrary and practical way to identify the make-up of each potentially smaller EHR Module that would need to be certified from a Complete EHR or large EHR Module. With these considerations in mind, we strongly encourage EHR technology developers to seek, where possible,

[40] *http://healthit.hhs.gov/portal/server.pt/community/onc_regulations_faqs/3163/faq_5/20767.*

certification for separate components of a certified Complete EHR or certified EHR Module that would provide the solutions that EPs, EHs, and CAHs seek to adopt. Additionally, from a practical perspective, we believe our more flexible CEHRT definition will spur EHR technology developers to move in this direction at a much more rapid pace.

5. Adaptations of Certified Complete EHRs or Certified EHR Modules

We stated in the Proposed Rule that it would be possible for an EHR technology developer of a certified Complete EHR or certified EHR Module (and only that EHR technology developer) to create an adaptation of a certified Complete EHR or certified EHR Module without the need for additional certification of the adaptation. We went on to say that we consider an ''adaptation'' of a certified Complete EHR or certified EHR Module to be a software application designed to run on a different medium, which includes the exact same capability or capabilities included in the certified Complete EHR or certified EHR Module. As an example, we indicated that an adaptation of a certified Complete EHR that is capable of running on a tablet device or smart phone could include the capabilities of a certified Complete EHR to e-prescribe, take electronic notes, and manage a patient's active medication list. In this example, we specified that the adaptation would be covered by the Complete EHR's certification so long as the adaptation included the full and exact same capabilities required for the particular certification criteria to which the Complete EHR was certified (i.e., in this case, the capabilities required by the certification criteria proposed at § 170.314(b)(3), (a)(9), and (a)(6), respectively)). We noted that the user of the adaptation would need to ensure, perhaps through contractual assurances from the EHR technology developer that provides such adaptation, that the adaptation does not introduce privacy and security vulnerabilities into the certified Complete EHR or certified EHR Module. We further noted that, while an EHR technology developer may create an adaptation without needing to obtain an additional certification, the adaptation would be subject to the provisions of the certification issued for the Complete EHR or EHR Module. ONC–ATCBs and ONC–ACBs maintain authority over the certifications that they issue and can take appropriate action when there is evidence of non-conformance with those certifications.

Comments. Many commenters supported our approach to adaptations. Some commenters did not, however, support extending a Complete EHR's or EHR Module's certification to adaptations without further evaluation by ONC–ACBs. These commenters expressed concern about an adaptation's privacy and security capabilities, noting that such capabilities will be fundamentally different from device to device. Commenters also requested that we further clarify the term ''full and exact same capabilities.'' Some commenters suggested a strict interpretation of the term so that EPs, EHs, and CAHs could be confident that their adapted EHR technology performs and interoperates as seamlessly as the certified Complete EHR or certified EHR Module. Last, commenters inquired about how this process would be monitored. For example, commenters asked whether EHR technology developers needed to seek formal inclusion of adaptations in their original certification and/or attest that the adaptation has the ''exact same capabilities'' as the certified Complete EHR or certified EHR Module.

Response. We are implementing our adaptation policy as explained in the Proposed Rule and supplemented by the additional guidance provided here in this final rule. As noted in the Proposed Rule, we believe adaptations can serve as innovative ways to facilitate efficient workflows and user interactions. While we believe our example recited above and in the Proposed Rule specifies what constitutes ''full and exact same capabilities,'' we provide the following as additional clarification. In order for a software application to be treated as an adaptation (and not as a unique, stand-alone EHR Module or Complete EHR for which a separate certification would be required) it must include the full and exact same capabilities required by the certification criteria to which the EHR technology it is serving as an adaptation of was certified. Stated another way, an adaptation cannot partially address the capabilities required by a certification criterion. To illustrate this simply, an adaptation of a certified Complete EHR would need to enable a user to record all of the demographics specified at § 170.314(a)(3) and would not be in compliance with this policy if it only provided a user the ability to record a patient's race and ethnicity. Further, we acknowledge that adaptations will naturally require the certified Complete EHR or certified EHR Module's user interface and other design features to be changed in order to perform efficiently on mobile platforms. Again, our concern is that the capabilities included in the adaptation and available to a user are a one-for-one match with the capabilities that have been adapted from the certified Complete EHR or certified EHR Module. In other words, an adaptation may include less overall capabilities than the certified Complete EHR or certified EHR Module, but for those capabilities it does include they must be the full and exact same capabilities for which certification is required. For example, it would be acceptable for an adaptation to include the full and exact same capabilities specified by 3 of the 10 certification criteria to which an EHR Module was certified.

We appreciate the concerns expressed by commenters related to privacy and security, but remind commenters of certification's limitations. Certification is not a substitute for, or guarantee of, compliance with the HIPAA Privacy and Security Rules. Certification is designed to provide EPs, EHs, and CAHs with basic technical capabilities that can support compliance with parts of the HIPAA Privacy and Security Rules. EPs, EHs, and CAHs remain responsible for implementing their CEHRT in ways that meet applicable privacy and security requirements under Federal law (such as the HIPAA Privacy Rule and Security Rule and 42 CFR Part 2) and applicable state law. We would expect that EHR technology developers would include the relevant privacy and security capabilities in their adaptations where appropriate. For example, we would expect that an adaptation designed to run on a mobile device would employ authentication, access control, and authorization capabilities consistent with those specified in the certification criterion adopted at § 170.314(d)(1). Similarly, we could see scenarios where electronic health information used or processed by an adaptation could be protected in accordance with the ''end-user device encryption'' certification criterion adopted at § 170.314(d)(7)(i). As noted above and in the Proposed Rule, an EP, EH, or CAH should take steps to ensure, perhaps through contractual assurances from the EHR technology developer that provides such adaptation, that privacy and security capabilities are implemented appropriately and that the adaptation does not introduce privacy and security vulnerabilities into the certified Complete EHR or certified EHR Module. An EP, EH, and CAH should also take independent steps, or again through contractual assurances from the EHR technology developer that provides such adaptation, to address any privacy and security vulnerabilities that may be introduced by the different medium(s) on which the adaptation runs.

An adaptation would need to be based on an already certified Complete EHR or certified EHR Module in order to be treated as being part of the certification issued to these EHR technologies. In this regard, an EHR technology developer would not need to obtain an additional certification for an adaptation nor have to attest to the functionality, capabilities, or otherwise for an adaptation. We believe that contractual relationships with customers and compliance with certifications issued by ONC–ATCBs and ONC–ACBs should be sufficient measures to ensure the integrity of adaptations, while eliminating the burden and costs of certification and attestation on EHR technology vendors and their customers (EPs, EHs, and CAHs). EPs, EHs, and CAHs should take note that absent an EHR technology developer actively seeking a separate certification for an adaptation (which would not be required under our policy), the adaptation itself would not be independently listed on the CHPL because it is considered part of the certification of a previously certified Complete EHR or certified EHR Module. Thus, an EP, EH, and CAH would need to select as part of its attestation process the certified Complete EHR or certified EHR Module from which the adaptation was created. Last, we seek to make clear that an EHR technology developer can always seek certification for its adaptation. Certification of the adaptation would lead to its listing on the CHPL and would permit the EHR technology developer to openly sell the adaptation to all potential purchasers since it would be separately certified.

IV. Provisions of the Proposed Rule Affecting the Permanent Certification Program for HIT (''ONC HIT Certification Program'')

A. Program Name Change

As explained in the Proposed Rule, we have established two certification programs, the ''temporary certification program for HIT'' and the ''permanent certification program for HIT'' (see 75 FR 36158 and 76 FR 1262, respectively). We noted in the Proposed Rule that we expected that the permanent certification program would replace the temporary certification program upon the effective date of this final rule. As we discussed, at that time, there would no longer be a need to continue to differentiate between the certification programs based on their expected duration. Therefore, we proposed to replace all references in Part 170 of the Code of Federal Regulations to the permanent certification program with ''ONC HIT Certification Program.''

Comments. A few comments expressed agreement with our proposal to change the program name. A commenter noted that having two names was somewhat confusing and that shifting to one name would be desirable.

Response. We thank these commenters for their support and have finalized our proposal. We are revising subpart E of Part 170, Title 45, Subtitle A, Subchapter D of the Code of Federal Regulations to replace all references to the ''permanent certification program'' with ''ONC HIT Certification Program.'' We believe this new program name provides clear attribution to the agency responsible for the program and an appropriate description of the program's scope, covering both current and future HIT certification activities. We also note that, as we indicated in the Proposed Rule and in our notice published in the **Federal Register** on November 3, 2011 (76 FR 68192), the temporary certification program will officially sunset upon the effective date of this final rule and will be replaced with the ONC HIT Certification Program. When the temporary certification program sunsets, ONC–Authorized Testing and Certification Bodies (ONC–ATCBs) will be prohibited from accepting new requests to test and certify EHR technology and will be permitted up to six months after the sunset date to complete all testing and certification activities associated with requests received prior to the sunset date. If these activities are not completed within the 6-month period, the EHR technology would have to be resubmitted for testing and certification under the ONC HIT Certification Program.

B. ''Minimum Standards'' Code Sets

In the Proposed Rule, we described the current process for the Secretary to identify and accept newer versions of ''minimum standards'' code sets. Section 170.555 allows ONC–ACBs to certify Complete EHRs and/or EHR Modules to newer versions of certain code sets identified as ''minimum standards'' in Subpart B of part 170 if the Secretary has accepted a newer version for certification and implementation of EHR technology. We explained that, based on our experience, newer versions of the ''minimum standards'' code sets that we have adopted are issued more frequently than our current process can reasonably accommodate. We also stated, based on the ''minimum standards'' code sets we have previously adopted and the ones proposed, that permitting EHR technology to be upgraded and certified to newer versions of these code sets would not normally pose an interoperability risk, cause unintended consequences, or place an undue burden on the HIT industry. Therefore, we proposed to revise § 170.555 such that, *unless* the Secretary prohibits the use of a newer version of a ''minimum standards'' code set identified in subpart B of part 170, the newer version could be used voluntarily for certification and implemented as an upgrade to a previously certified Complete EHR or EHR Module without adversely affecting the EHR technology's certified status. In consideration of this proposed new approach, we clarified that when we refer to a ''newer'' version of a ''minimum standard'' code set, we mean a final version or release as opposed to a draft version or release of a code set.

We outlined a process for determining when to prohibit the use of a newer version of a ''minimum standards'' code set that was similar to the process we used for accepting newer versions of ''minimum standards'' code sets. The public could inform ONC or the Secretary could proactively identify a newer version of a ''minimum standard'' code set that may not be appropriate for use. We indicated our expectation that we would still seek a recommendation from the HITSC, based on their assessment of the newer version and on any public comments that they receive, as to whether the Secretary should prohibit the use of the newer version of the ''minimum standard'' code set. After considering the HITSC's recommendation, the National Coordinator would make a recommendation to the Secretary as to whether or not to allow the continued use of the newer version. Finally, if the Secretary decides to prohibit the use of a newer version of a minimum standard code set, we stated that we would issue guidance indicating that the newer version of the adopted ''minimum standards'' code set cannot be used for certification under the ONC HIT Certification Program, and thus upgrading previously certified Complete EHRs and EHR Modules to the newer version would adversely affect their certified status.

As an exception to the process outlined above, we specified that, in limited circumstances, it may be necessary for the Secretary to act more quickly to prohibit the use of a newer version of a ''minimum standards'' code set. Instances could arise where the use of a newer version of a ''minimum standards'' code set may have an immediate negative effect on

interoperability, cause an obvious unintended consequence, or pose an undue burden on the HIT industry. Therefore, under such circumstances, we specified that the Secretary may choose to prohibit the use of a newer version of a ''minimum standards'' code set for purposes of certification and upgrading certified EHR technology without seeking a recommendation from the HITSC in advance.

To provide additional clarity and consistency, we proposed to also make minor revisions to the text of § 170.555, including removing the terms ''adopted'' and ''accepted'' and replacing the term ''Certified EHR Technology'' in § 170.555(b)(2) with ''A certified Complete EHR or certified EHR Module.''

Comments. Most commenters supported our proposal to revise the process for permitting the use of new versions of ''minimum standards'' code sets. Several commenters commended our proposed approach and indicated it would reduce regulatory complexity and burden by providing the industry with the flexibility to quickly utilize newer versions of adopted ''minimum standards'' code sets. A few of the commenters that agreed also expressed concern that it may be difficult for EPs, EHs, and CAHs to reconcile different code set releases if one EHR technology developer rolls them out faster than another. A few other commenters recommended that we should require backward compatibility as a condition for Secretary acceptance of newer versions of code sets. These commenters stated this would serve as a means of mitigating the challenges associated with different code set releases. A couple of commenters also recommended that providing technical support for previous versions should be a condition of certification of EHR technology to newer versions of ''minimum standards'' code sets. One commenter specifically suggested that support for the previous version be offered for at least 12 to 18 months unless otherwise abandoned due to extenuating circumstances (e.g., security or patient safety concerns). One commenter suggested that when a newer version release is available and accepted by the Secretary (with or without a recommendation from the HITSC) that there be a period of 180 days when vendors may test to either the previous or newer versions of the standard. Another commenter recommended that a regular and rational strategy be established to refresh the ''minimum standards'' called for in MU.

Response. We appreciate the comments submitted in support of our proposal and are revising § 170.555 such that, *unless* the Secretary prohibits the use of a newer version of a ''minimum standards'' code set identified in subpart B of part 170, the newer version could be used *voluntarily* for certification and implemented as an upgrade to a previously certified Complete EHR or certified EHR Module without adversely affecting the EHR technology's certified status. We believe this approach reduces regulatory complexity and provides the industry with the flexibility to utilize newer versions of adopted ''minimum standards'' code sets without regulatory interference. We are also finalizing our proposal to make the minor text changes to § 170.555, as well as the process we outlined in the Proposed Rule for determining when to prohibit the use of a newer version of a ''minimum standards'' code set and the exception to that process.

With respect to the comments regarding the additional condition of certification for technical support, timing for when new versions of the code sets are released, and a schedule to refresh the ''minimum standards'' that would be required as part of MU, we believe that these commenters may have misinterpreted the flexibility and approach offered by our proposal and the way in which newer versions of ''minimum standards'' code sets would be treated by the final rule. Therefore, we offer this additional explanation. In general, we understand that the code sets we have identified as ''minimum standards'' code sets are frequently updated to keep pace with industry needs. For example, when a new medication becomes available, a new code for that medication would be added to the next release of RxNorm. As finalized, our revision to § 170.555 permits an EHR technology developer to, for example, immediately include that newer version of RxNorm when presenting its Complete EHR or EHR Module for certification rather than having to use the older version adopted in the Code of Federal Regulations in order to get certified. As we explained, inclusion of the newer version would be voluntary, and the developer would still have the option for its EHR technology to be certified to the version specified in regulation. It also permits certified Complete EHRs and certified EHR Modules to be voluntarily upgraded to these newer versions without adversely affecting the EHR technology's certified status. With respect to comments about EPs, EHs, and CAHs reconciling different releases and requiring backwards compatibility, we do not believe that these are acute concerns with respect to the code sets we have designated as ''minimum standards'' code sets because newer releases should subsume or include the codes that were in a prior version (subject to the natural retirement/deprecation of no longer useful codes). As stated in the Proposed Rule, based on the ''minimum standards'' code sets we have previously adopted and proposed, we believe that permitting EHR technology to be upgraded and certified to newer versions of these code sets would not normally pose an interoperability risk, cause unintended consequences, or place an undue burden on the HIT industry. In limited circumstances where the use of newer versions of a ''minimum standards'' code set may have an immediate negative effect, we can use the process we described above for the Secretary to prohibit the use of a newer version of a ''minimum standards'' code set for purposes of certification and upgrading certified Complete EHRs and certified EHR Modules. Accordingly, we do not believe that it is necessary to establish a backwards compatibility condition for ''minimum standards'' code sets as suggested. Further, we believe that the process we have in place for prohibiting the use of newer versions will mitigate any potential adverse affect for EPs, EHs, or CAHs should a major change to an adopted minimum standard occur. With respect to the comment about the refresh cycles for ''minimum standards'' code sets, we intend to make such updates as part of the normal rulemaking cycle that we engage in to adopt new certification criteria editions. Thus, we expect that regulatory updates to newer versions of ''minimum standards'' code sets will be on predictable schedule.

C. Revisions to EHR Module Certification Requirements

1. Privacy and Security Certification

In the Proposed Rule, we proposed that EPs, EHs, and CAHs must have EHR technology that meets the proposed Base EHR definition. The proposed Base EHR definition referenced all of the proposed privacy and security certification criteria at § 170.314(d) except the optional ''accounting of disclosure'' certification criterion at § 170.314(d)(9). Based on the policy expressed by the proposed Base EHR definition and stakeholder feedback received since the S&CC July 2010 final rule, we proposed to eliminate the current privacy and security certification requirements in § 170.550(e) for EHR Modules starting

with the 2014 Edition EHR certification criteria.

Comments. Several commenters supported our proposed revisions to EHR Module certification and expressed agreement that it would reduce regulatory burden and enable greater flexibility. A few commenters disagreed with our position and contended that we should continue our existing approach to the privacy and security certification of EHR Modules as specified in § 170.550(e) with the 2014 Edition EHR certification criteria. A couple of commenters expressed concern that our approach could lead to certain negative effects if, as a result of this proposed change, the EHR technology certified and used by an EP, EH, or CAH to satisfy the Base EHR definition could not be configured to also apply those privacy and security capabilities to other separately certified EHR Modules an EP, EH, or CAH may choose to implement. Along those lines, some commenters requested greater clarity regarding our proposed EHR Module certification change and how it interacts with the Base EHR definition. One commenter suggested that if ONC finalizes this proposal that we should evaluate its effect to determine if additional requirements would subsequently be necessary. Another commenter recommended that remote components providing services to a Complete EHR or EHR Module should be secured with Transport Layer Security (TLS) and should not be required to be separately certified to the privacy and security requirements.

Response. In consideration of comments received, we are revising § 170.550(e) as proposed. Upon this final rule's effective date, EHR Modules presented for certification to the 2014 Edition EHR certification criteria will not be required to be certified to the privacy and security certification criteria adopted at § 170.314(d). We continue to believe, as echoed by many commenters, that our proposed change would reduce regulatory burden on EHR technology developers and the potential for EPs, EHs, and CAHs to purchase EHR Modules that have redundant or conflicting privacy and security capabilities.

With respect to the concern identified by some commenters, we reiterate what we stated in the Proposed Rule. EPs, EHs, and CAHs ultimately remain responsible for implementing their EHR technology in ways that meet applicable privacy and security requirements under Federal and applicable state law (e.g., the HIPAA Privacy Rule and Security Rule and 42 CFR Part 2). Certification is in no way a substitute or proxy for compliance with these legal requirements. Per the commenters' scenario and the other request for greater clarification on the Base EHR definition, we acknowledge it could be possible for an EP, EH, or CAH to adopt, for example, a certified EHR Module (certified EHR Module #1) that satisfies the Base EHR definition as well as other certified EHR Modules, and that those other certified EHR Modules might not be able to utilize or leverage the privacy and security capabilities included in certified EHR Module #1. Therefore, we strongly encourage EPs, EHs, and CAHs (presumably as they would with any other EHR technology necessary to meet MU or not) to carefully evaluate as part of their ongoing risk analysis processes whether the implementation of an additional separate certified EHR Module could pose new risks to privacy and security. As suggested by these commenters, we intend to monitor the effects of these changes to determine whether alternative requirements would be necessary as part of future rulemaking. For a more detailed discussion of the Base EHR definition, its requirements and relationship to CEHRT and certified EHR Modules, and our response to comments, we refer readers to section III.B.2 of this final rule. Finally, with respect to the commenter's two-part recommendation related to remote components providing services to a certified Complete EHR or certified EHR Module, we find the commenter's scenario and limited description of a ''remote component'' too ambiguous to issue a definitive response. In the Proposed Rule, we proposed that EHR technology presented for certification as an EHR Module would no longer need to be separately certified to the adopted privacy and security criteria—a proposal we have finalized. In general, we agree that TLS could be an appropriate standard in this situation, but, again, do not believe that the commenter provided sufficient detail on which to respond.

2. Certification to Certain New Certification Criteria

We proposed to revise § 170.550 to ensure certification of EHR Modules to the following 2014 Edition EHR certification criteria, as applicable: (1) Electronic recording of the numerator for each MU objective with a percentage-based measure (§ 170.314(g)(1) ''automated numerator recording''); (2) electronic recording of activities related to non-percentage-based measures (§ 170.314(g)(3) ''non-percentage-based measure use report''); and (3) user-centered design processes to be applied to EHR technology that includes certain capabilities (§ 170.314(g)(4) ''safety-enhanced design''). More specifically, we proposed to revise § 170.550 to ensure that EHR Modules that are presented for certification to certification criteria that include capabilities for supporting a MU objective with a percentage-based measure are certified to § 170.314(g)(1). However, we also proposed that this requirement would not apply if the EHR Module was certified to § 170.314(g)(2) ''automated measure calculation'' in lieu of certification to § 170.314(g)(1). We proposed to revise § 170.550 to ensure that EHR Modules that are presented for certification to certification criteria that include capabilities for supporting an MU objective with a non-percentage-based measure are certified to § 170.314(g)(3). Last, we proposed to revise § 170.550 to ensure that EHR Modules that are presented for certification to any of the certification criteria listed in proposed § 170.314(g)(4) are also certified to § 170.314(g)(4). We proposed to include these revisions at § 170.550(f).

Comments. We received a few comments expressing support for requiring certification to these certification criteria.

Response. We appreciate the support expressed by commenters and are finalizing our proposals to have ONC–ACBs ensure EHR Modules are certified to these certification criteria, except for our proposal concerning the ''non-percentage-based measure use report'' certification criterion at § 170.314(g)(3). As discussed earlier in this preamble, we are not finalizing the proposed ''non-percentage-based measure use report'' certification criterion as part of the 2014 Edition EHR certification criteria. Therefore, ONC–ACBs would not need to ensure that EHR Modules were certified to the certification criterion. We also note that, because we are not finalizing the proposed ''non-percentage-based measure use report'' certification criterion, we have re-designated the ''safety-enhanced design'' certification criterion to § 170.314(g)(3).

After consideration of comments received on our proposal to adopt a certification criterion related to quality management processes for EHR technology, we have adopted a ''quality management system'' certification criterion at § 170.314(g)(4). This certification criterion applies to all EHR technology certified to the 2014 Edition EHR certification criteria. Therefore, to ensure ONC–ACBs certify all EHR Modules presented for certification to the 2014 Edition EHR certification

criteria to this new certification criterion, we have revised § 170.550(f) to require that EHR Modules are certified to § 170.314(g)(4).

D. ONC–ACB Reporting Requirements

We proposed to revise § 170.523(f) to require ONC–ACBs to include an additional data element in the data set they must provide to ONC for the Complete EHRs and/or EHR Modules they certify. Specifically, we proposed that an ONC–ACB would need to provide ONC a hyperlink for each Complete EHR and EHR Module it certifies that would enable the public to access the test results that the ONC–ACB used to certify the EHR technology. As with all of the other data ONC–ACBs are required to report to ONC about certified Complete EHRs and certified EHR Modules, we proposed to make the hyperlink available on the CHPL with the respective certified Complete EHR or certified EHR Module. As noted in the Proposed Rule, we expect that ONC–ACBs would ensure the functionality of the hyperlink for a minimum of five years consistent with § 170.523(g), unless a certified Complete EHR or certified EHR Module is removed from the CHPL. Under such circumstances, we stated that the ONC–ACB would no longer need to ensure the functionality of the hyperlink, although retention of the test results would be required.

Comments. Many commenters supported our proposal. Some commenters, however, opposed publicly posting test results. Commenters that supported our proposal stated that publicly posting the test results would improve transparency. Some of these same commenters also indicated that the public availability of test results would empower customers. Specifically, they stated that customers could review and compare the test results against expected performance as a way to troubleshoot any implementation challenges posed by a certified Complete EHR or certified EHR Module. Conversely, commenters that expressed opposition to publicly posting test results stated that doing so could compromise EHR technology developers' intellectual property rights. These commenters expressed concern about the publication of source code as well as the publication of copyrighted materials that may be present in testing screenshots. A few commenters also argued that there was little value in publicly posting test results because the true value for consumers was in knowing whether the EHR technology was certified. As alternatives to, or rationale against, publicly posting test results, commenters suggested that test results could be obtained by consumers (e.g., EPs, EHs, and CAHs) during purchase negotiations and that ONC could post information about the testing and certification processes in lieu of posting test results. Commenters also noted that a standardized format for test results does not currently exist under the temporary certification program and suggested that such a format was necessary for testing results to be equitably treated and for any analysis or comparison of test results.

Response. We have considered the comments received on this proposal. We strongly believe that transparency should be an integral component of the ONC HIT Certification Program. Transparency can provide for additional access to and scrutiny of the ONC HIT Certification Program as well as improve program performance and increase public confidence in the EHR technology certified under the program.

We believe that an appropriate balance can be struck that supports transparency, protects EHR technology developers' potential intellectual property rights, and provides testing results in a consistent and identifiable manner. We have finalized our proposal and will require that ONC–ACBs submit a hyperlink of the test results used to issue a certification to a Complete EHR or EHR Module, which can be accessed by the public. In light of the concern expressed by some commenters, we intend to provide guidance to ONC–ACBs regarding the test results information that should be excluded from the publicly accessible hyperlink they submit to ONC. As an example, we expect ONC–ACBs would exclude from the publicly available hyperlink any screenshots produced as part of the testing process. Although we do not anticipate that source code would be visible in a test result report, if it is visible, we expect ONC–ACBs would exclude it from the information made available through the hyperlink. We would also expect any negative test results to be excluded from publicly posted test results because only passed test results would be necessary for obtaining certification of a Complete EHR or EHR Module from an ONC–ACB. We believe this should mitigate the concerns identified by commenters, and we will provide additional guidance to ONC–ACBs in the future if other unique circumstances not discussed here arise. We also intend, as suggested by commenters, to work closely with NVLAP to develop a standardized format for test results that can be used by all accredited testing laboratories and submitted to any ONC–ACB to be used for certification.

E. Continuation and Representation of Certified Status

1. 2011 or 2014 Edition EHR Certification Criteria Compliant

To align with our proposal to designate the certification criteria adopted in §§ 170.302, 170.304, and 170.306 collectively as the ''2011 Edition EHR certification criteria'' and to designate the certification criteria proposed in the Proposed Rule at § 170.314 as the ''2014 Edition EHR certification criteria,'' we proposed to revise § 170.523(k). The proposed revision to § 170.523(k) would require ONC–ACBs to ensure as part of certification that a developer of a Complete EHR or EHR Module would indicate in all marketing materials, communications, statements, and other assertions the certification criteria *edition* to which it had been certified rather than the compliance years the certification issued to the Complete EHR or EHR Module represented. We proposed that this revision would apply to all certifications issued after the effective date of this final rule.

As noted in the Proposed Rule, we considered multiple options to address certified Complete EHRs and certified EHR Modules already designated as ''2011/2012'' compliant and concluded that the best approach was to *not* require any changes to the ''2011/2012'' designation. Rather, we stated that we would simply make clear that certified Complete EHRs and certified EHR Modules that are designated as ''2011/2012 compliant'' would remain valid for purposes of the EHR reporting periods in FY/CY 2013. We requested public comment on this approach and any other approach that would present the least burden for EHR technology developers and the least confusion for the market.

We also proposed to revise § 170.523(k)(1)(i) by removing the following statement: ''* * * or guarantee the receipt of incentive payments'' because although incentives will be available under the Medicaid EHR Incentive Program until 2021, they will no longer be available under the Medicare EHR Incentive Program after 2016.

Comments. Commenters supported the concept of ''editions'' of certification criteria and stated that identifying EHR technology's compliance with editions of certification criteria would be less confusing than using multiple years as a means of identifying an EHR technology's certified status and validity.

Response. We thank the commenters for their support and are revising

§ 170.523(k) as proposed. When an ONC–ACB issues a certification it must require that the EHR technology developer include on its Web site(s) and in all marketing materials, communications, statements, and other assertions, the certification criteria *edition* to which the Complete EHR or EHR Module was certified. This revision applies to all certifications issued after the effective date of this final rule and means that EHR technology certified to the 2011 Edition EHR certification criteria will be designated as ''2011 Edition EHR certification criteria compliant'' and EHR technology certified to the 2014 Edition EHR certification criteria will be designated as ''2014 Edition EHR certification criteria compliant.'' We believe this revision will assist in eliminating confusion about the ''expiration'' of certifications, align with our revised definition of CEHRT, and provide the market with greater clarity regarding the capabilities certified Complete EHRs and certified EHR Modules include. As stated above and in the Proposed Rule, EHR technology that has already been designated as ''2011/2012 compliant'' does *not* need to be re-designated as ''2011 Edition EHR certification criteria complaint.'' Finally, consistent with our proposal, we are removing the statement: ''* * * or guarantee the receipt of incentive payments'' from § 170.523(k)(1)(i) to prevent confusion about the parameters of the EHR Incentive Programs.

2. Updating a Certification

To ensure that the information required by § 170.523(k)(1)(i) remains accurate and reflects the correct EHR certification criteria edition, ONC–ACBs, under § 170.550(d), are permitted to provide updated certifications to previously certified EHR Modules under certain circumstances. In the Permanent Certification Program final rule (76 FR 1306) and at § 170.502, we defined ''providing or provide an updated certification'' to an EHR Module as ''the action taken by an ONC–ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module(s).'' Based on our proposal in the Proposed Rule to no longer apply the privacy and security certification requirements at § 170.550(e) to EHR Modules certified to the proposed 2014 Edition EHR certification criteria, we proposed to revise the definition of ''providing or provide an updated certification'' at § 170.502. The proposed revised definition would eliminate the requirement that ONC–ACBs must verify whether any new privacy and security certification criteria apply when they issue an updated certification to an EHR Module.

We also noted in the Proposed Rule that the certification criteria and certification requirements that apply to previously certified EHR Modules may change with each new edition of certification criteria that is adopted by the Secretary. Therefore, we stated that we can provide the best guidance to stakeholders on when ''updating'' a certification would be permitted with each rulemaking for a certification criteria edition. For the 2014 Edition EHR certification criteria, we stated that if we were to adopt in a final rule the proposed certification criteria at § 170.314(g)(1) (automated numerator recording) and § 170.314(g)(3) (non-percentage-based measure use report), then no previously certified EHR Module could have its certification ''updated'' to the 2014 Edition EHR certification criteria because it would need to be certified to one of the above certification criteria (with the option of an EHR Module being certified to § 170.314(g)(2) in lieu of being certified to § 170.314(g)(1)).

Comments. We received no comments on this proposal.

Response. We are finalizing the proposed revisions to the definition ''providing or provide an updated certification'' at § 170.502. We also specify that ''updating'' an EHR Module's certification to the 2014 Edition EHR certification criteria will not be available. As noted previously in this preamble, we have adopted a ''quality management system'' certification criterion (§ 170.314(g)(4)) that applies to all EHR technology certified to the 2014 Edition EHR certification criteria. Therefore, when certifying EHR Modules to the 2014 Edition EHR certification criteria, ONC–ACBs must certify EHR Modules to this new certification criterion. Additionally, we have finalized the proposed new certification criteria ''automated numerator recording'' (§ 170.314(g)(1)) and ''safety-enhanced design'' (now designated as § 170.314(g)(3)). ONC–ACBs must also ensure that EHR Modules presented for certification to the 2014 Edition EHR certification criteria are, as applicable, certified to these new certification criteria. Consequently, an ONC–ACB may not issue ''updated'' certifications to previously certified EHR Modules for the 2014 Edition EHR certification criteria. As we noted in the Proposed Rule, ''updating'' a certification may still be a viable option under certain conditions when the Secretary adopts another edition of certification criteria in the future.

3. Representation of Meeting the Base EHR Definition

With respect to the Base EHR definition, we explained in the Proposed Rule that EPs, EHs, and CAHs would benefit from knowing which certified EHR technologies on the market meet the Base EHR definition because they would need to have EHR technology that meets the Base EHR definition to satisfy the proposed revised definition of CEHRT beginning with FY/CY 2014. We stated that it was unnecessary to expressly propose a requirement for ONC–ACBs to identify EHR technology that meets the Base EHR definition because EHR technology developers, in order to gain a competitive advantage in the market, would likely identify on their Web sites and in marketing materials, communications, statements, and other assertions whether their certified Complete EHR or certified EHR Module(s) also met the Base EHR definition (designed for either the ambulatory or inpatient setting). We did, however, consider (as a potential alternative and complementary approach) permitting ONC–ACBs when issuing certifications to Complete EHRs and EHR Modules that meet the Base EHR definition to formally indicate such fact to the EHR technology developer and permit the EHR technology developer in association with its EHR technology's certification to represent that the EHR technology meets the Base EHR definition. We requested public comment our approach and whether there was any other potential approach that we had not identified.

Comments. Many commenters supported the Base EHR concept and suggested that EHR technologies meeting the Base EHR definition should be listed as such, and searchable, on the Certified HIT Products List (CHPL). Commenters stated that specifically listing EHR technologies that meet the Base EHR definition on the CHPL would provide the most purchasing clarity for EPs, EHs, and CAHs. Some commenters also stated that leaving it up to the EHR technology developers to identify whether their EHR technologies met the Base EHR definition could be misleading to purchasers.

Response. We believe, as indicated in the Proposed Rule, that EHR technology

developers will be able to identify on their Web sites and in marketing materials, communications, statements, and other assertions whether their certified Complete EHR or certified EHR Module(s) meet the Base EHR definition (designed for either the ambulatory or inpatient setting). This will enable EHR technology developers to market the post-certification combination of multiple certified EHR Modules as meeting the Base EHR definition. We believe this is the best way to address situations where an EHR technology developer has EHR Modules certified at different times, but those EHR Modules together meet the Base EHR definition. This approach will also permit multiple affiliated EHR technology developers to market the post-certification combination of their certified EHR Modules if together they meet the Base EHR definition.

We do not believe that purchasers should be concerned about misleading practices related to the identification of certified Complete EHRs and certified EHR Modules as meeting the Base EHR definition. First, a certified Complete EHR by definition meets the Base EHR definition. Second, ONC–ACBs oversee the certifications they issue to Complete EHRs and EHR Modules. When ONC–ACBs are accredited, their conformance to ISO/IEC Guide 65:1996 (Guide 65) is verified. Section 14.3 of Guide 65 states that ''incorrect references to the certification system or misleading use of licenses, certificates or marks, found in advertisement, catalogues, etc., shall be dealt with by suitable action.'' Based on this provision, we are confident that any misleading practices by EHR technology developers as they relate to their certified EHR Modules will be dealt with appropriately by ONC–ACBs.

We understand the commenters' desire to have EHR technology listed on the CHPL designated as whether it meets the Base EHR definition. We believe, however, that it would be impractical and administratively burdensome to prospectively list or designate all EHR technologies that could be combined post-certification to meet the Base EHR definition. Rather, a more efficient and less burdensome approach will be to enable the CHPL Web site to identify whether EHR technologies selected from the CHPL meet the Base EHR definition. For example, if an EP, EH, or CAH selected on the CHPL EHR technology developer A's certified EHR Module and EHR technology developer B's certified EHR Module, we expect that the CHPL would be able to identify whether the certified EHR Modules together meet the Base EHR definition (i.e., have been certified to all of the certification criteria specified in the Base EHR definition and the requisite number of CQMs). This approach would permit EPs, EHs, and CAHs to determine whether they have EHR technology that meets the Base EHR definition and also limits inefficiencies and burdens associated with EHR technology developers having ONC–ACBs verify that their EHR technologies meet the Base EHR definition (potentially post certification), reporting this information to the CHPL, and/or having the CHPL attempt to prospectively identify all EHR technologies (and combinations) that meet the Base EHR definition.

F. EHR Technology Price Transparency

In response to stakeholder feedback, the Proposed Rule described our belief that the EHR technology marketplace could benefit from price transparency associated with certified Complete EHRs and certified EHR Modules. We further stated that price transparency could be achieved by requiring ONC–ACBs to ensure that EHR technology developers include clear pricing of the full cost to purchasers of their certified Complete EHR and/or certified EHR Module on their Web sites and in all marketing materials, communications, statements, and other assertions related to a Complete EHR's or EHR Module's certification. In other words, ONC–ACBs could require EHR technology developers to disclose a purchaser's full cost (a single price) for all of the capabilities for which certification was required and that were included in a certified Complete EHR or certified EHR Module. We noted in the Proposed Rule, however, that in no way would this requirement dictate the price an EHR technology developer could assign to its EHR technology. We requested comment on the feasibility and value of price transparency for certified Complete EHRs and certified EHR Modules in the manner described.

Comments. EHR technology developers and organizations representing EHR technology developers opposed this proposal. Providers and provider organizations supported the concept of price transparency, but not necessarily as proposed. Commenters questioned our proposed form of price transparency and stated that its anticipated value to purchasers was unclear because of the complexity and multiple costs associated with purchasing EHR technology. Alternatively, commenters stated that knowing a certified Complete EHR or certified EHR Module's ''total cost of ownership'' would be more valuable than just the price associated with the capabilities that the certification assigned to a Complete EHR or EHR Module represented. For commenters, total ownership costs included: Implementation costs (e.g., local implementation, subscription to an ASP, or web-based service); customization/configuration (e.g., configurations of interfaces); training; and maintenance. Commenters also suggested that price transparency should mean that, in a multiple EHR technology developer scenario, the amount paid to each EHR technology developer would be identified. Other commenters noted that our proposed price transparency approach added little benefit because EHR technology developers could offer a low initial cost for the acquisition of a certified Complete EHR or certified EHR Module and then charge additional costs for other essential components of total ownership, such as implementation. Commenters also pointed out that a single price could give a false impression of equality. They cited, for example, that two certified Complete EHRs may have the same price, but offer substantially different capabilities and services in addition to those capabilities for which certification is required.

Commenters stated that our proposal could hinder innovation and flexibility in product development, pricing, and market strategies. Some commenters stated, for example, that many products are not sold or licensed with only the capabilities for which certification is required and that our proposal could negatively alter current practices by confusing customers familiar with customary pricing and purchasing practices. A few commenters were also concerned about the proposal's impact on confidential, competitive and, some thought, proprietary marketing strategies. These commenters also noted that they were unaware of any other industry with the type of pricing dimensions and complexities as the HIT market and in which the Federal government required prices to be publicly available.

Commenters stated that it would be burdensome to include prices on all materials as proposed, particularly if prices change. A few EHR technology self-developers requested that we exempt them from the price transparency proposal because they would not be selling their certified Complete EHR or certified EHR Module on the open market. Commenters noted that Regional Extension Centers have taken extensive steps to identify the true cost of EHR technologies inclusive of software (in-house vs. hosted), services, training, maintenance, and other factors

in an effort to help their constituents properly compare certified Complete EHRs and certified EHR Modules. Last, commenters sought clarification regarding how EHR technology developers would be held accountable to this requirement (i.e., what would be the consequences for EHR technology developers).

Response. We appreciate the variety and specificity of comments issued in response to this proposal. For the reasons stated in the Proposed Rule as well as those raised by commenters in favor of this proposal, we continue to believe that there is value in requiring ONC–ACBs to ensure that EHR technology developers are transparent about the costs associated with certified Complete EHRs and certified EHR Modules. Further, we believe that such transparency can provide greater purchasing clarity for EPs, EHs, and CAHs. In considering that almost all commenters found fault with our proposal to list a purchaser's full cost or single price for a certified Complete EHR or certified EHR Module (for the various reasons identified in the comments above), we have finalized a modified approach based on those same comments and their suggestions for what would be helpful. This modified approach focuses on an EHR technology developer's responsibility to notify EPs, EHs, and CAHs about additional types of costs (i.e., one-time, ongoing, or both) that may affect a certified Complete EHR or certified EHR Module's total cost of ownership for the purposes of achieving MU.

We noted in the Proposed Rule that stakeholder feedback on unclear pricing prompted us to offer the proposal to require ONC–ACBs to ensure that EHR technology developers to specify the purchaser's full cost of a certified Complete EHR or certified EHR Module. We identified that stakeholders had conveyed to us that EHR technology developers were specifying prices for multiple groupings of capabilities even though the groupings did not correlate to the entire certified Complete EHR or certified EHR Module. Further, as commenters reinforced, EHR technologies that may be certified under the ONC HIT Certification Program could be sold or licensed with capabilities that are in addition to those that fall under the scope of certification.

We acknowledge that many factors, such as those mentioned by commenters (e.g., costs from purchasing EHR technology from multiple EHR technology developers, maintenance of the EHR technology, and training of staff on the EHR technology), go into a purchaser's total ownership cost for a certified Complete EHR or certified EHR Module(s). Our proposal sought, however, to clearly identify for purchasers the cost associated with the capabilities that the certification assigned to a Complete EHR or EHR Module represented, separate and apart from those capabilities and services that are not required for certification but are sold by EHR technology developers with the purchase of a certified Complete EHR or certified EHR Module. On balance, we believe that the best approach to address the concerns that prompted our proposal, as well as those received in response, is to amend § 170.523(k)(1) to add a third provision related to price transparency. Section § 170.523(k)(1) requires an ONC–ACB to ensure that a Complete EHR or EHR Module developer conspicuously includes on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification the information specified in paragraphs (k)(1)(i) and (k)(1)(ii). This new provision, finalized at § 170.523(k)(1)(iii), requires an ONC–ACB to ensure that a Complete EHR or EHR Module developer discloses any additional types of costs that an EP, EH, or CAH would pay to implement the capabilities a certified Complete EHR or certified EHR Module includes in order to attempt to meet MU objectives and measures. We clarify that these types of costs are in addition to those costs that an EP, EH, or CAH would pay to purchase (or upgrade to) the EHR technology capabilities for which certification is required. These may be one-time or recurring costs, or both. We also clarify that ONC–ACBs would only be required to ensure that EHR technology developers disclose the types of additional costs, and not the actual dollar amounts of such costs.

For example, if EHR technology is certified to the ''view, download, and transmit to a 3rd party'' certification criterion, and an EP would be expected to pay an ''ongoing'' monthly service fee to the EHR technology developer for it to host/administer this capability in order for the EP to meet the correlated MU objective and measure, the existence of this potential ''ongoing'' cost would need to be disclosed by the EHR technology developer. As another example, an EHR Module certified to the public health electronic lab reporting certification criterion (§ 170.314(f)(4)) would be able to create a valid HL7 message for electronic submission. However, for the purposes of achieving MU, a hospital may be expected to pay their EHR technology developer a separate ''one-time'' and/or ''ongoing'' interface development and configuration fee to establish connectivity between their certified EHR Module and a public health authority. In such a situation, the potential costs of the interface development and configuration fee would need to be disclosed. A final example would be where an EHR technology developer charges a ''one-time'' fee to integrate its certified EHR technology with a hospital's other certified EHR Modules or a health information exchange organization. Again, just like the other examples, the potential for this fee would need to be disclosed by the EHR technology developer. Building off these examples, we would expect that an EHR technology developer could satisfy § 170.523(k)(1)(iii) by disclosing: 1) the type(s) of additional cost; and 2) to what the cost is attributed. In reference to the first example above, an EHR technology might state that ''an additional ongoing fee may apply to implement XYZ online patient service.'' In situations where the same types of cost apply to different services, listing each as part of one sentence would be acceptable, such as ''a one-time fee is required to establish interfaces for reporting to immunization registries, cancer registries, and public health agencies.''

We believe that the limited scope required by this new disclosure will not hinder innovation and flexibility in product development pricing, and marketing strategies, nor is it likely to implicate confidential or proprietary information. We remind commenters that certification already requires certain transparency provisions. Under the ONC HIT Certification Program, ONC–ACBs must ensure that EHR technology developers specify certain information about their certified Complete EHR or certified EHR Module on their Web sites, in all marketing materials, communication statements, and other assertions (see § 170.523(k)(1)(i) and (ii)). This information conveys all of the capabilities that the certification issued to the Complete EHR or EHR Module represents and what must be provided to an EP, EH, or CAH in order for the EHR technology developer to properly convey the benefit (i.e., certification) assigned to the certified Complete EHR or certified EHR Module. Further, this information also notifies the customer of any additional software that the EHR technology developer relied on to meet certain certification criteria. In cases where additional software is relied on, it is also encompassed by the

certification issued to the certified Complete EHR or certified EHR Module. From a transparency perspective, this new requirement will provide clarity to purchasers regarding the potential additional types of costs they may face when implementing a certified Complete EHR or certified EHR Module. It may also help prevent purchasers from being surprised by additional costs beyond those associated with the adoption and implementation of the capabilities that comprise their CEHRT.

We described ''self-developed'' EHR technology in the Permanent Certification Program final rule (76 FR 1300–1301). We described self-developed EHR technology to mean a Complete EHR or EHR Module that has been designed, modified, or created by, or under contract for, a person or entity that will assume the total costs for its testing and certification and will be a primary user of the Complete EHR or EHR Module. We further noted that this distinction served to distinguish between those Complete EHRs and EHR Modules that would be created once and most likely sold to many EPs, EHs, and CAHs from those that would be certified once and used primarily by the person or entity who paid for testing and certification. On the developer level, we used the terms ''self-developer'' and commercial vendor to distinguish between the two types of developers. As requested by commenters, EHR technology self-developers would be exempt from the new requirement because they will not be marketing or making their certified Complete EHRs or certified EHR Modules commercially available for sale. To obtain this exemption, EHR technology self-developers will need to provide written notification to the ONC–ACB when presenting their EHR technology for certification that they are an EHR technology self-developer and their EHR technology will not be marketed or made commercially available for sale to health care providers.

ONC–ACBs are responsible for ensuring compliance with § 170.523(k)(1) and will determine appropriate consequences if EHR technology developers fail to disclose the information specified in § 170.523(k)(1).

G. Certification and Certification Criteria for Other Health Care Settings

The HITECH Act did not authorize the availability of incentives under the EHR Incentive Programs for all health care providers. Consequently, in the Proposed Rule, we noted that the certification criteria proposed for adoption focused primarily on enabling EHR technology to be certified and subsequently adopted and used by EPs, EHs, and CAHs who seek to demonstrate MU under the EHR Incentive Programs. We discussed, however, the National Coordinator's statutory authority to establish a voluntary certification program or programs for other types of HIT besides the EHR technology that could be used to demonstrate meaningful use. We explained that any steps towards certifying other types of HIT, including EHR technology such as ''Complete EHRs'' or ''EHR Modules'' for settings other than inpatient or ambulatory, would first require the Secretary to adopt certification criteria for other types of HIT and/or other types of health care settings. With this consideration, we sought public comment on whether we should focus any certification efforts towards the HIT used by health care providers that are ineligible to receive incentives under the EHR Incentive Programs.

In particular, we requested comments on whether we should consider adopting certification criteria for other health care settings, such as the long-term care, post-acute care, and mental and behavioral health settings. We asked that commenters specify the certification criteria that would be appropriate as well as the benefits they believe a regulatory approach would provide. Last, we asked that the public consider whether the private sector could alternatively address any perceived need or demand for such certification and specifically mentioned that the Certification Commission for Health Information Technology (CCHIT) has certification programs for long-term and post-acute care as well as behavioral health EHR technology.[41]

Comments. Commenters strongly supported certification for other health care settings. A few commenters suggested that we develop certification criteria for other health care settings. However, the majority of commenters also noted that the lack of financial incentives for other health care settings (e.g., long term, post acute, home health, hospice, and behavioral settings) was a significant barrier and would render attempts to adopt certification or certification criteria for other health care settings infeasible. Multiple commenters noted that voluntary certification programs for other health care settings have been developed by the private sector with industry-wide stakeholder input. Commenters specifically pointed to the certification programs run by the CCHIT, which cover long-term and post-acute care, skilled nursing facilities, and home health. Comments stated that private sector certification programs provide for greater flexibility, such as being able to revise and develop standards more in line with the pace of technology development. Commenters also noted that these programs are synchronized with applicable standards adopted to support MU, such as standards for transitions of care and privacy and security.

Commenters recommended that we focus on interoperability and health information exchange among all health care settings. Specifically, commenters suggested that we identify a subset of MU certification criteria and standards that support standards-based exchange of health information that protect the privacy and security of the health information being exchanged. Some commenters also suggested that we identify certification criteria that would support the ability of providers practicing in other health care settings to comply with federal reporting requirements. Commenters also recommended that we encourage EHR technology developers to obtain certification for EHR Modules that would specifically support these types of capabilities, like the exchange of a transition of care/referral summary.

Response. We appreciate the interest in other health care settings expressed by commenters. We agree that it makes good policy sense to support interoperability and the secure electronic exchange of health information between all health care settings. We believe the adoption of EHR technology certified to a minimal amount of certification criteria adopted by the Secretary can support this goal. To this end, we encourage EHR technology developers to certify EHR Modules to the transitions of care certification criteria (§ 170.314(b)(1) and (2)) as well as any other certification criteria that may make it more effective and efficient for EPs, EHs, and CAHs to electronically exchange health information with health care providers in other health care settings. The adoption of EHR technology certified to these certification criteria can facilitate the secure electronic exchange of health information. We concur with commenters that there are currently private sector organizations that are addressing requests for certification programs for other health care settings.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to

[41] *http://www.cchit.org/get_certified/cchit-certified-2011.*

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.

In the Proposed Rule, published March 7, 2012 (77 FR 13832), we solicited public comment on each of these issues for revisions to OMB control number 0990–0378. We did not receive any comments on this collection of information. We have finalized at § 170.523(f)(8) the requirement, as proposed, for ONC–ACBs to additionally 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 Complete EHRs and EHR Modules. Having not obtained any information that would suggest we reconsider our original burden estimates, we have maintained those same estimates.

Abstract

Under the ONC HIT 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-Authorized Certification Bodies (ONC–ACBs) 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. These collections of information were approved under OMB control number 0990–0378. In the Proposed Rule, we proposed to revise § 170.523(f) and, correspondingly, proposed to revise OMB control number 0990–0378 by requiring ONC–ACBs to include one additional data element in the list of information about Complete EHRs and EHR Modules they report to ONC.

Section 170.523(f) requires an ONC–ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified as well as certain minimum information about each certified Complete EHR and/or EHR Module. We proposed to require ONC–ACBs to additionally 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. We proposed to add this requirement at § 170.523(f)(8).

For the purposes of estimating this additional potential burden, we used the following assumptions. We assumed that all of the estimated applicants will apply and become ONC–ACBs (i.e., 6 applicants) and that they will report weekly (i.e., respondents will respond 52 times per year). We assumed an equal distribution among ONC–ACBs in certifying EHR technology on a weekly basis. As such, based on the number of Complete EHRs and EHR Modules listed on the CHPL at the end of September of 2011 (approximately one year since the CHPL's inception), we estimated that, on average, each ONC–ACB will report 4 test results hyperlinks to ONC on a weekly basis.

We believe that it will take approximately 5 minutes to report each hyperlink to ONC. Therefore, as reflected in the table below, we estimated an additional 20 minutes of work per ONC–ACB each week. Under the regulatory impact statement section, we discuss the estimated costs associated with reporting the hyperlinks to ONC.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 170.523(f)(8)	6	52	.33	103

With the additional collection of information at § 170.523(f)(8), we added 103 burden hours to our burden estimate in OMB control number 0990–0378. Our estimates for the total burden hours under OMB control number 0990–0378 are expressed in the table below.

ESTIMATED ANNUALIZED TOTAL BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 170.503(b)	2	1	1	2
45 CFR 170.520	6	1	1	6
45 CFR 170.523(f)	6	52	1.33	415
45 CFR 170.523(g)	n/a	n/a	n/a	n/a
45 CFR 170.523(i)	6	2	1	12
Total burden hours for OMB control number 0990–0378				435

VII. Regulatory Impact Statement

A. Statement of Need

Section 3004(b)(1) of the PHSA requires the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria. On January 13, 2010, the Department issued an interim final rule with a request for comments to adopt an initial set of standards, implementation specifications, and certification criteria. On July 28, 2010, the Department published in the **Federal Register** a final rule to complete the adoption of the initial set of standards, implementation specifications, and certification criteria. Collectively, the initial set is referred to as the 2011 Edition EHR certification criteria. This final rule adopts another edition of standards, implementation specifications, and certification criteria that we refer to as the 2014 Edition EHR certification criteria. The 2014 Edition EHR certification criteria support the MU objectives and measures under the EHR Incentive Programs and will be used to test and certify EHR technology (Complete EHRs and EHR Modules). EPs, EHs, and CAHs must adopt and implement certified Complete EHRs and/or certified EHR Modules in order to have CEHRT. EPs, EHs, and CAHs who seek to qualify for incentive payments under the EHR Incentive Programs are required by statute to use CEHRT.

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. Comment and Response

Comments. A few other commenters stated we did not account for the costs that public health agencies will incur by having to meet the standards we adopt for certification criteria that support reporting to public health agencies. Some commenters stated that the regulatory impact analysis does not account for costs that EPs, EHs, and CAHs will incur in adopting and implementing CEHRT. One commenter suggested that we should increase our average overall hours for development and preparation of EHR technology for certification to the 2014 Edition EHR certification criteria by a multiplier of four to account for integration of these new features into current EHR workflows.

Response. The information technology public health agencies use or would need to employ or modify in order to receive data according to the standards we adopt for EHR technology certification is not within the scope of this rulemaking. In promulgating this final rule, we have considered the standards adopted by public health agencies before including them in the relevant certification criteria.

The costs that EPs, EHs, and CAHs will incur in adopting and implementing certified Complete EHRs and certified EHR Modules are not within the scope of this final rule. Those costs would include the costs of integrating new features into their EHR workflows. Those costs are estimated in the Stage 2 final rule published elsewhere in this issue of the **Federal Register**.

2. Executive Orders 12866 and 13563—Regulatory Planning and Review Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that this final rule is not an economically significant rule because our primary estimate of the costs to prepare Complete EHRs and EHR Modules to be tested and certified will be less than $100 million in any given year. Nevertheless, because of the public interest in this final rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the final rule.

a. Costs

This rule adopts standards, implementation specifications, and certification criteria that establish the capabilities that EHR technology would need to demonstrate to be certified. Our analysis focuses on the direct effects of the provisions of this final rule—the costs incurred by EHR technology developers to develop and prepare Complete EHRs and EHR Modules to be tested and certified in accordance with the certification criteria adopted by the Secretary. That is, we focus on the technological development and preparation costs necessary for a Complete EHR or EHR Module already certified to the 2011 Edition EHR certification criteria to be upgrade to the adopted 2014 Edition EHR certification criteria and for developing a new Complete EHR or EHR Module to meet the 2014 Edition EHR certification criteria. The estimated costs for having EHR technology actually tested and certified were discussed in the Permanent Certification Program final rule (76 FR 1318–23). Last, we estimate the costs for ONC–ACBs to report to ONC hyperlinks to the test results used to certify EHR technology.

i. Development and Preparation Costs for 2014 Edition EHR Certification Criteria

The development costs we estimate are categorized based on the type of 2014 Edition EHR certification criteria discussed in this final rule (i.e., new, revised, and unchanged). The numbers of Complete EHRs and EHR Modules that we estimate will be developed to each 2014 Edition EHR certification criterion are based on the statistics we obtained from the CHPL on July 6, 2012. We attempted to identify the total number of Complete EHRs and EHR Modules that were developed to the 2011 Edition EHR certification criteria as of July 6, 2012. By this we mean that we first attempted to discern how many Complete EHRs and EHR Modules were certified that would not constitute a newer version of the same EHR technology. Second, we attempted to determine how many certified Complete EHRs and certified EHR Modules shared much of the same development costs. For example, when a Complete EHR is certified first and then an EHR technology developer subsequently seeks one or more EHR Module certifications for portions of that Complete EHR in order to provide its customers with more options. Using this number, we adjusted it based on additional considerations unique to the 2014 Edition EHR certification criteria such as the adoption of optional certification criteria, certification criteria included in the Base EHR definition, and the revised CEHRT definition. The revised CEHRT definition will only require EPs, EHs, and CAHs to possess the CEHRT they need to demonstrate MU for the stage they seek to accomplish, which could conceivably directly affect the number of EHR technologies developed to certain certification criteria that support MU menu objectives and measures. Using the final estimate of Complete EHRs and EHR Modules that we believe will be developed to meet each

certification criterion, we have established an estimated range of 10% less and 10% more EHR technologies being developed to each 2014 Edition EHR certification criterion. We believe this will account for potential new entrants to the market as well as for those EHR technologies developed to meet the 2011 Edition EHR certification criteria that may not be upgraded to the 2014 Edition EHR certification criteria because of such factors and company mergers or acquisitions and the loss of market share for some Complete EHRs and EHR Modules. For unchanged certification criteria, we have only calculated development and preparation costs for a potential 10% increase in new EHR technologies being developed and prepared to meet the certification criteria.

As noted in the Proposed Rule, we are not aware of an available independent study (e.g., a study capturing the efforts and costs to develop and prepare Complete EHRs and EHR Modules to meet the requirements of the 2011 Edition EHR certification criteria) that we could rely upon as a basis for estimating the efforts and costs required to develop and prepare EHR technology to meet the 2014 Edition EHR certification criteria. Therefore, we have relied upon our own research to estimate the effort required to develop and prepare EHR technology to meet the requirements of the 2014 Edition EHR certification criteria. We have identified 3 levels of effort that we believe can be associated with the development and preparation of EHR technology to meet the requirements of the 2014 Edition EHR certification criteria. These levels of effort are the *average* range of hours we would expect to be necessary to develop EHR technology to meet the requirements of the 2014 Edition EHR certification criteria. This means that a few EHR technology developers' costs may be less than this range and a few may exceed the range. Level 1 is for certification criteria that we believe will require the least amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 40–100 hours. Level 2 is for certification criteria that we believe will require a moderate amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 100–300 hours. Level 3 is for certification criteria that we believe will require the most amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 300–400 hours.

We have based the effort levels on the hours necessary for a software developer to develop and prepare the EHR technology for testing and certification. The U.S. Department of Labor, Bureau of Labor Statistics estimates that the mean hourly wage for a software developer is $44.27.[42] We have also calculated the costs of an employee's benefits. We have calculated these costs 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 the average software developer's wage with benefits to $60 per hour.

To calculate our low cost estimates for each certification criterion in the tables below, we have multiplied the low number of the estimated range of EHR technologies expected to be developed and prepared by the low number of estimated hours (''level of effort'' described above) for a software developer to develop and prepare the EHR technologies for testing and certification. To calculate our high cost estimates for each certification criterion in the tables below, we have multiplied the high number of the estimated range of EHR technologies expected to be developed and prepared to the criterion by the high number of estimated hours (''level of effort'' described above) for a software developer to develop and prepare the EHR technologies for testing and certification. For the following tables (Tables 7 through Table 13), dollar amounts are expressed in 2012 dollars.

In comparison to the listed certification criteria in the regulatory impact analysis for the Proposed Rule, we note the following changes based on the certification criteria we adopted. We have included the two new adopted certification criteria: data portability (§ 170.314(b)(7); and quality management systems (§ 170.414(g)(4)). We have moved the proposed unchanged certification criteria that have been adopted as revised certification criteria into the revised certification criteria section. These include: ''drug-formulary checks'' (§ 170.314(a)(10)); ''vital signs, body mass index, and growth charts'' (§ 170.314(a)(4)); ''smoking status'' (§ 170.314(a)(11)); ''patient lists'' (§ 170.314(a)(14)); and ''patient reminders'' (§ 170.314(a)(15)) [now combined and collectively referred to as ''patient list creation'']. Last, we have moved the new ''view, download, and transmit to 3rd party'' certification criterion (§ 170.314(e)(1)) from a level 3 effort down to a level 2 effort. We changed the level of effort because we did not adopt our proposals regarding images and WCAG 2.0 level AA for this certification criterion and because many of the EHR technologies that will be designed to meet this certification criterion have already met the 2011 Edition ''timely access'' certification criterion (§ 170.304(g)).

New Certification Criteria

TABLE 7—2014 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 1 EFFORT

Regulation section	Certification criterion	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(a)(9)	Electronic notes	420–514	1.01	3.08
170.314(a)(13)	Family health history	420–514	1.01	3.08
170.314(b)(3)	Electronic prescribing (inpatient)	101–123	.24	.74
170.314(b)(7)	Data portability	670–818	1.61	4.91

[42] *http://www.bls.gov/oes/current/oes151132.htm.*

TABLE 7—2014 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 1 EFFORT—Continued

Regulation section	Certification criterion	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(f)(5)	Cancer case information	320–392	.77	2.35
170.314(g)(4)	Quality management systems	670–818	1.61	4.91
Total			6.25	19.07

TABLE 8—2014 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation section	Certification criterion	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and Preparation costs—high ($M)
170.314(a)(12)	Image results	420–514	2.52	9.25
170.314(b)(6)	Transmission of electronic laboratory tests and values/results to ambulatory providers.	146–178	.88	3.20
170.314(d)(4)	Amendments	566–691	3.40	12.44
170.314(e)(1)	View, download, and transmit to 3rd party	567–693	3.40	12.47
170.314(e)(3)	Secure messaging	320–392	1.92	7.06
170.314(f)(6)	Transmission to cancer registries	320–392	1.92	7.06
170.314(g)(1)	Automated numerator recording	398–486	2.39	8.75
Total			16.43	60.23

TABLE 9—2014 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 3 EFFORT

Regulation section	Certification criterion	Estimated # of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(a)(16)	Electronic medication administration record	101–123	1.82	2.95
170.314(g)(3)	Safety-enhanced design	567–693	10.21	16.63
Total			12.03	19.58

Revised Certification Criteria

TABLE 10—2014 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 1 EFFORT

Regulation section	Certification criterion	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(a)(2)	Drug-drug, drug-allergy interaction checks	484–591	1.16	3.55
170.314(a)(3)	Demographics	530–648	1.27	3.89
170.314(a)(4)	Vital signs, body mass index, and growth charts.	502–613	1.20	3.68
170.314(a)(5)	Problem list	504–616	1.21	3.70
170.314(a)(10)	Drug-formulary checks	484–591	1.16	3.55
170.314(a)(11)	Smoking status	536–655	1.29	3.93
170.314(a)(14)	Patient list creation	473–578	1.14	3.47
170.314(a)(15)	Patient-specific education resources	480–587	1.15	3.52
170.314(b)(3)	Electronic prescribing (ambulatory)	445–544	1.07	3.26
170.314(b)(5)	Incorporate laboratory tests and values/results (ambulatory setting).	167–205	.40	1.23

TABLE 10—2014 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 1 EFFORT—Continued

Regulation section	Certification criterion	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(c)(2)	Clinical quality measures—incorporate and calculate.	497–608	1.19	3.65
170.314(d)(3)	Audit report(s)	670–818	1.61	4.91
170.314(e)(2)	Clinical summaries	432–528	1.04	3.17
170.314(f)(2)	Transmission to immunization registries	456–557	1.09	3.34
170.314(f)(3)	Transmission to public health agencies—syndromic surveillance.	447–546	1.07	3.28
170.314(f)(4)	Transmission of reportable laboratory tests and values/results.	60–74	.14	.44
Total			17.19	52.57

TABLE 11—2014 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation Section	Certification criterion	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(b)(1)	Transitions of care—receive, display, and incorporate transition of care/referral summaries.	514–628	3.08	11.30
170.314(b)(4)	Clinical information reconciliation	498–609	2.99	10.96
170.314(c)(3)	Clinical quality measures—submission	497–608	2.98	10.94
170.314(d)(2)	Auditable events and tamper resistance	670–818	4.02	14.72
170.314(d)(7)	End-user device encryption	667–816	4.00	14.69
170.314(g)(2)	Automated measure calculation	460–562	2.76	10.12
Total			19.83	72.73

TABLE 12—2014 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 3 EFFORT

Regulation Section	Certification criterion	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(a)(8)	Clinical decision support	474–580	8.53	17.40
170.314(b)(2)	Transitions of care—create and transmit transition of care/referral summaries.	514–628	9.25	18.84
170.314(c)(1)	Clinical quality measures—capture and export.	497–608	8.95	18.24
Total			26.73	54.48

Unchanged Certification Criteria

TABLE 13—2014 EDITION UNCHANGED EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation Section	Certification criterion	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(a)(1)	CPOE	62	.37	1.12
170.314(a)(6)	Medication list	57	.34	1.03
170.314(a)(7)	Medication allergy list	58	.35	1.04
170.314(a)(17)	Advance directives	11	.07	.20

TABLE 13—2014 EDITION UNCHANGED EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT—Continued

Regulation Section	Certification criterion	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(b)(5)	Incorporate laboratory tests and values/results (inpatient setting).	19	.11	.34
170.314(d)(1)	Authentication, access control, and authorization.	76	.46	1.37
170.314(d)(5)	Automatic log-off	76	.46	1.37
170.314(d)(6)	Emergency access	73	.44	1.31
170.314(d)(8)	Integrity	75	.45	1.35
170.314(d)(9)	Accounting of disclosures	13	.08	.23
170.314(f)(1)	Immunization information	51	.31	.92
Total			3.44	10.28

ii. Overall Development and Preparation Estimated Costs Over a 3-Year Period

In total, we estimate the overall costs for a 3-year period to be $101.90 million to $288.94 million, with a cost mid-point of approximately $195.42 million. If we were to evenly distribute the overall estimated costs to develop and prepare Complete EHRs and EHR Modules between calendar years 2012 and 2014, we believe they would likely be in the range of $33.97 million to $96.31 million per year with an annual cost mid-point of approximately $65.14 million. We have used the mid-point cost as our primary annual cost estimate for this regulatory impact analysis.

We do not believe that the estimated costs will be spread evenly over these three years due to market pressures, primarily consisting of EPs, EHs, and CAHs needing to adopt and implement EHR technology certified to the 2014 Edition EHR certification criteria in order to have CEHRT in FY/CY 2014. Based on this market pressure, in the Proposed Rule, we distributed the majority of the estimated costs in 2012 (40%) and 2013 (50%), while only distributing 10% of the estimated costs in 2014. With the additional flexibility that we have adopted in the CEHRT definition for FY/CY 2013, namely permitting EPs, EHs, and CAHs to meet the CEHRT definition for FY/CY 2014 in FY/CY 2013, we believe that the market pressure for EHR technology certified to the 2014 Edition EHR certification criteria to be available sooner will further increase. Given this consideration and the fact that we have issued this final rule sooner than we anticipated when publishing the Proposed Rule, we have revised our distribution of estimated costs to place more of the total estimated costs in 2012. As such, the estimated costs attributable to this final rule are distributed as follows: 45% for 2012, 45% for 2013, and 10% for 2014. This distribution of estimated costs for the year in which this final rule is published is also consistent with the distribution we used in the S&CC July 2010 final rule (75 FR 44648) for the year in which it was published. Table 14 below expresses the distribution of estimated costs for 2012 through 2014 in 2012 dollars.

TABLE 14—DISTRIBUTED TOTAL DEVELOPMENT AND PREPARATION COSTS FOR COMPLETE EHR AND EHR MODULE DEVELOPERS (3-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (%)	Total low cost estimate ($M)	Total high cost estimate ($M)	Primary mid-point total cost estimate ($M)
2012	45	45.85	130.02	87.93
2013	45	45.85	130.02	87.93
2014	10	10.20	28.90	19.56
3-Year Totals		101.90	288.94	195.42

iii. Costs for Reporting Test Results Hyperlinks

Costs to ONC–ACBs

Under § 170.523(f)(8), ONC–ACBs are required to provide ONC, no less frequently than weekly, a hyperlink with each EHR technology it certifies that provides the public with the ability to access the test results used to certify the EHR technology. As stated in the collection of information section, the reporting of this information will be required on a weekly basis and it will take each ONC–ACB about 20 minutes to prepare and electronically transmit an estimated four test results hyperlinks with the other required information to ONC each week.

We believe that an employee equivalent to the Federal Classification of GS–9 Step 1 could report the hyperlink to ONC. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, DC, 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 15 below and are expressed in 2012 dollars.

TABLE 15—ANNUAL COSTS FOR AN ONC–ACB TO REPORT TEST RESULTS HYPERLINKS TO ONC

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)(8)	GS–9 Step 1	17.16	$22.39	$8.06	$522.52

To estimate the highest possible cost, we assume that all of the applicants we estimated for the purposes of the collection of information (i.e., six) will apply and become ONC–ACBs under the ONC HIT Certification Program. Therefore, we estimate the total annual development and reporting cost under the ONC HIT Certification Program to be $3,136 (rounded using a total of 103 hours).

Costs to the Federal Government

We do not believe that the collection of information requirement of § 170.523(f)(8), through our posting of test results hyperlinks on the CHPL, will require us to incur any additional costs than the costs we estimated for having personnel post a list of all certified Complete EHRs and certified EHR Modules on our Web site (i.e., the CHPL), which was $10,784 on an annualized basis (76 FR 1323).

b. Benefits

We believe that there will be several benefits that may arise from this final rule. Foremost, EHR technology certified to the 2014 Edition EHR certification criteria will be capable of supporting EPs, EHs, and CAHs' attempts to demonstrate MU under the EHR Incentive Programs. The 2014 Edition EHR certification criteria also promote enhanced interoperability, functionality, utility, and security of EHR technology through the capabilities they include and the standards they require EHR technology to meet for certification. The capabilities specified in the 2014 Edition EHR certification criteria will help ensure that health care providers have the necessary information technology tools to improve patient care, and reduce medical errors and unnecessary tests. The standards adopted will aid in fostering greater interoperability.

The provisions in this final rule will increase the competition and innovation in the HIT marketplace that was spurred by the Secretary's adoption of the 2011 Edition EHR certification criteria. The revised CEHRT definition, the process for approving newer versions of minimum standards, and the revised privacy and security certification of EHR Modules will reduce the regulatory burden and add flexibility for EHR technology developers, EPs, EHs, and CAHs. Further, the ''splitting'' of certain certification criteria into multiple certification criteria should increase the opportunity and flexibility for EHR technology developers to have more EHR technology eligible for certification. Last, the provisions of this final rule are supportive of other initiatives, such as the Partnership for Patients, Medicare Shared Savings Program, and other quality measure programs administered by CMS.

3. Regulatory Flexibility Act

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 Complete EHRs and EHR Module developers represent a small segment of the overall information technology industry, we believe that the entities impacted by this final rule most likely fall under the North American Industry Classification System (NAICS) code 541511 ''Custom Computer Programming Services'' specified at 13 CFR 121.201 where the SBA publishes ''Small Business Size Standards by NAICS Industry.'' The SBA size standard associated with this NAICS code is set at $25.5 million in annual receipts [43] 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 Complete EHR or EHR Module. 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 Complete EHR and EHR Module developers 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 the Complete EHR and EHR Module developers to correlate to the SBA size standard. However, although not correlated to the size standard for NAICS code 541511, we do have information indicating that over 60% of EHR technology developers that have had Complete EHRs and/or EHR Modules certified to the 2011 Edition EHR certification criteria have less than 51 employees.

We estimate that this final rule will have effects on Complete EHR and EHR Module developers, some of which may be small entities. However, we believe that we have established 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. In order for a Complete EHR or EHR Module to provide the capabilities that an EP, EH, or CAH would be required to use under the Stage 2 final rule, it will need to comply with the applicable 2014 Edition EHR certification criteria adopted by the Secretary. Moreover, we note that this final rule does not impose the costs cited in the regulatory impact analysis as compliance costs, but rather as investments which Complete EHR and EHR Module developers voluntarily take on and expect to recover with an appropriate rate of return. Accordingly, we do not believe that this final rule will create a significant impact on a substantial number of small entities. The Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

4. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final

[43] 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.*

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 the Secretary has adopted.

5. 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 1 year of $100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately $139 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.

The Office of Management and Budget 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. In § 170.102, remove the ''Complete EHR'' definition, add in alphanumeric order the definitions ''2011 Edition EHR certification criteria,'' ''2014 Edition EHR certification criteria,'' ''Base EHR,'' ''Common MU Data Set,'' ''Complete EHR, 2011 Edition,'' and ''Complete EHR, 2014 Edition,'' and revise the definition of ''Certified EHR Technology'' to read as follows:

§ 170.102 Definitions.

2011 Edition EHR certification criteria means the certification criteria at §§ 170.302, 170.304, and 170.306.

2014 Edition EHR certification criteria means the certification criteria at § 170.314.

Base EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality;

(iv) To exchange electronic health information with, and integrate such information from other sources;

(v) To protect the confidentiality, integrity, and availability of health information stored and exchanged; and

(3) Has been certified to the certification criteria adopted by the Secretary at: § 170.314(a)(1), (3), and (5) through (8); (b)(1), (2), and (7); (c)(1) through (3); (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.

* * * * *

Certified EHR Technology means:

(1) For any Federal fiscal year (FY) or calendar year (CY) up to and including 2013:

(i) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria; or

(ii) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria, and the resultant combination also meets the requirements included in the definition of a Qualified EHR; or

(iii) EHR technology that satisfies the definition for FY and CY 2014 and subsequent years specified in paragraph (2);

(2) For FY and CY 2014 and subsequent years, the following: EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that has:

(i) The capabilities required to meet the Base EHR definition; and

(ii) All other capabilities that are necessary to meet the objectives and associated measures under 42 CFR 495.6 and successfully report the clinical quality measures selected by CMS in the form and manner specified by CMS (or the States, as applicable) for the stage of meaningful use that an eligible professional, eligible hospital, or critical access hospital seeks to achieve.

Common MU Data Set means the following data expressed, where indicated, according to the specified standard(s):

(1) Patient name.

(2) Sex.

(3) Date of birth.

(4) Race—the standard specified in § 170.207(f).

(5) Ethnicity—the standard specified in § 170.207(f).

(6) Preferred language—the standard specified in § 170.207(g).

(7) Smoking status—the standard specified in § 170.207(h).

(8) Problems—at a minimum, the version of the standard specified in § 170.207(a)(3).

(9) Medications—at a minimum, the version of the standard specified in § 170.207(d)(2).

(10) Medication allergies—at a minimum, the version of the standard specified in § 170.207(d)(2).

(11) Laboratory test(s)—at a minimum, the version of the standard specified in § 170.207(c)(2).

(12) Laboratory value(s)/result(s).

(13) Vital signs—height, weight, blood pressure, BMI.

(14) Care plan field(s), including goals and instructions.

(15) Procedures—

(i) At a minimum, the version of the standard specified in § 170.207(a)(3) or § 170.207(b)(2).

(ii) *Optional.* The standard specified at § 170.207(b)(3).

(iii) *Optional.* The standard specified at § 170.207(b)(4).

(16) Care team member(s).

Complete EHR, 2011 Edition means EHR technology that has been developed to meet, at a minimum, all mandatory 2011 Edition EHR certification criteria for either an ambulatory setting or inpatient setting.

Complete EHR, 2014 Edition means EHR technology that meets the Base EHR definition and has been developed to meet, at a minimum, all mandatory 2014 Edition EHR certification criteria for either an ambulatory setting or inpatient setting.

* * * * *

■ 3. Add § 170.202 to read as follows:

§ 170.202 Transport standards.

The Secretary adopts the following transport standards:

(a) *Standard.* ONC Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299).

(b) *Standard.* ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in § 170.299).

(c) *Standard.* ONC Transport and Security Specification (incorporated by reference in § 170.299).

■ 4. Add § 170.204 to read as follows:

§ 170.204 Functional standards.

The Secretary adopts the following functional standards:

(a) *Accessibility. Standard.* Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance (incorporated by reference in § 170.299).

(b) *Reference source. Standard.* HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton) (incorporated by reference in § 170.299). (1) *Implementation specifications.* HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, (incorporated by reference in § 170.299).

(2) *Implementation specifications.* HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide, (incorporated by reference in § 170.299).

(c) *Clinical quality measure-by-measure data.* Data Element Catalog, (incorporated by reference in § 170.299).

■ 5. In § 170.205, republish the introductory text and add paragraphs (a)(3), (d)(3), (e)(3), and (g) through (k) to read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) * * *

(3) *Standard.* HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, (incorporated by reference in § 170.299). The use of the ''unstructured document'' document-level template is prohibited.

* * * * *

(d) * * *

(3) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* PHIN Messaging Guide for Syndromic Surveillance (incorporated by reference in § 170.299) and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance (incorporated by reference in § 170.299).

(e) * * *

(3) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4, (incorporated by reference in § 170.299).

* * * * *

(g) *Electronic transmission of lab results to public health agencies. Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in § 170.299) with Errata and Clarifications, (incorporated by reference in § 170.299) and ELR 2.5.1 Clarification Document for EHR Technology Certification, (incorporated by reference in § 170.299).

(h) *Clinical quality measure data import, export, and electronic submission. Standard.* HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, (incorporated by reference in § 170.299).

(i) *Cancer information. 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), (incorporated by reference in § 170.299).

(j) *Electronic incorporation and transmission of lab results. Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, (incorporated by reference in § 170.299).

(k) *Clinical quality measure aggregate electronic submission. Standard.* Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2 (incorporated by reference in § 170.299).

■ 6. In § 170.207, republish the introductory text and add paragraphs (a)(3), (b)(3), (b)(4), revise paragraphs (c), (d), (e), and (f) and add paragraphs (g) through (j) to read as follows:

§ 170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) * * *

(3) *Standard.* IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in § 170.299).

(b) * * *

(3) *Standard.* The code set specified at 45 CFR 162.1002(a)(4).

(4) *Standard.* The code set specified at 45 CFR 162.1002(c)(3) for the indicated procedures or other actions taken.

(c) *Laboratory tests.* (1) *Standard.* Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transaction from a laboratory (incorporated by reference in § 170.299).

(2) *Standard.* 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. (incorporated by reference in § 170.299).

(d) *Medications.* (1) *Standard.* Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.

(2) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release (incorporated by reference in § 170.299).

(e) *Immunizations.* (1) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009 version (incorporated by reference in § 170.299).

(2) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, updates through July 11, 2012 (incorporated by reference in § 170.299).

(f) *Race and Ethnicity. 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 (see ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity,'' available at *http://www.whitehouse.gov/omb/fedreg_1997standards*).

(g) *Preferred language. 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).

(h) *Smoking status. Standard.* 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

(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

(i) *Encounter diagnoses. Standard.* The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

(j) *Family health history.* HL7 Version 3 Standard: Clinical Genomics; Pedigree, (incorporated by reference in § 170.299).

■ 7. In § 170.210:

■ a. Republish the introductory text;

■ b. In paragraph (a)(1), add the phrase '', (January 27, 2010)'' after ''140–2'';

■ c. In paragraph (c), remove ''180–3 (October, 2008))'' and add in its place ''180–4 (March 2012))''; and

■ d. Add paragraphs (e) through (h) to read as follows:

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:

* * * * *

(e) *Record actions related to electronic health information, audit log status, and encryption of end-user devices.* (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 at § 170.210(h) when EHR technology is in use.

(ii) The date and time must be recorded in accordance with the standard specified at § 170.210(g).

(2)(i) The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the audit log status is changed.

(ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g).

(3) The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the encryption status of electronic health information locally stored by EHR technology on end-user devices is changed. The date and time each action occurs in accordance with the standard specified at § 170.210(g).

(f) *Encryption and hashing of electronic health information.* Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the FIPS Publication 140–2 (incorporated by reference in § 170.299).

(g) *Synchronized clocks.* The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).

(h) *Audit log conten*t. ASTM E2147–01(Reapproved 2009), (incorporated by reference in § 170.299)

■ 8. Amend § 170.299 by revising paragraphs (b) through (j) and adding paragraphs (k) through (n) to read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(b) American National Standards Institute, Health Information Technology Standards Panel (HITSP) Secretariat, 25 West 43rd Street—Fourth Floor, New York, NY 10036, *http://www.hitsp.org.*

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for § 170.205.

(2) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428–2959 USA; Telephone (610) 832–9585 or *http://www.astm.org/.*

(1) ASTM E2147–01 (Reapproved 2009) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems, approved September 1, 2009, IBR approved for § 170.210.

(2) ASTM E2369–05: Standard Specification for Continuity of Care Record (CCR), year of adoption 2005, ASTM approved July 17, 2006, IBR approved for § 170.205.

(3) ASTM E2369–05 (Adjunct to E2369): Standard Specification Continuity of Care Record,—Final Version 1.0 (V1.0), November 7, 2005, IBR approved for § 170.205.

(d) Centers for Disease Control and Prevention, 2500 Century Parkway, Mailstop E–78, Atlanta, GA 30333, USA (800–232–4636); *http://www.cdc.gov/ehrmeaningfuluse/.*

(1) HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009, IBR approved for § 170.207.

(2) IIS: HL7 Standard Code Set CVX—Vaccines Administered, updates through July 11, 2012, IBR approved for § 170.207.

(3) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7)Standard Protocol Implementation Guide Version 2.2, June 2006, IBR approved for § 170.205.

(4) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(5) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, ADT Messages A01, A03, A04, and A08, HL7 Version 2.5.1 (Version 2.3.1 Compatible), Release 1.1, August 2012, IBR approved for § 170.205.

(6) Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, ADT MESSAGES A01, A03, A04, and A08, HL7 Version 2.5.1, Addendum to PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data (Release 1.1), August 2012, IBR approved for § 170.205.

(7) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4, August 1, 2012, IBR approved for § 170.205.

(8) Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0, August 2012, IBR approved for § 170.205.

(9) ELR 2.5.1 Clarification Document for EHR Technology Certification, July 16, 2012, IBR approved for § 170.205.

(e) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786–3000

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for § 170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry, Version 3.0, December 8, 2008 IBR approved for § 170.205.

(f) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677–7777 or *http://www.hl7.org/*

(1) Health Level Seven Standard Version 2.3.1 (HL7 2.3.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, April 14, 1999, IBR approved for § 170.205.

(2) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, February 21, 2007, IBR approved for § 170.205.

(3) Health Level Seven Implementation Guide: Clinical Document Architecture (CDA) Release 2—Continuity of Care Document (CCD), April 01, 2007, IBR approved for § 170.205.

(4) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU^R01, HL7 Informative Document, February, 2010, IBR approved for § 170.205.

(5) HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton); Release 1, July 2010, IBR approved for § 170.204.

(6) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, Release 3, December 2010, IBR approved for § 170.204.

(7) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide, Release 1, HL7 Draft Standard for Trial Use, March 2011, IBR approved for § 170.204.

(8) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012, IBR approved for § 170.205.

(9) HL7 Clinical Document Architecture, Release 2.0, Normative Edition, May 2005, IBR approved for § 170.205.

(10) HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU – R01] Draft Standard for Trial Use, July 2012, IBR approved for § 170.205.

(11) HL7 Version 3 Standard: Clinical Genomics; Pedigree, Release 1, Edition 2011, March 2012, IBR approved for § 170.207.

(12) HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, DTSU Release 2 (Universal Realm), Draft Standard for Trial Use, July 2012, IBR approved for § 170.205.

(13) HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata and Clarifications, September, 29, 2011, IBR approved for § 170.205.

(14) Quality Reporting Document Architecture Category III, Release 1, Implementation Guide for CDA Release 2 (US Realm) Based on HL7 CDA Release 2.0, August 2012, IBR approved for § 170.205.

(g) Internet Engineering Task Force (IETF), University of Delaware, Newark, DE 19716, Telephone (302) 831–8247, *http://www.ietf.org/rfc.html.*

(1) Network Time Protocol (Version 3) Specification, Implementation and Analysis, March 1992, IBR approved for § 170.210.

(2) Network Time Protocol Version 4: Protocol and Algorithms Specification, June 2010, IBR approved for § 170.210.

(h) Library of Congress, Network Development and MARC Standards Office, Washington, DC 20540–4402, Tel: (202) 707–6237 or *http://www.loc.gov/standards/iso639-2/.*

(1) ISO 639–2. Codes for the Representation of Names of Languages Part 2: Alpha-3 Code, April 8, 2011, IBR approved for § 170.207.

(2) [Reserved]

(i) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and Facsimile (480) 767–1042 or *http://www.ncpdp.org.*

(1) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, IBR approved for § 170.205.

(2) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008, (Approval date for ANSI: November 12, 2008), IBR approved for § 170.205.

(j) National Institute of Standards and Technology, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930, *http://csrc.nist.gov/groups/STM/cmvp/standards.html.*

(1) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, January 27, 2010, IBR approved for § 170.210.

(2) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, May 30, 2012, IBR approved for § 170.210.

(k) Office of the National Coordinator for Health Information Technology (ONC), 200 Independence Avenue SW., Suite 729–D, Washington, DC 20201, *http://healthit.hhs.gov.*

(1) Applicability Statement for Secure Health Transport, Version 1.1, July 10, 2012, IBR approved for § 170.202; available at *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__direct_project/3338.*

(2) XDR and XDM for Direct Messaging Specification, Version 1, March 9, 2011, IBR approved for § 170.202; available at *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__direct_project/3338.*

(3) Transport and Security Specification, Version 1.0, June 19, 2012, IBR approved for § 170.202.

(l) Regenstrief Institute, Inc., LOINC® c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202–3012; Telephone (317) 423–5983 or *http://loinc.org/.*

(1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for § 170.207.

(2) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, Released June 2012, IBR approved for § 170.207.

(m) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; Telephone (301) 594–5983 or *http://www.nlm.nih.gov/.*

(1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for § 170.207.

(2) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012, IBR approved for § 170.207.

(3) US Extension to SNOMED CT® March 2012 Release, IBR approved for § 170.207.

(4) RxNorm, August 6, 2012 Full Release Update, IBR approved for § 170.207.

(5) Data Element Catalog, Version: August 2012, IBR approved for § 170.204.

(n) World Wide Web Consortium (W3C)/MIT, 32 Vassar Street, Room 32–G515, Cambridge, MA 02139 USA, *http://www.w3.org/standards/*

(1) Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008, IBR approved for § 170.204.

(2) [Reserved]

■ 9. In § 170.300, republish paragraphs (a) and (b), revise paragraph (c) and add paragraph (d) to read as follows:

§ 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules.

(b) When a certification criterion refers to two or more standards as alternatives, the use of at least one of the alternative standards will be considered compliant.

(c) Complete EHRs and EHR Modules are not required to be compliant with certification criteria or capabilities specified within a certification criterion that are designated as optional.

(d) In § 170.314, all certification criteria and all capabilities specified within a certification criterion have general applicability (i.e., apply to both ambulatory and inpatient settings) unless designated as ''inpatient setting only'' or ''ambulatory setting only.''

(1) *''Inpatient setting only''* means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an inpatient setting.

(2) *''Ambulatory setting only''* means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an ambulatory setting.

■ 10. Add § 170.314 as follows:

§ 170.314 2014 Edition electronic health record certification criteria.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Clinical.* (1) *Computerized provider order entry.* Enable a user to electronically record, change, and access the following order types, at a minimum:

(i) Medications;

(ii) Laboratory; and

(iii) Radiology/imaging.

(2) *Drug-drug, drug-allergy interaction checks. (i) Interventions.* Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

(ii) Adjustments. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

(3) *Demographics.* (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.

(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.

(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g) and whether a patient declines to specify a preferred language.

(ii) Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality.

(4) *Vital signs, body mass index, and growth charts.* (i) *Vital signs.* Enable a user to electronically record, change, and access, at a minimum, a patient's height/length, weight, and blood pressure. Height/length, weight, and blood pressure must be recorded in numerical values only.

(ii) *Calculate body mass index.* Automatically calculate and electronically display body mass index based on a patient's height and weight.

(iii) *Optional—Plot and display growth charts.* Plot and electronically display, upon request, growth charts for patients.

(5) *Problem list.* Enable a user to electronically record, change, and access a patient's active problem list:

(i) *Ambulatory setting.* Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3); or

(ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

(6) *Medication list.* Enable a user to electronically record, change, and access a patient's active medication list as well as medication history:

(i) *Ambulatory setting.* Over multiple encounters; or

(ii) *Inpatient setting.* For the duration of an entire hospitalization.

(7) *Medication allergy list.* Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history:

(i) *Ambulatory setting.* Over multiple encounters; or

(ii) *Inpatient setting.* For the duration of an entire hospitalization.

(8) *Clinical decision support. (i) Evidence-based decision support interventions.* Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:

(A) Problem list;

(B) Medication list;

(C) Medication allergy list;

(D) Demographics;

(E) Laboratory tests and values/results; and

(F) Vital signs.

(ii) Linked referential clinical decision support. (A) EHR technology must be able to:

(*1*) Electronically identify for a user diagnostic and therapeutic reference information; or

(*2*) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (2).

(B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section.

(iii) *Clinical decision support configuration.* (A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

(B) EHR technology must enable interventions to be electronically triggered:

(*1*) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section.

(*2*) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section.

(*3*) *Ambulatory setting only.* When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(*1*) of this section.

(iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(8)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

(v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:

(A) For evidence-based decision support interventions under paragraph (a)(8)(i) of this section*:*

(*1*) Bibliographic citation of the intervention (clinical research/guideline);

(*2*) Developer of the intervention (translation from clinical research/guideline);

(*3*) Funding source of the intervention development technical implementation; and

(*4*) Release and, if applicable, revision date(s) of the intervention or reference source.

(B) For linked referential clinical decision support in paragraph (a)(8)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(2) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(9) *Electronic notes.* Enable a user to electronically record, change, access, and search electronic notes.

(10) *Drug-formulary checks.* EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.

(11) *Smoking status.* Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).

(12) *Image results.* Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

(13) *Family health history.* Enable a user to electronically record, change, and access a patient's family health history according to:

(i) At a minimum, the version of the standard specified in § 170.207(a)(3); or

(ii) The standard specified in § 170.207(j).

(14) *Patient list creation.* Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:

(i) Problems;

(ii) Medications;

(iii) Medication allergies;

(iv) Demographics;

(v) Laboratory tests and values/results; and

(vi) *Ambulatory setting only.* Patient communication preferences.

(15) *Patient-specific education resources.* EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests and values/results:

(i) In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (2); and

(ii) By any means other than the method specified in paragraph (a)(15)(i) of this section.

(16) *Inpatient setting only—electronic medication administration record.* (i) In combination with an assistive technology that provides automated information on the ''rights'' specified in paragraphs (a)(16)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s):

(A) *Right patient.* The patient to whom the medication is to be administered matches the medication to be administered.

(B) *Right medication.* The medication to be administered matches the medication ordered for the patient.

(C) *Right dose.* The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) *Right route.* The route of medication delivery matches the route specified in the medication order.

(E) *Right time.* The time that the medication was ordered to be administered compared to the current time.

(ii) *Right documentation.* Electronically record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

(17) *Inpatient setting only—advance directives.* Enable a user to electronically record whether a patient has an advance directive.

(b) Care coordination. (1) *Transitions of care—receive, display, and incorporate transition of care/referral summaries.* (i) *Receive.* EHR technology must be able to electronically receive transition of care/referral summaries in accordance with:

(A) The standard specified in § 170.202(a).

(B) *Optional.* The standards specified in § 170.202(a) and (b).

(C) *Optional.* The standards specified in § 170.202(b) and (c).

(ii) *Display.* EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: § 170.205(a)(1), § 170.205(a)(2), and § 170.205(a)(3).

(iii) *Incorporate.* Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3), EHR technology must be able to:

(A) Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(B) Data incorporation. Electronically incorporate the following data expressed according to the specified standard(s):

(*1*) *Medications.* At a minimum, the version of the standard specified in § 170.207(d)(2);

(*2*) *Problems.* At a minimum, the version of the standard specified in § 170.207(a)(3);

(*3*) *Medication allergies.* At a minimum, the version of the standard specified in § 170.207(d)(2).

(C) *Section views.* Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at § 170.205(a)(3).

(2) *Transitions of care—create and transmit transition of care/referral summaries.* (i) *Create.* Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(A) *Encounter diagnoses.* The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified § 170.207(a)(3);

(B) *Immunizations.* The standard specified in § 170.207(e)(2);

(C) Cognitive status;

(D) Functional status; and

(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) *Transmit.* Enable a user to electronically transmit the transition of care/referral summary created in paragraph (b)(2)(i) of this section in accordance with:

(A) The standard specified in § 170.202(a).

(B) *Optional.* The standards specified in § 170.202(a) and (b).

(C) *Optional.* The standards specified in § 170.202(b) and (c).

(3) *Electronic prescribing.* Enable a user to electronically create prescriptions and prescription-related

information for electronic transmission in accordance with:

(i) The standard specified in § 170.205(b)(2); and

(ii) At a minimum, the version of the standard specified in § 170.207(d)(2).

(4) *Clinical information reconciliation.* Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

(i) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.

(ii) Enable a user to create a single reconciled list of medications, medication allergies, or problems.

(iii) Enable a user to review and validate the accuracy of a final set of data and, upon a user's confirmation, automatically update the list.

(5) *Incorporate laboratory tests and values/results.* (i) *Receive results.* (A) *Ambulatory setting only.* (*1*) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j) and, at a minimum, the version of the standard specified in § 170.207(c)(2).

(*2*) Electronically display the tests and values/results received in human readable format.

(B) *Inpatient setting only.* Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

(6) *Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers.* EHR technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in § 170.205(j) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in § 170.207(c)(2).

(7) *Data portability.* Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(i) *Encounter diagnoses.* The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);

(ii) *Immunizations.* The standard specified in § 170.207(e)(2);

(iii) Cognitive status;

(iv) Functional status; and

(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.

(c) Clinical quality measures. (1) *Clinical Quality Measures—capture and export.* (i) *Capture.* For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of ''patient reason,'' ''system reason,'' or ''medical reason.''

(ii) *Export.* EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

(2) *Clinical quality measures—import and calculate.* (i) *Import.* EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i).

(ii) *Calculate.* EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.

(3) *Clinical quality measures—electronic submission.* Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) In accordance with the standards specified at § 170.205(h) and (k); and

(ii) That can be electronically accepted by CMS.

(d) Privacy and security. (1) *Authentication, access control, and authorization.* (i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.

(2) *Auditable events and tamper-resistance.* (i) *Record actions.* EHR technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1);

(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 EHR technology in accordance with the standard specified in § 170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see 170.314(d)(7) of this section).

(ii) *Default setting.* EHR technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraphs (d)(2)(i)(B) or (C), or both paragraphs (d)(2)(i)(B) and (C).

(iii) *When disabling the audit log is permitted.* For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that EHR technology permits to be disabled, the ability to do so must be restricted to a limited set of identified 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 EHR technology.

(v) *Detection.* EHR technology must be able to detect whether the audit log has been altered.

(3) *Audit report(s).* Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards at § 170.210(e).

(4) *Amendments.* Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (d)(4)(i) or (ii) of this section.

(i) *Accepted amendment.* For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.

(ii) *Denied amendment.* For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.

(5) *Automatic log-off.* Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.

(6) *Emergency access.* Permit an identified set of users to access electronic health information during an emergency.

(7) *End-user device encryption.* Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.

(i) EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops.

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(1).

(B) *Default setting.* EHR technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.

(ii) EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.

(8) *Integrity.* (i) Create a message digest in accordance with the standard specified in § 170.210(c).

(ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(9) *Optional—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) EHR technology must provide patients (and their authorized representatives) with an online means to view, download, and transmit to a 3rd party the data specified below. Access to these capabilities must be through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(A) *View.* Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data:

(*1*) The Common MU Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).

(*2*) *Ambulatory setting only.* Provider's name and office contact information.

(*3*) *Inpatient setting only.* Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(B) *Download.* (*1*) Electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in human readable format or formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(*i*) *Ambulatory setting only.* All of the data specified in paragraph (e)(1)(i)(A)(*1*) and (*2*) of this section.

(*ii*) *Inpatient setting only.* All of the data specified in paragraphs (e)(1)(i)(A)(*1*) and (*3*) of this section.

(*2*) *Inpatient setting only.* Electronically download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(2) of this section).

(C) *Transmit to third party.* (*1*) Electronically transmit the ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(*1*) of this section in accordance with the standard specified in § 170.202(a).

(*2*) *Inpatient setting only.* Electronically transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with the standard specified in § 170.202(a).

(ii) *Activity history log.* (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:

(*1*) The action(s) (i.e., view, download, transmission) that occurred;

(*2*) The date and time each action occurred in accordance with the standard specified at § 170.210(g); and

(*3*) The user who took the action.

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

(2) *Ambulatory setting only—clinical summary.* (i) *Create.* Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(3).

(ii) *Customization.* Enable a user to customize the data included in the clinical summary.

(iii) *Minimum data from which to select.* EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:

(A) Common MU Data Set (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set)

(B) The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids.

(3) *Ambulatory setting only—secure messaging.* Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

(i) Both the patient (or authorized representative) and EHR technology user are authenticated; and

(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(f) *Public health.* (1) *Immunization information.* Enable a user to electronically record, change, and access immunization information.

(2) *Transmission to immunization registries.* EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:

(i) The standard and applicable implementation specifications specified in § 170.205(e)(3); and

(ii) At a minimum, the version of the standard specified in § 170.207(e)(2).

(3) *Transmission to public health agencies—syndromic surveillance.* EHR technology must be able to

electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) *Ambulatory setting only.* (A) The standard specified in § 170.205(d)(2). (B) *Optional.* The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

(ii) *Inpatient setting only.* The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

(4) *Inpatient setting only—transmission of reportable laboratory tests and values/results.* EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

(5) *Optional—ambulatory setting only—cancer case information.* Enable a user to electronically record, change, and access cancer case information.

(6) *Optional—ambulatory setting only—transmission to cancer registries.* EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

(g) *Utilization.* (1) *Automated numerator recording.* For each meaningful use objective with a percentage-based measure, EHR technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

(2) *Automated measure calculation.* For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(3) *Safety-enhanced design.* User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1), (2), (6) through (8), and (16) and (b)(3) and (4).

(4) *Quality management system.* For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single QMS was used for applicable capabilities, it would only need to be identified once.

(ii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others.

(iii) If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

§§ 170.500 through 170.599 [Amended]

■ 11. In subpart E, consisting of §§ 170.500 through 170.599, remove the phrases ''permanent certification program for HIT'' and ''permanent certification program'' and add in their place ''ONC HIT Certification Program'' wherever they may occur.

■ 12. Amend § 170.502 by revising the definition of ''providing or provide an updated certification'' to read as follows:

§ 170.502 Definitions.

* * * * *

Providing or provide an updated certification means the action taken by an ONC–ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the EHR Module(s).

* * * * *

■ 13. In § 170.523, republish the introductory text, add paragraph (f)(8), revise paragraphs (k)(1)(i) and (ii), and add paragraph (k)(1)(iii) to read as follows:

§ 170.523 Principles of proper conduct for ONC–ACBs.

An ONC–ACB shall:

* * * * *

(f) * * *

(8) A hyperlink to the test results used to certify the Complete EHRs and/or EHR Modules that can be accessed by the public.

* * * * *

(k) * * *

(1) * * *

(i) ''This [Complete EHR or EHR 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 information an ONC–ACB is required to report to the National Coordinator under paragraph (f) of this section for the specific Complete EHR or EHR Module at issue; and

(iii) Any additional types of costs that an EP, EH, or CAH would pay to implement the Complete EHR's or EHR Module's capabilities in order to attempt to meet meaningful use objectives and measures. EHR technology self-developers are excluded from this requirement.

* * * * *

■ 14. In § 170.550, revise paragraph (e), redesignate paragraph (f) as paragraph (g), and add a new paragraph (f) to read as follows:

§ 170.550 EHR Module certification.

* * * * *

(e) *Privacy and security certification.* For certification to the 2011 Edition EHR certification criteria, EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC–ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) When certifying an EHR Module to the 2014 Edition EHR certification

criteria, an ONC–ACB must certify the EHR Module in accordance with the certification criteria at:

(1) Section 170.314(g)(1) if the EHR Module has capabilities presented for certification that would support a meaningful use objective with a percentage-based measure;

(2) Section 170.314(g)(3) if the EHR Module is presented for certification to one or more listed certification criteria in § 170.314(g)(3); and

(3) Section 170.314(g)(4).

* * * * *

■ 15. Revise § 170.555 to read as follows:

§ 170.555 Certification to newer versions of certain standards.

(a) ONC–ACBs may certify Complete EHRs and/or EHR Module(s) to a newer version of certain identified minimum standards specified at subpart B of this part, unless the Secretary prohibits the use of a newer version for certification.

(b) *Applicability of a newer version of a minimum standard.* (1) ONC–ACBs are not required to certify Complete EHRs and/or EHR Module(s) according to newer versions of standards identified as minimum standards in subpart B of this part, unless and until the incorporation by reference of a standard is updated in the **Federal Register** with a newer version.

(2) A certified Complete EHR or certified EHR Module may be upgraded to comply with newer versions of standards identified as minimum standards in subpart B of this part without adversely affecting its certification status, unless the Secretary prohibits the use of a newer version for certification.

Dated: August 21, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–20982 Filed 8–23–12; 2:30 pm]

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List Four Subspecies of Great Basin Butterflies as Endangered or Threatened Species; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2012–0058; 4500030113]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List Four Subspecies of Great Basin Butterflies as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on a petition to list four subspecies of Great Basin butterflies (White River Valley skipper (*Hesperia uncas grandiosa*), Steptoe Valley crescentspot (*Phyciodes cocyta arenacolor*), Baking Powder Flat blue butterfly (*Euphilotes bernardino minuta*), and bleached sandhill skipper (*Polites sabuleti sinemaculata*)) in Nevada as endangered or threatened species and designate critical habitat under the Endangered Species Act of 1973, as amended (Act). After review of the best available scientific and commercial information, we find that listing these four butterfly and skipper subspecies is not warranted at this time. However, we ask the public to submit to us any new information that becomes available concerning the threats to the White River Valley skipper, Steptoe Valley crescentspot, Baking Powder Flat blue butterfly, and bleached sandhill skipper or their habitats at any time.

DATES: The finding announced in this document was made on September 4, 2012.

ADDRESSES: This finding is available on the internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2012–0058. The supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Nevada Fish and Wildlife Office, 1340 Financial Boulevard, Suite 234, Reno, NV 89502. Please submit any new information, materials, comments, or questions concerning this finding to the above address.

FOR FURTHER INFORMATION CONTACT: Edward D. Koch, State Supervisor, Nevada Fish and Wildlife Office (see ADDRESSES); by telephone (775–861–6300), or by facsimile (775–861–6301). If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), requires that, for any petition to revise the Lists of Endangered and Threatened Wildlife and Plants that contains substantial scientific or commercial information that the listing may be warranted, we make a finding within 12 months of the date of the receipt of the petition. In this finding, we will determine that the petitioned action is either: (1) Not warranted, (2) warranted, or (3) warranted, but the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are an endangered or threatened species, and expeditious progress is being made to add or remove qualified species from the Lists of Endangered and Threatened Wildlife and Plants. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding; that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register**.

Previous Federal Actions

These four subspecies were included in our Category 2 candidate list for November 21, 1991 (56 FR 58804). A Category 2 candidate species was a species for which we had information indicating that a proposal to list it as threatened or endangered under the Act may be appropriate, but for which additional information on biological vulnerability and threat was needed to support the preparation of a proposed rule. Please see Table 1 to cross reference the names on the 1991 Category 2 candidate list with the names of the four subspecies petitioned for listing.

TABLE 1—FOUR GREAT BASIN, NV, BUTTERFLIES: PREVIOUS AND CURRENT COMMON AND SCIENTIFIC NAMES

Common name		Scientific name	
Previous	Current	Previous	Current
White River Valley skipper	White River Valley skipper	*Hesperia uncas* ssp	*Hesperia uncas grandiosa*
Steptoe Valley crescentspot	Steptoe Valley crescentspot	*Phyciodes pascoensis* ssp	*Phyciodes cocyta arenacolor*
Baking Powder Flat blue butterfly	Baking Powder Flat blue butterfly	*Euphilotes battoides* ssp	*Euphilotes bernardino minuta*
Denio sandhill skipper	Bleached sandhill skipper	*Polites sabuleti sinemaculata*	*Polites sabuleti sinemaculata*

In the February 28, 1996, Candidate Notice of Review (CNOR) (61 FR 7595), we adopted a single category of candidate species defined as follows: ''Those species for which the Service has on file sufficient information on biological vulnerability and threat(s) to support issuance of a proposed rule to list but issuance of the proposed rule is precluded.'' In previous CNORs, species meeting this definition were known as Category 1 candidates for listing. Thus, as of the 1996 CNOR, the Service no longer considered Category 2 species as candidates, including the four petitioned butterfly and skipper subspecies, and did not include them in the 1996 candidate list or any subsequent CNORs. The decision to no longer consider Category 2 species as candidates was designed to reduce confusion about the status of these species and to clarify that we no longer regarded these species as candidates for listing.

On January 29, 2010, we received a petition dated January 25, 2010, from WildEarth Guardians requesting that 10 subspecies of Great Basin butterflies in Nevada and California be listed as endangered or threatened species with critical habitat under the Act. The 10 subspecies of Great Basin butterflies are: White River Valley skipper, Steptoe Valley crescentspot, Baking Powder Flat blue butterfly, bleached sandhill skipper, Carson Valley silverspot (*Speyeria nokomis carsonensis*), Carson Valley wood nymph (*Cercyonis pegala carsonensis*), Mono Basin skipper (*Hesperia uncas giulianii*), Railroad Valley skipper (*Hesperia uncas fulvapalla*), Railroad Valley skipper (*Hesperia uncas reeseorum*), and Mattoni's blue butterfly (*Euphilotes*

pallescens mattonii). In a March 26, 2010, letter to the petitioner, we responded that we had reviewed the information presented in the petition and determined that issuing an emergency regulation temporarily listing the 10 subspecies as per section 4(b)(7) of the Act was not warranted, although this was not requested in the petition. On October 4, 2011, we made our 90-day finding that the petition did not present substantial scientific or commercial information indicating that listing 6 of the 10 subspecies (Carson Valley silverspot, Carson Valley wood nymph, Mattoni's blue butterfly, Mono Basin skipper, and the two Railroad Valley skipper subspecies) may be warranted (76 FR 61532). However, we determined that the petition presented substantial scientific or commercial information indicating that listing of the other four subspecies (White River Valley skipper, Steptoe Valley crescentspot, Baking Powder Flat blue butterfly, and bleached sandhill skipper) may be warranted, and we initiated a status review for these subspecies. This notice constitutes the 12-month finding on the January 29, 2010, petition to list the White River Valley skipper, Steptoe Valley crescentspot, Baking Powder Flat blue butterfly, and bleached sandhill skipper as endangered or threatened species and designate critical habitat under the Act.

Summary of Procedures for Determining the Listing Status of Species

Review of Status Based on Five Factors

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR 424) set forth the procedures for adding a species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, a species may be determined to be an endangered or threatened species based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In making this finding, information pertaining to the White River Valley skipper, Steptoe Valley crescentspot, Baking Powder Flat blue butterfly, and bleached sandhill skipper in relation to the five factors provided in section 4(a)(1) of the Act is discussed below. In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat, and we then attempt to determine how significant a threat it is. If the threat is significant, it may drive or contribute to the risk of extinction of the species such that the species may warrant listing as an endangered or threatened species as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors are operative threats that act on the species to the point that the species may meet the definition of an endangered or threatened species under the Act.

Evaluation of the Status of Each of the Four Butterfly and Skipper Subspecies

For each of the four butterfly and skipper subspecies, we provide a description of the subspecies and its habitat and biology, an evaluation of listing factors for that subspecies, and our finding as to whether the petitioned action is warranted or not for that subspecies.

The four butterfly and skipper subspecies evaluated in this finding are invertebrates endemic to the Great Basin region of Nevada. The four subspecies are from the phylum Arthropoda, class Insecta, and order Lepidoptera. Taxonomic families for the four subspecies are: Hesperiidae, Nymphalidae, and Lycaenidae.

The petition provides information regarding the four subspecies' rankings according to NatureServe, which considers the butterflies and skippers at the subspecies taxonomic level and ranks each as ''critically imperiled'' or ''imperiled'' at the global, national, or State level (WildEarth Guardians 2010, pp. 3–4). While the petition states that these ''definitions of 'critically imperiled' and 'imperiled' are at least equivalent to definitions of 'endangered' or 'threatened' under the [Act],'' this is not an appropriate comparison. According to its own Web site, NatureServe's assessment of any species ''does not constitute a recommendation by NatureServe for listing [that species]'' under the Act (NatureServe 2008, p. 1). In addition, NatureServe's assessment procedures include ''different criteria, evidence requirements, purposes and taxonomic coverage [from those of] government lists of endangered and threatened species, and therefore these two types of lists should not be expected to coincide'' (NatureServe 2008, p. 1).

Species Information for the White River Valley Skipper

Taxonomy and Species Description

We accept the characterization of the White River Valley skipper (*Hesperia uncas grandiosa*) as a valid subspecies based on its description by Austin and McGuire (1998, p. 778). This subspecies is in the Hesperiidae family (Austin 1998a, p. 838). Male wingspans range from 0.63 to 0.7 inch (in) (16.0–17.6 millimeters (mm)). The upperside of the wings are clay color. The forewing margin is blackish. The apex has a large yellowish macule (spot, patch). The stigma (patch of scent scales) is broad and black with a silver central line. The hindwing has a black costa and narrow outer margin. The fringes of both wings are pale gray. The underside of the forewing is paler than the upperside. The apical macules are white. The area beneath the stigma and wing base is black. The hindwing is olive-gray colored. The postmedian and sub-basal macules are white. The veins are white medially and extend to the outer margin (Austin and McGuire 1998, p. 778). Females range from 0.74 to 0.82 in (18.8–20.7 mm). The upperside of the wings is similar to that of the males but is darker. The outer margin is broader than that of the males. The apical macules are paler. The hindwing is blacker than the male's hindwing. The fringes of both wings are very pale gray. The underside of the wing is similar to that of the male, but it is more blackish medially on the forewing. The hindwing postmedial macules are larger and the white on the hindwing veins extend to the outer margin usually (Austin and McGuire 1998, p. 778). Please refer to Austin and McGuire (1998, p. 778) for a more detailed description of this subspecies.

Distribution and Habitat

Descriptions of locations where the White River Valley skipper has been found are rather vague. The White River Valley skipper's type locality (location where the specimen from which a species is described and named was collected) is a narrow marshy area in the

White River channel, White River Valley, located 1 mile (mi) (1.6 kilometer (km)) north of the Nye County boundary in White Pine County, Nevada (Austin and McGuire 1998, p. 778; Nevada Natural Heritage Program (NNHP) 2010) (on private and Bureau of Land Management (BLM) administered lands). This area is approximately 1.5 mi (2.4 km) southwest of the Ruppes/Boghole area (White Pine County), where this subspecies has also been observed on BLM and private lands (NNHP 2006, p. 47). The subspecies is known from alkaline *Distichlis spicata* (salt grass) flats in the White River Valley from Sunnyside (includes the Flag Springs area) (Nye County) north to the type locality, a distance of about 20 mi (32 km) (on unspecified BLM and private lands), and from Big Smoky Valley at unspecified locations (northwestern Nye County) (Austin and McGuire 1998, p. 778). This subspecies was also found at Kirch Wildlife Management Area (WMA) (two areas at south ends of Tule and Adams-McGill Reservoirs (on State lands) (Nye County) (Boyd, pers. comm. 2012a, p. 2; b, p. 1) and at Moorman Springs (Nye County) (Boyd, pers. comm. 2012b, p. 1) (on BLM and private lands).

A specimen that may be this subspecies was collected 1 mi (1.6 km) south of Blind Spring, Spring Valley (White Pine County) (Austin and McGuire 1998, p. 785). In 1998, Austin and McGuire (1998, pp. 778–779) tentatively included populations from Spring Valley (based on one male specimen) and Lake Valley (based on two male specimens with no site specificity given) (Lincoln County), Nevada, within the range of this subspecies. During a general terrestrial invertebrate survey conducted in 2006 at 76 locations in eastern Nevada, a single male was encountered east of Cleve Creek in Spring Valley (White Pine County) (Ecological Sciences, Inc. 2007, p. 28) and was attributed to this subspecies. This location is near other areas (not specified by authors) where the subspecies has been previously documented, and is not considered to be a significant range extension (Ecological Sciences, Inc. 2007, p. 28). The size of each known occupied site or the extent of this subspecies' host plant(s), or host plant abundance, has not been reported.

Biology

The White River Valley skipper flies during June, July, and August (Austin and McGuire 1998, p. 778; Austin *et al., in litt.* 2000, p. 4). Though adult nectar sources have not been reported, it is possible that they nectar on a variety of plants that are in flower during their flight period. The apparent larval host plant is *Juncus mexicanus* (Mexican rush) (Austin and Leary 2008, p. 11). This perennial plant species occurs in moist habitats (Kartesz 1987, p. 1503; Reed 1988, pp. 8, 10; Austin and Leary 2008, p. 11). In Nevada, it is known from western and southern counties, including Nye County (Kartesz 1987, p. 1503; *http://www plants.usda.gov* Web site accessed April 24, 2012). In the western United States, in addition to Nevada, it occurs in Oregon, California, Arizona, New Mexico, Colorado, and Texas (*http://www plants.usda.gov* Web site accessed April 24, 2012).

There is little biological information available at the subspecies level, but some inferences can be made from biological information from related species at the species level. Information for the white-vein skipper (*Hesperia uncus*) indicates eggs are pale greenish-white and are laid singly on or near the host plant (Scott 1986, p. 435). Larvae eat leaves, and they live in tied-leaf nests (Scott 1986, p. 435). Males perch during the day on small hill tops seeking females (Scott 1986, p. 435).

The best available information does not include surveys documenting this subspecies' population dynamics, nor its overall abundance, number or size of populations, number of extirpated populations, if any, or population trends.

Five-Factor Evaluation for the White River Valley Skipper

Information pertaining to the White River Valley skipper in relation to the five factors provided in section 4(a)(1) of the Act is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Potential factors that may affect the habitat or range of the White River Valley skipper are discussed in this section, including: (1) Water development, (2) land development, (3) livestock grazing, (4) nonnative plant invasion, (5) agriculture, (6) mining and energy development, and (7) climate change.

Water Development

Riparian communities and associated springs, seeps, and small streams comprise a small area of the Great Basin and Mojave Desert regions, but provide habitat for 70 percent of the butterfly species in these regions (Brussard and Austin 1993, cited in Brussard *et al.* 1998, p. 508). The petition suggests that the historical range for the petitioned butterfly and skipper subspecies has been reduced (WildEarth Guardians 2010, p. 6), but specific supporting information is not provided. Habitat associated with riparian and aquatic habitats, including springs and seeps, has been reduced in Nevada due to various purposes such as water diversions, development, livestock grazing, recreation, mining, and power generation (Sada *et al.* 1992, p. 76; Noss *et al.* 1995, p. 76; Brussard *et al.* 1998, pp. 531–532; Sada *et al.* 2001, pp. 11–16; Sada 2008, pp. 49–50). Commitments of water resources beyond perennial yield may result in detrimental impacts to habitats in a designated basin. Groundwater extraction that exceeds aquifer recharge may result in surface water level decline, spring drying and degradation, or the loss of aquatic habitat (Zektser *et al.* 2005, pp. 396–397).

The Nevada State Engineer (NSE) approves and permits groundwater rights in Nevada and defines perennial yield as ''The amount of usable water of a groundwater reservoir that can be withdrawn and consumed economically each year for an indefinite period of time. It cannot exceed the sum of the *Natural Recharge,* the *Artificial* (or *Induced*) *Recharge,* and the *Incidental Recharge* without causing depletion of the groundwater reservoir'' (Nevada Division of Water Planning (NDWP) undated, p. 236). The NSE estimates perennial yield for 256 basins and sub-basins (areas) in Nevada, and may ''designate'' a groundwater basin, meaning the basin's ''* * * permitted ground water rights approach or exceed the estimated average annual recharge and the water resources are being depleted or require additional administration'' (NDWP undated, p. 81). In the interest of public welfare, the NSE may declare preferred uses (such as municipal water supply, irrigation, or minimum stream flows) within such basins (NDWP, undated, pp. 81–82). Table 2 shows the perennial yield and committed groundwater rights for selected basins in Nevada applicable to this finding (Southern Nevada Water Authority (SNWA), *in litt.* 2011, p. 4).

TABLE 2—PERENNIAL YIELD AND COMMITTED GROUNDWATER RIGHTS FOR SELECTED BASINS IN NEVADA (SNWA, *in litt.* 2011, P. 4)

Hydrographic area	Perennial yield in acre-feet/year (cubic meters/year)	Committed groundwater rights in acre-feet/year (cubic meters/year)
Cave Valley	5,000–13,700 (6,167,409–16,898,701)	47–51 (57,974–62,908)
Lake Valley	12,000 (14,801,782)	17,062 (21,045,667)
Spring Valley	80,000–94,800 (98,678,548–116,934,080)	21,702–22,507 (26,769,023–27,761,976)
Steptoe Valley	70,000 (86,343,730)	114,144 (140,794,553)
White River Valley	37,000 (45,638,829)	33,077 (40,799,879)

The petition and others suggest that water development may impact the White River Valley skipper (Austin *et al., in litt.* 2000, p. 4; NatureServe 2009a, p. 2; WildEarth Guardians 2010, pp. 38–40). Lowering of the groundwater table could impact the White River Valley skipper by adversely impacting *Juncus mexicanus,* the apparent host plant for this subspecies. This plant species grows in moist habitats such as wetlands (Reed 1988, pp. 8, 10; Austin and Leary 2008, p. 11).

The NNHP estimates that approximately 50 percent of the springs and brooks in both the upper White River (which includes Ruppes Place/Boghole, where the subspecies has been located) and lower White River (which includes Sunnyside, where the subspecies has been located) has been eliminated, converted to other land uses, or degraded due to various activities including water development (NNHP 2007, p. 44). The NNHP estimates that approximately 60 percent of wetlands, springs, and brooks in Big Smoky Valley (where the subspecies has been observed) has been eliminated, converted to other land uses, or degraded by various activities including water development (NNHP 2007, p. 35). However, the NNHP (2007) does not delineate these areas on a map or define them in terms of acreage; therefore, the amount of White River Valley skipper habitat or the total number of occupied sites (made difficult because locations where the skipper has been seen are not specific) that may occur within these broad, vague areas and may be impacted by the various activities are not documented. The extent to which the various land use practices have degraded or converted these areas is also not individually delineated or quantified by NNHP (2007). Therefore, we are not able to determine the amount of overlap between the estimated wetland impacts identified by the NNHP and the distribution of the White River Valley skipper.

The White River Valley and Lake Valley hydrographic areas are ''designated'' basins by the NSE and permitted groundwater rights approach or exceed the estimated average annual recharge of the basin (Table 2; Nevada Department of Conservation and Natural Resources Web site accessed at *http://dcnr.nv.gov* on May 15 and July 24, 2012). As a ''designated'' basin, the NSE has authority under NRS § 534.120 to establish additional rules, regulations, or orders to protect that basin's water resources (SNWA, *in litt.* 2011, p. 41). If such additional rules, regulations, or orders are established in the future, they may also provide some protection to species dependent on these water resources, such as the White River Valley skipper. The NSE can declare preferred uses (such as domestic, municipal, industrial, irrigation, or other uses) in a designated groundwater basin. To date, neither the White River Valley nor Lake Valley hydrographic area has preferred uses identified.

Specifically, the petition identifies the Southern Nevada Water Authority (SNWA) proposed groundwater pumping project in central eastern Nevada as a threat to the White River Valley skipper and other butterflies (WildEarth Guardians 2010, p. 39). The following information on the SNWA groundwater pumping project is also relevant to and incorporated by this reference into the discussions of the Steptoe Valley crescentspot and the Baking Powder Flat blue butterfly later in this document.

The proposed Clark, Lincoln, and White Pine Counties Groundwater Development Project Draft Environmental Impact Statement (EIS) (BLM 2011a) addresses SNWA's proposed project to construct and operate a system of groundwater conveyance facilities, including pipelines, pumping stations, power lines, a substation, pressure reduction stations, an underground reservoir, a treatment plant, and associated ancillary facilities to import up to 176,655 acre-feet/year (afy) (217,900,737 cubic meters/year (m^3y)) from central eastern Nevada (Lincoln and White Pine Counties) to Las Vegas Valley (Clark County) (BLM 2011a, pp. 1–2; Executive Summary (ES)–1).

Valleys that may be affected by the project's groundwater drawdowns and that may also support three of the four petitioned subspecies, including the White River Valley Skipper, are Cave Valley, Lake Valley, Spring Valley, Steptoe Valley, and White River Valley. Currently, some specific features of the proposed project are known (e.g., main pipeline and associated facilities (power transmission, pump stations)) (BLM 2011a, p. 2–5). Locations of future facilities for groundwater development including number and location of wells, routes and lengths of collector pipelines, distribution lines, and access roads are not yet known (BLM 2011a, p. 2–5). The impacts of future facility development and groundwater withdrawal, which is analyzed conceptually in BLM's draft EIS, will be specifically addressed in subsequent National Environmental Policy Act (NEPA) analyses (BLM 2011a, p. 2–5).

This project is also contingent on the approval of SNWA's water rights applications by the NSE (BLM 2011a, p. ES–14). On March 22, 2012, the NSE issued four rulings on SNWA's water right applications for their proposed project totaling up to approximately 84,000 afy (103,612,476 m^3y) (Nevada Department of Conservation and Natural Resources Web site accessed at *http://dcnr.nv.gov* on April 12, 2012); this amount is a reduction from SNWA's recent request of approximately 105,000 afy (129,515,595 m^3y). These four rulings are for Spring, Cave, Dry Lake, and Delamar Valleys. Each of these applications is subject to a minimum of 2 years of biological and hydrological data collection prior to exportation; a hydrological monitoring, mitigation, and management program; a biological monitoring plan, and a computer groundwater flow model that must be updated to assist in predicting impacts. If unanticipated impacts to existing water rights, conflicts with existing domestic wells, or pumping is harmful to the public interest or is not environmentally sound, SNWA would

be required to take measures to mitigate the impacts which could include pumping curtailment. The proposed project's main pipeline is scheduled for phased construction from 2013 to 2023 (BLM 2011a, pp. ES–14–ES–15, ES–19). The entire project is scheduled to be constructed and operational by approximately 2050 (BLM 2011a, p. 2–30).

Determining whether groundwater development is a threat to springs, streams, or wetlands and therefore a potential threat to those petitioned subspecies whose habitats are associated with moist areas depends upon whether: (1) The basins in which withdrawals are occurring or proposed exceed perennial yield or have a hydrologic connection to springs and groundwater flow systems; (2) the springs, streams, or wetlands are upgradient and outside of the zone of influence of the carbonate aquifer (i.e., they occur in the alluvial aquifer or mountain block aquifer instead); or (3) the springs, streams, or wetlands are too far away from proposed pumping to be impacted (Welch *et al.* 2007, pp. 71–79). Simply comparing permitted groundwater or surface water rights to the perennial yield of a hydrographic area is inadequate to determine if a site or biotic entity will be impacted as additional factors should be considered as indicated above (SNWA, *in litt.* 2011, p. 5). There needs to be hydraulic connectivity between groundwater pumping and the site. If there is no hydraulic connectivity, a site will not be impacted. A site may only be lightly impacted if the distance is great or the transmissivity is low.

Hydraulic connectivity is influenced by hydrogeologic conditions (groundwater flow systems, groundwater flow paths, flow direction, flow barriers, etc.) (SNWA, *in litt.* 2011, p. 5). Comparing the amount of permitted groundwater rights to a basin's estimated recharge or perennial yield does not indicate that pumping exceeds the recharge or that resources are being threatened (SNWA, *in litt.* 2011, p. 5). Permit holders may not pump their entire amount due to self-imposed restrictions, agreements, or permit requirements (SNWA, *in litt.* 2011, p. 5). The manner and purpose of the water right use can also influence potential impacts from groundwater or surface withdrawal (SNWA, *in litt.* 2011, p. 6). A permit for agricultural use will not consume the entire amount since a portion is returned to the groundwater system through irrigation itself or through the inefficiency of the conveyance system (SNWA, *in litt.* 2011, p. 6). Management of groundwater development, monitoring, and conservation and mitigation measures can reduce impacts of water withdrawal to a site and species (SNWA 2011, p. 6).

Groundwater flow modeling efforts for SNWA's proposed project are described in BLM's draft EIS (BLM 2011a, pp. 3.3–80–3.3–85), as well as the uncertainties and limitations expected with regional groundwater flow models that cover a large area with complex hydrogeologic conditions (BLM 2011a, pp. 3.3–85–3.3–87). While the model is a reasonable tool for regional-scale drawdown trends (BLM 2011a, p. 3.3–86), it is not an accurate predictor for site-specific changes in flow for streams or springs (BLM 2011a, p. 3.3–87).

Two stipulations related to SNWA's proposed project were reached between SNWA and four Department of the Interior bureaus (the Service, the Bureau of Indian Affairs (BIA), the BLM, and the National Park Service (NPS)) in 2006 and 2008 (SNWA, *in litt.* 2011, p. 8). The goals of the Spring Valley Stipulation (BIA *et al.* 2006, p. 4) are to (1) manage SNWA groundwater development in Spring Valley to avoid unreasonable adverse effects to groundwater-influenced ecosystems (e.g., springs) and maintain the biological integrity and ecological health of the area of interest over the long-term, and (2) avoid effects to groundwater-influenced ecosystems within the boundary of Great Basin National Park. The goals of the Delamar Valley, Dry Lake Valley, and Cave Valley (DDC) Stipulation (BIA *et al.* 2008, Exhibit A, p. 2) are to manage the development of groundwater by SNWA in Delamar Valley, Dry Lake Valley, and Cave Valley hydrographic areas without causing (1) injury to Federal water rights and (2) any unreasonable adverse effects to Federal resources and special status species within the area of interest as a result of groundwater withdrawals in those basins by SNWA; and (3) to take actions that protect and recover special status species that are currently listed pursuant to the Act and that avoid listing of currently non-listed special-status species. Both stipulations have a list of requirements related to management, creation of technical and management teams, a consensus-based decisionmaking process, and monitoring and mitigation which, if the SNWA project is constructed, will benefit and avoid and minimize threats relevant to the White River Valley skipper, Steptoe Valley crescentspot, and the Baking Powder Flat blue butterfly (SNWA, *in litt.* 2011, pp. 8–10).

In addition to the two stipulations, an Adaptive Management Plan has been prepared by SNWA for its proposed project. It includes a list of measures that can be implemented based on the environmental resource impacted, the severity, and likely cause(s) (BLM 2011a, Appendix E, Appendix A, pp. A–46–A–57). The Adaptive Management Plan acknowledges the uncertainties in predicting effects of groundwater withdrawal on hydrologic flow systems. The plan will identify and implement practicable adaptive management measures to address adverse environmental impacts relevant to the three butterfly and skipper subspecies including avoiding, minimizing, or mitigating: (1) Adverse environmental impacts to groundwater-dependent ecosystems and their biological communities, (2) effects of actions that could contribute to listing of species under the Act, and (3) adverse environmental impacts to water features that support fish and wildlife species. Specific actions to be implemented would be determined at a later date based on data collection and monitoring results.

The proposed project construction and operation may impact White River Valley skipper habitat (BLM 2011a, p. 3.6–27). The White River Valley skipper was not detected in the project's ROW surveys of groundwater development areas (BLM 2011a, pp. 3.6–18–3.6–19; 3.6–94). Based on the groundwater flow model estimate for 200 years post full buildout, the skipper's occupied areas at Ruppes Place/Boghole (SNWA, *in litt.* 2011, p. 17) and areas at the Flag Springs Complex/Sunnyside/Kirch Wildlife Management Area (SNWA, *in litt.* 2011, p. 19) are located outside of the greater than 10-foot (3.0-m) drawdown contour (or any other contour range) (BLM 2011a, p. 3.3–102). However, based on the model estimate, there is a potential 17 percent flow decrease at 200-years post full buildout at Flag Springs 3 (BLM 2011a, p. 3.3–108). The Flag Springs Complex and Sunnyside Creek are biological monitoring sites under the DDC Stipulation and are hydrologic monitoring sites under the Hydrologic Monitoring and Mitigation Plan for Delamar, Dry Lake, and Cave Valleys (Exhibit A of the DDC Stipulation (BIA *et al.* 2008,)) (SNWA, *in litt.* 2011, p. 19), which would be monitored for early signs of impacts to these areas with mitigating measures available to reduce adverse impacts to the area and thus to the White River Valley skipper. While the Service recognizes that uncertainties remain regarding potential impacts to water resources, all but one location occupied by White River Valley skipper

occur outside of the estimated drawdown contour in the White River Valley.

Based on the groundwater flow model estimate for 200 years post full buildout (BLM 2011a, p. 3.3–102), an unknown portion of this skipper's occupied habitat is located within the greater than 10-foot (3.0-m) drawdown contour and could be impacted at Blind Spring in Spring Valley. Because its apparent larval host plant, *Juncus mexicanus,* is a wetland species, habitat for the White River Valley skipper could be affected by the SNWA water development project (BLM 2011a, p. 3.6–74). Though monitoring is occurring using surface-water gages, groundwater monitoring wells, and a piezometer on or near Cleve Creek (Spring Valley), possible future project impacts to White River Valley skipper in Spring Valley are unclear (SNWA, *in litt.* 2011, p. 20). As indicated earlier, there is uncertainty whether the White River Valley skipper is actually found in Spring Valley (Austin and McGuire 1998, pp. 778–779).

Based on the recent water right application rulings issued by the NSE for reduced pumping amounts in Spring Valley (Nevada Department of Conservation and Natural Resources Web site accessed at *http://dcnr.nv.gov* on April 12, 2012), it appears that potential impacts at Blind Spring would be reduced. Additionally, these recent rulings require that the pumping in Spring Valley occur in stages with an initial pumping of 38,000 afy (46,872,311.0 m^3y) for 8 years and the full amount of approximately 61,000 afy (75,242,393.2 m^3y) being pumped only if previous stages indicate it is appropriate based on data collection and management plans indicated above (biological and hydrological data collection; hydrological monitoring, mitigation, and management program; biological monitoring plan, and a computer groundwater flow model) (Nevada Department of Conservation and Natural Resources Web site accessed at *http://dcnr.nv.gov* on April 12, 2012).

Lake Valley is also shown to be impacted by pumping (BLM 2011a, p. 3.3–102; SNWA, *in litt.* 2011, pp. 20–21), but as described in the *Distribution and Habitat* section, there is uncertainty whether the White River Valley skipper occurs in Lake Valley (Austin and McGuire 1998, pp. 778–779). Without specific locations indicated for specimens collected in Lake Valley, it is difficult to determine possible impacts to this subspecies from SNWA's proposed project in this valley. We conclude that SNWA's proposed groundwater development project would not impact populations of this subspecies in Big Smoky Valley as these populations occur too far west of the proposed project area and occur outside of the area(s) that would be affected by the groundwater project.

While human water demands have impacted wetland areas in the White River and Big Smoky Valleys, the White River Valley skipper is rather widespread throughout its known distribution in these valleys. Other locations (Spring Valley and Lake Valley) where the subspecies may be found are tentative locations based on Austin and McGuire (1998, pp. 778–779). The possible host plant for the White River Valley skipper, *Juncus mexicanus,* has not been confirmed as the host plant at any location where the skipper has been observed (Austin and Leary 2008, p. 11). Because of these uncertainties related to some of the subspecies' reported locations as well as its host plant, overall potential impacts due to SNWA's proposed project are difficult to determine. However, based on the possible impact to only one occupied White River Valley skipper location (Flag Springs 3), the recent water right application rulings issued by the NSE for reduced pumping amounts in Spring Valley and the presumed reduction in potential impacts at Blind Spring as well as the initial staged pumping in Spring Valley (Nevada Department of Conservation and Natural Resources Web site accessed at *http://dcnr.nv.gov* on April 12, 2012), we do not anticipate major impacts to the White River Valley skipper from SNWA's proposed project.

In addition, the SNWA water project has multiple design features developed to reduce adverse effects to groundwater-influenced ecosystems. The Spring Valley Stipulation (BIA *et al.* 2006, Exhibit A, p. 10), which was negotiated between SNWA, the Service, BIA, BLM, and the NPS, requires an adaptive management approach in implementation of the water development project, monitoring, mitigation (may include geographic redistribution, reduction, or cessations in groundwater withdrawals; provision of consumptive water supply requirements using surface and groundwater sources; augmentation of water supply for Federal water rights and resources using surface and groundwater sources; and other measures agreed to by the parties or the NSE consistent with the stipulation), creation of technical and management teams, and a consensus-based decisionmaking process. These project design features will likely result in reduced potential effects of the project on habitat suitability for the White River Valley skipper.

While water development has occurred in parts of the White River Valley skipper's range (White River Valley and Big Smoky Valley), we found no information indicating effects from past water development have resulted in loss or degradation of White River Valley skipper habitat. The SNWA water project could affect groundwater flow in certain parts of the White River Valley skipper's known and possible range (White River Valley, Spring Valley, and Lake Valley), but not in other parts of its range (Big Smoky Valley). The SNWA water project also has multiple design features developed to reduce adverse effects to groundwater-influenced ecosystems. At this time, the best available information does not indicate that water development is modifying the White River Valley skipper's habitat to the extent that it represents a threat to this subspecies now or in the future.

Land Development

Different levels of development can greatly alter the amount of larval host plants and adult nectar sources for butterflies, affecting directly the distribution and abundance of individual species and indirectly the microclimate (Blair and Launer 1997, p. 119). Blair and Launer (1997, p. 116) found the abundance of the 23 butterfly species included in their California study varied across the development gradient from natural to urban. The butterfly community contained fewer species in more developed sites compared to the relatively undeveloped oak-woodland community (Blair and Launer 1997, p. 117). Species richness and diversity was greatest at moderately disturbed sites while the relative abundance decreased from the natural to the urban areas (Blair and Launer 1997, p. 113).

Bock *et al.* (2007, pp. 40–41) found that low-density housing developments in former ranch lands of Arizona impacted butterfly species abundance and variety to a lesser degree than in developed urban or suburban landscapes as documented elsewhere by others. Summerville and Crist (2001) studied the effects of habitat fragmentation on patch use by butterflies and skippers. They found that butterflies and skippers select habitat based on quantity (size) and quality (flower availability); moderately-sized patches of high quality may function equally to larger patches of lower quality (Summerville and Crist 2001, p. 1367). Species did not respond

equally to fragmentation, with rare species no longer using patches where less than 40 percent of the habitat remained (Summerville and Crist 2001, p. 1365). While some common species appeared unaffected by fragmentation, other common species were significantly affected (Summerville and Crist 2001, p. 1365).

The petition suggests that land development may impact this subspecies (WildEarth Guardians 2010, pp. 38–40). A portion of the springs and wetlands in the upper and lower White River and Big Smoky Valleys have been eliminated, converted, or degraded due to land uses, such as land development (NNHP 2007, pp. 35, 44). The NNHP (2007) does not delineate these areas in terms of location, acreage, or by land use practice. Although the White River Valley skipper is known to occur in several locations within these valleys, the number of sites or the amount of White River Valley skipper habitat that may be impacted by land development is not documented.

The best available information does not indicate that land development is occurring in habitat that is occupied by the White River Valley skipper. We did not receive any information as a result of our 90-day petition finding notice, nor did we locate information indicating that land development is negatively impacting the habitat or the known populations of the White River Valley skipper. Therefore, the best available information does not indicate that land development is modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Livestock Grazing

Potential impacts of livestock grazing include selective grazing for native plant species and reducing cover, trampling of plants and soil, damage to soil crusts, reduction of mycorrhizal fungi, increases in soil nitrogen, increases in erosion and runoff, increases in fire frequency, and contribution to nonnative plant introductions (Fleishner 1994, pp. 631–635; Belsky *et al.* 1999, pp. 8–11; Paige and Ritter 1999, pp. 7–8; Belsky and Gelbard 2000, pp. 12–18; Sada *et al.* 2001, p. 15).

In relation to butterflies, as noted in the petition, livestock grazing can impact host plants as well as nectar sources, trample larvae and the host or nectar plants, degrade habitats, and assist in the spread of nonnative plant species that can dominate or replace native plant communities and thereby impact larval host and adult nectar species (WildEarth Guardians 2010, pp. 22–23). While the petition states that light or moderate grazing can assist in maintaining butterfly habitats (WildEarth Guardians 2010, p. 23), heavy grazing is considered incompatible with the conservation of some butterflies (Sanford 2006, p. 401; Selby 2007, pp. 3, 29, 33, 35).

Kruess and Tscharntke (2002, p. 1570) found an increase of species richness and abundance from pastures to ungrazed grasslands in Germany for grasshoppers, butterflies, bees, and wasps. Decreased grazing on pastures resulted in increased species richness and abundance for adult butterflies. Vogel *et al.* (2007, p. 78) evaluated three restoration practices in prairie habitat in Iowa on butterfly communities and found that the total butterfly abundance was highest in areas restored through burning and grazing, and was lowest in areas that were only burned. Species richness did not differ among the practices. Species diversity was highest in areas that were only burned. Individual butterfly species responses to the restoration practices were variable.

BLM regulatory authority for grazing management is provided at 43 CFR part 4100 (Regulations on Grazing Administration Exclusive of Alaska). Livestock grazing permits and leases contain terms and conditions determined by BLM to be appropriate to achieve management and resource condition objectives on the public lands and other lands administered by the BLM, and to ensure that habitats are, or are making significant progress toward, being restored or maintained for BLM special status species (43 CFR 4180.1(d)). Grazing practices and activities include the development of grazing-related portions of implementation or activity plans, establishment of terms and conditions of permits, leases, and other grazing authorizations, and range improvement activities such as vegetation manipulation, fence construction, and development of water for livestock.

BLM grazing administration standards for a particular state or region must address habitat for endangered, threatened, proposed, candidate, or special status species, and habitat quality for native plant and animal populations and communities (43 CFR 4180.2(d)(4) and (5)). The guidelines must address restoring, maintaining, or enhancing habitats of BLM special status species to promote their conservation, and maintaining or promoting the physical and biological conditions to sustain native populations and communities (43 CFR 4180.2(e)(9) and (10)).

The petition and others suggest that livestock grazing may impact this subspecies (NatureServe 2009a, p. 2; WildEarth Guardians 2010, pp. 38–40), but specific information supporting this claim is not provided. A portion of the springs and wetlands in the upper and lower White River and Big Smoky Valleys have been eliminated, converted, or degraded due to other land uses, such as livestock grazing (NNHP 2007, pp. 35, 44). The NNHP (2007) does not delineate these areas in terms of location, acreage, or by land use practice. The type locality (1 mi (1.6 km) north of the Nye County line) is on private and BLM lands. It is not known how livestock grazing is managed on the private lands, but general knowledge of the area indicates it is not heavily grazed during the late spring to early summer period (Lowrie *in litt.* 2012, p. 1). The Ruppes/Boghole location is on private and BLM lands. It is not known how grazing is managed on the private lands, but the area has been grazed in the past (Lowrie *in litt.* 2012, p. 7), and the site appears to continue to provide suitable habitat for the skipper (Lowrie *in litt.* 2012, p. 7).

The type locality and the Ruppes/Boghole sites are surrounded by three BLM grazing allotments (Dee Gee Spring to the east, North Cove to the west; and Swamp Cedar to the northwest) (Lowrie *in litt.* 2012, p. 1), which may support limited suitable habitat (Lowrie *in litt.* 2012, pp. 5–6). The allotments are permitted for cattle grazing during the late winter to early summer, though none are grazed the entire period (Lowrie *in litt.* 2012, pp. 1–3). The animal unit months have generally been reduced since 1999 for all three allotments; each allotment has received growing season rest in various years since 1999 (Lowrie *in litt.* 2012, pp. 3–5).

The Kirch WMA encompasses about 14,800 ac (5,989 ha) of public State lands with five major reservoirs (*www.NDOW.org,* p. 6; accessed April 27, 2012). Based on observations in 2005 when the White River Valley skipper was observed on the WMA, Boyd (pers. comm. 2012b, p. 1) thought grazing by feral horses may have occurred at the south end of Tule Reservoir. The area is primarily a recreational area with limited fishing, hunting, camping, and OHV use during certain times.

The presumed larval host plant, *Juncus mexicanus,* is common and can be found in several Nevada counties in moist habitats. The adults likely feed on a variety of plants flowering during their flight period. The best available information does not indicate declines in larval or adult plant species in

occupied White River Valley skipper habitat due to livestock grazing. Activities involving grazing management within any suitable White River Valley skipper habitat on BLM lands are addressed in consideration of the Ely District Record of Decision and Approved Resource Management Plan (RMP) (BLM 2008a) (see Factor D discussion under White River Valley skipper), BLM's authority under Regulations on Grazing Administration Exclusive of Alaska, BLM's 6840 Manual (BLM 2008b) (see Factor D discussion under White River Valley skipper), and possibly NEPA.

We did not receive any additional information as a result of our 90-day petition finding notice, nor did we locate information indicating that livestock grazing is negatively impacting the habitat or White River Valley skipper populations. Thus, the best available information does not indicate that livestock grazing is modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Nonnative Plant Invasion

Nonnative species can present a range of threats to native ecosystems, including extinction of native species, alteration of ecosystem functions, and introduction of infectious diseases (Schlaepfer *et al.* 2011, p. 429). However, not all nonnative species cause economic or biological harm and only a small percentage become established and result in harmful effects (Williamson and Fitter 1996 and Davis 2009, cited in Schlaepfer *et al.* 2011, p. 429). Nonnative species can provide a conservation value, for example, by providing food or habitat for rare species (Schlaepfer *et al.* 2011, p. 431).

The introduction of nonnative or invasive plant species or types of vegetation (forbs, shrubs, grasses, etc.) can threaten butterfly populations because these introduced species may compete with and decrease the quantity and quality of larval host plants and adult nectar sources (76 FR 12667, March 8, 2011). This competition resulting in loss of host plants and nectar sources has been observed with the Quino checkerspot butterfly (*Euphydryas editha quino*) (62 FR 2313, January 16, 1997) and Fender's blue butterfly (*Icaricia icarioides fenderi*) (65 FR 3875, January 25, 2000). However, Graves and Shapiro (2003, p. 430) found that California butterflies use numerous nonnative plant species positively and negatively. Some of them are using these nonnative plant species for depositing eggs and feeding, which has led to range expansions, increased population size, extension of the breeding season as well as the opportunity to remain in an area where the native host plant species has been lost. Nonnative plant species have also allowed butterfly species from outside the State to invade and breed in California. There are also instances where egg laying has occurred on a nonnative plant species that is toxic to the larvae.

There has been an increased focus on the roles that State, county, and private entities have in controlling invasive plants. For example, the Noxious Weed Control and Eradication Act of 2004 is intended to assist eligible weed management entities to control or eradicate harmful nonnative weeds on both public and private lands and is an amendment to the Plant Protection Act of 2000 (1 U.S.C. 7701 *et seq.,* p. 1) which, in part, determined that detection, control, eradication, suppression, prevention, and retardation of the spread of noxious weeds is necessary to protect the agriculture, environment, and economy in the United States. Additionally, Executive Order 13112 was signed on February 3, 1999, establishing an interagency National Invasive Species Council in charge of creating and implementing a National Invasive Species Management Plan. The Management Plan directs Federal efforts, including overall strategy and objectives, to prevent, control, and minimize invasive species and their impacts (National Invasive Species Council 2008, p. 5). However, the Executive Order also directs the Council to encourage planning and action at local, tribal, state, regional, and ecosystem levels to achieve the goals of the National Invasive Species Management Plan, in cooperation with stakeholders (e.g., private landowners, states) and existing organizations addressing invasive species.

Noxious and invasive weed treatments on BLM lands involving reseeding can occur through the Emergency Stabilization and Burned Area Rehabilitation Program, a program available to BLM districts (including Ely and Winnemucca Districts) which evaluates conditions following wildland fire. Actions can be taken to protect soils, riparian areas, cultural resources, as well as to reduce potential invasive plant species spread. Invasive plant species control is a management objective stated in many RMPs, including the RMPs for Ely and Winnemucca Districts.

BLM commonly uses herbicides on lands to control invasive plant species. In 2007, BLM completed a programmatic EIS (BLM 2007a) and Record of Decision (BLM 2007b) for vegetation treatments on BLM-administered lands in the western United States. This program approves the use of 4 new herbicides, provides updated analyses of 18 currently used herbicides, and identifies herbicides that the BLM will no longer use on public lands. Information is unavailable on how frequently the programmatic EIS has been used for most states or whether actions implemented under this EIS have been effective; and while not authorizing any specific on-the-ground actions, it guides the use of herbicides for field-level planning. Site-specific NEPA analysis is still required at the project level (BLM 2007a, pp. ES–1–ES–2).

A portion of the springs and wetlands in the upper and lower White River and Big Smoky Valleys has been eliminated, converted, or degraded due to other land uses, such as nonnative species invasion (NNHP 2007, pp. 35, 44). It is likely nonnative and invasive plant species occur to some extent because numerous nonnative and invasive plant species occur in Nevada, though this has not been quantified within the habitat of the White River Valley skipper. The White River Valley skipper is possibly associated with *Juncus mexicanus* as its larval host plant which is common in the White River Valley and other moist habitats in Nevada. Nonnative plant species do not appear to be competing with *Juncus mexicanus,* causing its decline or the decline of potential adult nectar plants.

Activities involving nonnative plant species management within the White River Valley skipper habitat on BLM lands would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), BLM's authority under Regulations on Grazing Administration Exclusive of Alaska, the Plant Protection Act of 2000, BLM's programmatic EIS for vegetation treatments on BLM's administered lands in the western United States (BLM 2007a), BLM's 6840 Manual (BLM 2008b), and possibly NEPA (see Factor D). Activities involving nonnative plant species management and control on private lands within the White River Valley habitat could also be addressed in consideration of the Plant Protection Act of 2000. We did not receive any information as a result of the 90-day petition finding notice, nor did we locate information indicating that nonnative plant species in general, or that a specific nonnative or invasive plant species, actually occur in and are negatively impacting the habitat and

populations of the White River Valley skipper. Consequently, the best available information does not indicate that nonnative plant species are modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Agriculture

Agricultural practices can eliminate suitable habitat, resulting in losses of butterfly species. Fleishman *et al.* (1999, pp. 214–215) states that artificial riparian areas such as irrigated croplands support fewer butterfly species than native habitats; that most butterfly species found in agricultural sites are widespread generalists often found in disturbed sites; that less common species, as well as those restricted in native larval host plants, are less likely to or do not occur in agricultural sites, and though agriculture can provide habitat for some butterfly species, these modified habitats cannot replace the natural undisturbed riparian ecosystems.

The petition and others suggest that the White River Valley skipper may be impacted by agriculture (NatureServe 2009a, p. 2; WildEarth Guardians 2010, pp. 38–40), though specific information is not provided to support this claim. A portion of the springs and wetlands in the upper and lower White River and Big Smoky Valleys has been eliminated, converted, or degraded due to other land uses, including agriculture (NNHP 2007, pp. 35, 44). The best available information does not indicate that agriculture is occurring in areas that are occupied by the White River Valley skipper. We did not receive any information as a result of the 90-day petition finding notice, nor did we locate information that indicates agriculture is negatively impacting the White River Valley skipper populations, host plants, or nectar sources. Thus, the best available information does not indicate that agriculture is modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Mining and Energy Development

Possible impacts to butterflies due to mining exploration and development, renewable and nonrenewable energy exploration and development, as well as associated power line installation include loss of habitat, habitat fragmentation, increased dispersal barriers, increases in predators, and disturbance due to human presence.

The Federal Land Policy and Management Act of 1976 (FLPMA) (43 U.S.C. 1701 *et seq.*) is the primary Federal law governing most land uses on BLM administered lands. Section 102(a)(8) of FLPMA specifically recognizes that wildlife and fish resources are included as uses for which these lands are to be managed. BLM has management and permitting authorities to regulate and condition oil and gas lease permits under FLPMA and the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*). BLM usually incorporates stipulations as a condition of issuing leases. The BLM's planning handbook has program-specific guidance for fluid materials (including oil and gas) that specifies that RMP decision-makers will consider restrictions on areas subject to leasing, including closures, and lease stipulations (BLM 2000, Appendix C, p. 16). The handbook also specifies that all stipulations must have waiver, exception, or modification criteria documented in the plan, and indicates that the least restrictive constraint to meet the resource protection objective should be used (BLM 2000, Appendix C, p. 16).

There are specific, major power line installation projects in eastern Nevada. The Southwest Intertie Project, proposed by Idaho Power Company, involves installation of an approximately 520-mi (836.7–km) 500-kilovolt (kV) transmission line from Shoshone, Idaho, to Las Vegas, Nevada (BLM 1993, p. 1; 2008c, p. 1). Though the White River Valley skipper is known from the project area, impacts to it from this project were not identified (BLM 1993, pp. 3–75–3–89). The Record of Decision approving this action was published in 2008 (BLM 2008c). The One Nevada Transmission Line Project, proposed by NV Energy, involves construction of a 236-mile (252.3–km) 500-kV transmission line with telecommunication and appurtenant facilities, construction and expansion of substations, and a loop in the existing Falcon-Gonder transmission line in White Pine, Nye, Lincoln, and Clark Counties (BLM 2010c, p. ES–2). The White River Valley skipper was not observed during wildlife surveys conducted for this project (BLM 2010c, Appendix 3D, Table 2, pp. 1–5). A Record of Decision approving this project was published in 2011 (BLM 2011b).

A Programmatic EIS for the Designation of Energy Corridors on Federal Land in the 11 Western States was published in 2008 (Department of Energy (DOE) and BLM 2008). This EIS addresses section 368 of the Energy Policy Act of 2005, which directs the designation of corridors for oil, gas, and hydrogen pipelines, and electricity transmission and distribution facilities on Federal lands. Federal agencies are required to conduct environmental reviews to complete the designation and incorporate the designated corridors into agency land use and RMPs or equivalent plans. This EIS proposes only designation of corridors, and no environmental impacts are attributed to this action. Section 368 does not require agencies to consider or approve specific projects, applications for ROW, or other permits within any designated corridor, nor does section 368 direct, license, or permit any activity on the ground. Any interested applicant would need to apply for a ROW authorization, and the agency would consider each application under the requirements of various laws and related regulations (DOE and BLM 2008, pp. S–1–S–2). The proposed action would designate more than 6,000 mi (9,600 km) with an average width of 3,500 ft (1 km) of energy corridors across the West (DOE and BLM 2008, p. S–17). Federal land not presently in transportation or utility rights-of-way is proposed for use in Nevada (373 mi or 600 km) (DOE and BLM 2008, p. S–18). The Record of Decision for this action was published in 2009 (BLM 2009b). BLM RMPs will be amended as appropriate to address these issues (BLM 2009b, pp. 31–34).

The White River Valley skipper may be impacted by mining and energy development according to the petition (WildEarth Guardians 2010, p. 39), though specific information is not provided to support this claim. The NNHP indicates that a portion of the springs and wetlands in the upper and lower White River and Big Smoky Valleys have been eliminated, converted, or degraded due to other land uses, including mining and energy development, but these areas were not delineated (NNHP 2007, pp. 35, 44). Actions involving mineral and energy development within White River Valley skipper habitat on BLM-administered lands would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), the FLPM A of 1976, the Mineral Leasing Act of 1920, BLM's 6840 Manual (BLM 2008b), and NEPA. The best available information does not indicate that mining and energy development are occurring in occupied White River Valley skipper habitat. We did not receive any information as a result of the 90-day petition finding notice, nor did we locate information that indicates mining or energy development is negatively impacting the subspecies' habitat or White River Valley skipper populations. Thus, the best available information does not

indicate that mining and energy development are modifying the subspecies' habitat to an extent that they represent a threat to this subspecies now or in the future.

Climate Change

The effects on species and ecosystems due to climate change are numerous. For example, there are direct effects due to different temperatures on the physiology of an organism (McCarty 2001, p. 321). Precipitation amounts directly affect vegetation distribution (McCarty 2001, p. 321). Climate can also have indirect effects on species through the sensitivity of habitats or food supply to temperature and precipitation (McCarty 2001, p. 321).

Climate change is expected to affect the timing and flow of streams, springs, and seeps in the Great Basin (Chambers 2008a, p. 20), which support the moist meadows upon which some butterflies depend (WildEarth Guardians 2010, p. 9). Earlier spring snowmelt appears to be affecting the date of blooming for some plants in the Great Basin (Chambers 2008b, p. 29). As stated in the petition, potential changes in the bloom date of meadow plants due to climate change could affect the use of these plants by butterflies (WildEarth Guardians 2010, p. 9). Drought in the Great Basin could negatively affect riparian habitats, moist meadows, and similar habitats, especially those already stressed by other factors (Major 1963 cited by West 1983, p. 344). As climate changes, droughts may become more common in the Great Basin (Chambers *et al.* 2008, p. 3) and American Southwest (Seager *et al.* 2007, pp. 1181–1183), modifying future precipitation (WildEarth Guardians 2010, p. 8). Increased carbon dioxide may favor invasion of annual grasses such as the nonnative *Bromus tectorum* (cheatgrass) (Smith *et al.* 2000, pp. 79, 81). Increased temperatures and carbon dioxide levels have various effects on plant growth and chemistry, which may affect insect abundance and persistence (Stiling 2003, pp. 486–488). Increasing temperatures can also affect insect development and reproduction (Sehnal *et al.* 2003, pp. 1117–1118).

The rate at which a species can adapt and change its boundaries may be vital to understanding how species will respond to climate change (McCarty 2001, p. 327). Studies of groups of species show most are responding to climate change; what is also important is to study those that do not seem to be responding (McCarty 2001, pp. 327–328). These species may be less sensitive to temperature, or they may be unable to respond to current moderate increases in temperature (McCarty 2001, p. 328).

According to Loarie *et al.* (2009, p. 1052), species and ecosystems will need to shift northward an average of 0.3 mi (0.42 km) per year to avoid the effects of increasing temperatures associated with climate change. Loarie *et al.* (2009, p. 1053) also state that distances may be greater for species in deserts and xeric (dry habitat) shrublands, where climate change is predicted to have greater effect than in some other ecosystems. The petition asserts that it is unlikely that small, isolated populations of butterflies in the Great Basin, dependent on reduced habitats, will be able to shift to other habitats in the face of climate change (WildEarth Guardians 2010, p. 9). Many species in the Great Basin have specialized habitat requirements and limited mobility, which influence their ability to adapt to anthropogenic environmental change (Fleishman 2008, p. 61). The petition states that species and habitats already stressed by other factors may be less able to cope with climate change (WildEarth Guardians 2010, p. 10).

Certain butterflies have shown an ability to adjust to changing climatic conditions. Parmesan (2006, p. 643) reported that butterflies frequently show a correlation between spring temperatures and dates of first appearance. According to Forister and Shapiro (2003 cited in Parmesan 2006, p. 643), 70 percent of 23 species of central California butterflies advanced their first flight date by an average of 24 days over 31 years. Parmesan (1996, pp. 765–766) showed a range shift for Edith's checkerspot butterfly (*Euphydryas edithia*); this butterfly's ''population extinctions'' occurred in relation to both latitude and elevation showing a shift of extant population locations northward and upward.

The average temperature in the Great Basin has increased 0.6–1.1 degrees Fahrenheit (0.3–0.6 degrees Celsius) during the last 100 years (Chambers 2008b, p. 29) and is expected to increase by 3.6–9.0 degrees Fahrenheit (2–5 degrees Celsius) over the next century (Cubashi *et al.* 2001, cited Chambers 2008b, p. 29).

Recent projections of climate change in the Great Basin over the next century include: Increased temperatures, with an increased frequency of extremely hot days in summer; more variable weather patterns and more severe storms; more winter precipitation in the form of rain, with potentially little change or decreases in summer precipitation; and earlier, more rapid snowmelt (U.S. Environmental Protection Agency 1998, pp. 1–4; Chambers and Pellant 2008, pp. 29–33). While the petition asserts that climate change may impact this subspecies (WildEarth Guardians 2010, pp. 38–40), it is difficult to predict local climate change impacts, due to substantial uncertainty in trends of hydrological variables, limitations in spatial and temporal coverage of monitoring networks, and differences in the spatial scales of global climate models and hydrological models (Bates *et al.* 2008, p. 3).

We found no information on how climate change may impact the White River Valley skipper's potential host plant, *Juncus mexicanus,* or adult nectar sources. In general, increasing temperatures and drought frequency, more winter precipitation in the form of rain, possible decreases in summer rain, and earlier, rapid snowmelt could impact the host plant by causing physiological stress, altering phenology, reducing recruitment events, and reducing seed establishment. However, at this time, it is difficult to predict local climate change impacts to *Juncus mexicanus* or to White River Valley skipper's adult nectar sources, and how individual plant species will react to climate change. Thus, while information indicates that climate change has the potential to affect vegetation and habitats used by the White River Valley skipper in the Great Basin, there is much uncertainty regarding which habitat attributes could be affected, and the timing, magnitude, and rate of their change as it relates to this subspecies.

We did not receive any information as a result of our 90-day petition finding notice, nor did we locate specific information that indicates climate change is negatively impacting White River Valley skipper populations or their habitats. Therefore, the best available information does not indicate that climate change is modifying the subspecies' habitat to an extent that it represents a threat to this subspecies now or in the future.

Summary of Factor A

While several activities such as water and land development, livestock grazing, nonnative species invasion, agriculture, and mining and energy development may be impacting a portion of wetland areas in White River and Big Smoky Valleys, available information does not indicate that these impacts are occurring in occupied White River Valley skipper habitat. The available information does not indicate that these activities or climate change are negatively impacting White River Valley skipper populations. Since the White River Valley skipper may be associated with wetland areas, impacts

from water development could impact the subspecies; however, all but one occupied skipper locations are outside the greater than 10-foot (3.0-m) drawdown contour for the SNWA proposed project, and major impacts are not anticipated for this subspecies in White River Valley. Other locations in Spring and Lake Valleys that may support the subspecies are located within the greater than 10-foot (3.0-m) drawdown contour for the SNWA proposed project but potential impacts from groundwater pumping would be reduced due to the recent NSE rulings. While information indicates that climate change has the potential to affect vegetation used by this subspecies, much uncertainty remains regarding which plant attributes may be affected, and the timing, magnitude, and rate of their change.

We conclude based on the best scientific and commercial information available that the present or threatened destruction, modification, or curtailment of its habitat or range does not currently pose a threat to the White River Valley skipper, nor is it likely to become a threat to the subspecies in the future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Rare butterflies and moths are prized by collectors, and an international trade exists for insect specimens for both live and decorative markets, as well as the specialist trade that supplies hobbyists, collectors, and researchers (Morris *et al.* 1991, pp. 332–333; Williams 1996, pp. 30–37). The specialist trade differs from both the live and decorative market in that it concentrates on rare and threatened species (U.S. Department of Justice 1993, pp. 2–3). In general, the rarer the species, the more valuable it is (Morris *et al.* 1991, p. 333).

Collecting can be a threat to some butterfly species, such as the Fender's blue butterfly (65 FR 3875). Generally, small populations are at the highest risk. Overcollecting and repeated handling and marking of females for scientific purposes in low abundance years can negatively impact populations through loss of reproductive individuals and genetic variability (65 FR 3875). Collection of dispersing females can also reduce the probability that new colonies will be founded. Collectors may serve as a threat because they may not recognize when butterfly populations are becoming depleted below a threshold necessary for survival or recovery (65 FR 3875).

We are unaware of any studies analyzing impacts of removal of individuals from populations of the White River Valley skipper. According to Austin and McGuire (1998, p. 778), 20 males and 14 females were collected between 1984 and 1989 at one site. No additional information is known about the numbers of specimens collected in the past, and we are not aware of any ongoing or current collecting of this subspecies. Given the low number of individuals collected over this 6-year period, the length of time since the collections were made, and the lack of information about the relative impact to the populations, the available information does not indicate that collection may be a threat to this subspecies.

We found no information indicating that overutilization has led to the loss of populations or a significant reduction in numbers of individuals for this subspecies. Therefore, we conclude based on the best scientific and commercial information available that overutilization for commercial, recreational, scientific, or educational purposes does not currently pose a threat to the White River Valley skipper, nor is it likely to become a threat in the future.

Factor C. Disease or Predation

We found no information on the incidence of disease in the White River Valley skipper.

We assume predation by other species, such as birds or insects, on eggs, larvae, pupae, or adult White River Valley skipper occurs, but we found no information indicating that predation levels are any greater than levels typical of the biological community in which the White River Valley skipper occurs.

Available information does not indicate that there are impacts from disease or predation on the White River Valley skipper. Therefore, we conclude based on the best scientific and commercial information available that disease or predation does not currently pose a threat to the White River Valley skipper, nor is either likely to become a threat to the subspecies in the future.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

This discussion under Factor D applies to all four subspecies and is incorporated by this reference into the Factor D discussion for Steptoe Valley crescentspot, Baking Powder Flat blue butterfly, and bleached sandhill skipper.

Nevada does not have the ability to protect invertebrates under current State law pertaining to wildlife. The Nevada Department of Wildlife is limited in its ability to protect insects under current regulations (Nevada Revised Statutes (NRS)). Nevada State law protects species that the Wildlife Commission determines to be imperiled (NRS 503.585). While some invertebrates such as mollusks and crustaceans may be protected because they can be classified under wildlife (NRS 501.110), butterflies are not covered under this statute. No butterfly or skipper species are currently protected by State law in Nevada (Nevada Administrative Code 503.020–503.080). Therefore, no regulatory protection is offered under Nevada State law for the White River Valley skipper, Steptoe Valley crescentspot, Baking Powder Flat blue butterfly, or bleached sandhill skipper. Although not protected by State law, the best available information, as discussed in Factor B, does not indicate that collection or other forms of overutilization is a threat to the White River Valley skipper.

As discussed earlier under Factor A, the NSE approves and permits groundwater rights in Nevada. A basin's perennial yield is considered during this process, and the NSE may ''designate'' a groundwater basin indicating that the water resources in that basin are being depleted or require additional administration. The White River Valley and the Lake Valley hydrographic areas are ''designated'' basins, and the NSE has authority to establish additional rules, regulations, or orders to protect the basin's water resources. These additional rules, regulations, or orders, if established in the future, may provide some protection to species dependent on these water resources, such as the White River Valley skipper. The best available information does not indicate that water development is impacting White River Valley skipper populations.

As discussed above, a portion of habitat for the White River Valley skipper occurs on lands administered by BLM, a Federal land-management agency within the U.S. Department of the Interior. Numerous laws, regulations, and policies have been developed to assist the agency in management of these lands.

All Federal agencies are required to adhere to NEPA for projects they fund, authorize, or carry out. The Council on Environmental Quality's regulations for implementing NEPA (40 CFR 1500–1518) state that agencies shall include a discussion on the environmental impacts of the various project alternatives, any adverse environmental effects which cannot be avoided, and any irreversible or irretrievable commitments of resources involved (40 CFR 1502). Additionally, activities on non-Federal lands are subject to NEPA

if there is a Federal nexus. NEPA is a disclosure law and does not require subsequent minimization or mitigation measures by the Federal agency involved. Although Federal agencies may include conservation measures for sensitive species as a result of the NEPA process, any such measures are typically voluntary in nature and are not required by the statute.

BLM's RMPs are the basis for all actions and authorizations involving BLM-administered land and resources. They establish allowable resource uses; resource conditions, goals, and objectives to be attained; program constraints and general management practices needed to attain the goals and objectives; general implementation sequences; and intervals and standards for monitoring and evaluating each plan to determine its effectiveness and the need for amendment or revision (43 CFR 1601.0–5(k)).

RMPs provide a framework and programmatic guidance for site-specific activity plans. These plans address livestock grazing, oil and gas field development, travel management (managing vehicle routes and access), wildlife habitat management, and other activities. Actions potentially affecting the White River Valley skipper, as well as the Steptoe Valley skipper and Baking Powder Flat blue butterfly, would be addressed under the Ely District Record of Decision and Approved RMP (BLM 2008a); actions potentially affecting the bleached sandhill skipper would be addressed under the Winnemucca District RMP and EIS (BLM 2010a). Activity plan decisions normally also require NEPA (42 U.S.C. 4321 *et seq.*) analysis.

BLM policy and guidance for species of concern occurring on BLM-administered land is addressed under BLM's 6840 Manual ''Special Status Species Management'' (BLM 2008b). This manual provides agency policy and guidance for the conservation of special status plants and animals and the ecosystems on which they depend, but it is not a regulatory document. The objectives for BLM special status species are ''to conserve and/or recover ESA-listed species and the ecosystems on which they depend so that ESA protections are no longer needed for these species and to initiate proactive conservation measures that reduce or eliminate threats to Bureau sensitive species to minimize the likelihood of and need for listing of these species under the ESA.'' (BLM 2008b, p. 3). All four of the butterfly and skipper subspecies addressed in this finding are designated BLM sensitive species (BLM 2007a, pp. J–6, J–7, J–37).

BLM also operates under its Regulations on Grazing Administration Exclusive of Alaska, codified at 43 CFR part 4100, which include requirements that grazing administration standards address habitat for special status species and habitat quality for native plant and animal populations and communities (43 CFR 4180.2(d)(4) and (5)) that livestock grazing permits and leases contain terms and conditions determined by BLM to be appropriate to achieve management and resource condition objectives on the public lands. See discussion under Livestock Grazing, above.

These BLM policies and guidance address species of concern, actions covered by RMPs, and regulatory authority for grazing and oil and gas leasing and operating activities. As discussed under Factor A, the best available information does not indicate that activities, such as livestock grazing, nonnative species control, and mining and energy development that are regulated by various policies, guidance, and laws on Federal lands, are impacting White River Valley skipper populations. We conclude based on the best scientific and commercial information available that the inadequacy of existing regulatory mechanisms does not currently pose a threat to the White River Valley skipper, nor is it likely to become a threat to the subspecies in the future.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Potential other natural or manmade factors that may affect the continued existence of the White River Valley skipper are discussed in this section and include: (1) Limited range and (2) small population size(s).

A limited range or small population size(s) can be a threat for some species that may increase the likelihood of extinction. Characteristic butterfly population fluctuations and short generation times, combined with small populations, can influence genetic diversity and long-term persistence (Britten *et al.* 2003, pp. 229, 233). Concern may arise for butterflies that occur as single populations or in a few disjunct populations, and the number of populations may be more important than population size when assessing the status of a butterfly (Sanford 2006, p. 401). Lack of dispersal corridors or resistance to barriers to dispersal may inhibit gene flow between populations, and increase the likelihood of extinction (Wilcox and Murphy 1985, pp. 882–883). The combination of few populations, small ranges, and restricted habitats can make a species susceptible to extinction or extirpation from portions of its range due to random events such as fire, drought, disease, or other occurrences (Shaffer 1987, pp. 71–74; Meffe and Carroll 1994, pp. 190–197).

Limited range and small population numbers or sizes are considered in determining whether a natural or anthropogenic threat, or a combination of threats, may be affecting a particular subspecies. However, in the absence of information identifying chance events, other threats, the potential for such chance events to occur in occupied habitats, and connecting these threats to a restricted geographic range of a subspecies, we generally do not consider chance events, restricted geographic range, or rarity by themselves to be threats to a subspecies. In addition, butterfly populations are highly dynamic and from year to year butterfly distributions can be highly variable (Weiss *et al.* 1997, p. 2); and desert species seem prone to dramatic fluctuations in number (Scott 1986, p. 109).

As indicated earlier, the White River Valley skipper is known from the White River Valley in White Pine and Nye Counties and from Big Smoky Valley in Nye County. It may also occupy areas in Spring and Lake Valleys in White Pine and Lake Valley Counties, respectively. The aerial extent of each occupied site or of the subspecies' apparent host plant has not been reported. Little information is available related to its distribution and numbers of populations, and no information is available related to population sizes, loss of populations, if any, or population trends for the White River Valley skipper. The best available information does not include comprehensive surveys for this subspecies, though researchers have recommended these surveys to determine if additional populations exist.

Without data to indicate population trends, it is difficult to support claims of adverse impacts to the White River Valley skipper. We found no information on connections between chance events and population impacts for the White River Valley skipper. Since this subspecies is distributed over several populations, potential impacts due to stochastic events may be reduced. In the absence of chance events connected to known populations, we do not consider small population numbers or restricted range by themselves to be threats to this subspecies. The best available information does not indicate the White River Valley skipper is negatively

impacted by limited range or small population numbers. We conclude based on the best scientific and commercial information available that other natural or manmade factors do not currently pose a threat to the White River Valley skipper, nor are they likely to become a threat to the subspecies in the future.

Synergistic Interactions Between Threat Factors

We have evaluated individual threats to the White River Valley skipper. This subspecies faces potential threats from water development, land development, livestock grazing, nonnative plant invasion, agriculture, mining and energy development, climate change, limited range, and small population size. In considering whether the threats to a species may be so great as to warrant listing under the Act, we must look beyond the possible impacts of potential threats in isolation and consider the potential cumulative impacts of all of the threats facing a species.

In making this finding, we considered whether there may be cumulative effects to the White River Valley skipper from the combined impacts of the existing stressors such that even if each stressor individually does not result in population-level impacts, that cumulatively the effects may be significant. We considered whether the combined effects of water development, land development, and mining and energy development may result in a significant impact to the White River Valley skipper because these potential impacts have the potential to result in some level of habitat loss. However, we conclude that synergistic effects between water development, land development, and mining and energy development are unlikely to result in a significant overall population impact to the White River Valley skipper because the water development activities have been ongoing in the valleys and the proposed water development project is not anticipated to cause major impacts because only one known occupied White River Valley skipper location may be impacted to some unknown extent. Impacts from land development and mining and energy development were not found to be occurring in the subspecies' habitat.

While livestock grazing and nonnative plant invasion could impact the White River Valley skipper and its habitat, livestock grazing and nonnative plant species invasion are not known to be resulting in population declines of either host plants or nectar plants in occupied locations. We conclude that livestock grazing and nonnative plant species invasion combined with potential impacts from water development would not be of sufficient severity, frequency, or geographic scope to result in significant habitat impacts or cause population-level impacts to the White River Valley skipper. Agriculture was not found to occur within this subspecies' habitat, and therefore, will not have a cumulative impact on the White River Valley skipper.

Limited range and small population size could make the White River Valley skipper more vulnerable to potential threats discussed above. However, we cannot conclude that synergistic effects between limited range and small population size and other potential threats are operative threats to the continued existence of the White River Valley skipper given the lack of information on the range and population size of this butterfly. There is no information on population size or change in population abundance for the White River Valley skipper, and the limited information on occurrence (distribution) is insufficient to define this skipper's range.

Synergistic interactions are possible between effects of climate change and effects of other potential threats such as water development, livestock grazing, and nonnative plant invasion. Increases in carbon dioxide and temperature and changes in precipitation are likely to affect vegetation, and the White River Valley skipper is closely associated with the presence of vegetation. However, it is difficult to project how climate change will affect vegetation because certain plant species may increase in cover while other species may decrease. Uncertainty about how different plant species will respond under climate change, combined with uncertainty about how changes in plant species composition would affect suitability of White River Valley skipper habitat, make projecting possible synergistic effects of climate change on the White River Valley skipper too speculative.

Finding for the White River Valley Skipper

As required by the Act, we considered the five factors in assessing whether the White River Valley skipper is an endangered or threatened species throughout all of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by this subspecies.

Factors potentially affecting the White River Valley skipper, including water development, land development, livestock grazing, nonnative species invasion, agriculture, mining and energy development, or climate change, and limited range and small population size, are either limited in scope or lack documentation that they are occurring in occupied habitat and adversely impacting the subspecies. Though climate change may be affecting the White River Valley skipper and its habitats, and effects are likely to increase in the future, available information does not support a determination that climate change has or will result in a population-level impact to this subspecies. Available information does not indicate that overutilization, disease, or predation are threats to the White River Valley skipper. The available information also does not indicate that existing regulatory mechanisms are inadequate to protect the subspecies from potential threats. Furthermore, there is no information to suggest that the combined factors acting together are a threat to the White River Valley skipper. Based on our review of the best scientific and commercial information available, we find these potential stressors, either singly or in combination with one another, are not threats to the White River Valley skipper or its habitat.

We found no information to indicate that threats are of sufficient imminence, intensity, or magnitude such that the White River Valley skipper is in danger of extinction (endangered) or likely to become endangered within the foreseeable future (threatened), throughout all of its range. Therefore, we find that listing the White River Valley skipper as an endangered or threatened species is not warranted throughout its range.

Significant Portion of the Range

Having determined that the White River Valley skipper does not meet the definition of an endangered or a threatened species, we must next consider whether there are any significant portions of the range where the White River Valley skipper is in danger of extinction or is likely to become endangered in the foreseeable future. The Act defines ''endangered species'' as any species which is ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as any species which is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' 16 U.S.C. 1532(6) and 1532(20). The definition of ''species'' is also relevant to this discussion. The Act defines ''species'' as follows: ''The term 'species' includes any subspecies of fish

or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.'' 16 U.S.C. 1532(16). The phrase ''significant portion of its range'' (SPR) is not defined by the statute, and we have never addressed in our regulations: (1) The consequences of a determination that a species is either endangered or likely to become so throughout a significant portion of its range, but not throughout all of its range; or (2) what qualifies a portion of a range as ''significant.''

Two recent district court decisions have addressed whether the SPR language allows the Service to list or protect less than all members of a defined ''species'': *Defenders of Wildlife* v. *Salazar,* 729 F. Supp. 2d 1207 (D. Mont. 2010), concerning the Service's delisting of the Northern Rocky Mountains gray wolf (74 FR 15123, April 2, 2009); and *WildEarth Guardians* v. *Salazar,* 2010 U.S. Dist. LEXIS 105253 (D. Ariz. September 30, 2010), concerning the Service's 2008 finding on a petition to list the Gunnison's prairie dog (73 FR 6660, February 5, 2008). The Service had asserted in both of these determinations that, under the Act, it had authority, in effect, to protect only some members of a ''species,'' as defined by the Act (i.e., species, subspecies, or DPS). Both courts ruled that the determinations were arbitrary and capricious on the grounds that this approach violated the plain and unambiguous language of the Act. The courts concluded that reading the SPR language to allow protecting only a portion of a species' range is inconsistent with the Act's definition of ''species.'' The courts concluded that once a determination is made that a species (i.e., species, subspecies, or DPS) meets the definition of ''endangered species'' or ''threatened species,'' it must be placed on the list in its entirety and the Act's protections applied consistently to all members of that species throughout its range (subject to modification of protections through special rules under sections 4(d) and 10(j) of the Act).

Consistent with that interpretation, and for the purposes of this finding, we interpret the phrase ''significant portion of its range'' in the Act's definitions of ''endangered species'' and ''threatened species'' to provide an independent basis for listing. Thus there are two situations (or factual bases) under which a species would qualify for listing: A species may be endangered or threatened throughout all of its range, or a species may be endangered or threatened in only a significant portion of its range. If a species is in danger of extinction throughout an SPR, it, the species, is an ''endangered species.'' The same analysis applies to ''threatened species.'' Based on this interpretation and supported by existing case law, the consequence of finding that a species is endangered or threatened in only a significant portion of its range is that the entire species shall be listed as endangered or threatened, respectively, and the Act's protections shall be applied across the species' entire range.

We conclude, for the purposes of this finding, that interpreting the SPR phrase as providing an independent basis for listing is the best interpretation of the Act because it is consistent with the purposes and the plain meaning of the key definitions of the Act; it does not conflict with established past agency practice (i.e., prior to the 2007 Solicitor's Opinion), as no consistent, long-term agency practice has been established; and it is consistent with the judicial opinions that have most closely examined this issue. Having concluded that the phrase ''significant portion of its range'' provides an independent basis for listing and protecting the entire species, we next turn to the meaning of ''significant'' to determine the threshold for when such an independent basis for listing exists.

Although there are potentially many ways to determine whether a portion of a species' range is ''significant,'' we conclude, for the purposes of this finding, that the significance of the portion of the range should be determined based on its biological contribution to the conservation of the species. For this reason, we describe the threshold for ''significant'' in terms of an increase in the risk of extinction for the species. We conclude that a biologically based definition of ''significant'' best conforms to the purposes of the Act, is consistent with judicial interpretations, and best ensures species' conservation. Thus, for the purposes of this finding, and as explained further below, a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction.

We evaluate biological significance based on the principles of conservation biology using the concepts of redundancy, resiliency, and representation. Resiliency describes the characteristics of a species and its habitat that allow it to recover from periodic disturbance. Redundancy (having multiple populations distributed across the landscape) may be needed to provide a margin of safety for the species to withstand catastrophic events. Representation (the range of variation found in a species) ensures that the species' adaptive capabilities are conserved. Redundancy, resiliency, and representation are not independent of each other, and some characteristic of a species or area may contribute to all three. For example, distribution across a wide variety of habitat types is an indicator of representation, but it may also indicate a broad geographic distribution contributing to redundancy (decreasing the chance that any one event affects the entire species), and the likelihood that some habitat types are less susceptible to certain threats, contributing to resiliency (the ability of the species to recover from disturbance). None of these concepts is intended to be mutually exclusive, and a portion of a species' range may be determined to be ''significant'' due to its contributions under any one or more of these concepts.

For the purposes of this finding, we determine if a portion's biological contribution is so important that the portion qualifies as ''significant'' by asking whether, without that portion, the representation, redundancy, or resiliency of the species would be so impaired that the species would have an increased vulnerability to threats to the point that the overall species would be in danger of extinction (i.e., would be ''endangered''). Conversely, we would not consider the portion of the range at issue to be ''significant'' if there is sufficient resiliency, redundancy, and representation elsewhere in the species' range that the species would not be in danger of extinction throughout its range if the population in that portion of the range in question became extirpated (extinct locally).

We recognize that this definition of ''significant'' (a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction) establishes a threshold that is relatively high. On the one hand, given that the consequences of finding a species to be endangered or threatened in an SPR would be listing the species throughout its entire range, it is important to use a threshold for ''significant'' that is robust. It would not be meaningful or appropriate to establish a very low threshold whereby a portion of the range can be considered ''significant'' even if only a negligible increase in extinction risk would result from its loss. Because nearly any portion of a species' range can be said to contribute some increment to a species'

viability, use of such a low threshold would require us to impose restrictions and expend conservation resources disproportionately to conservation benefit: Listing would be rangewide, even if only a portion of the range of minor conservation importance to the species is imperiled. On the other hand, it would be inappropriate to establish a threshold for ''significant'' that is too high. This would be the case if the standard were, for example, that a portion of the range can be considered ''significant'' only if threats in that portion result in the entire species' being currently endangered or threatened. Such a high bar would not give the SPR phrase independent meaning, as the Ninth Circuit held in *Defenders of Wildlife* v. *Norton,* 258 F.3d 1136 (9th Cir. 2001).

The definition of ''significant'' used in this finding carefully balances these concerns. By setting a relatively high threshold, we minimize the degree to which restrictions will be imposed or resources expended that do not contribute substantially to species conservation. But we have not set the threshold so high that the phrase ''in a significant portion of its range'' loses independent meaning. Specifically, we have not set the threshold as high as it was under the interpretation presented by the Service in the *Defenders* litigation. Under that interpretation, the portion of the range would have to be so important that current imperilment there would mean that the species would be currently imperiled everywhere. Under the definition of ''significant'' used in this finding, the portion of the range need not rise to such an exceptionally high level of biological significance. (We recognize that if the species is imperiled in a portion that rises to that level of biological significance, then we should conclude that the species is in fact imperiled throughout all of its range, and that we would not need to rely on the SPR language for such a listing.) Rather, under this interpretation, we ask whether the species would be endangered everywhere without that portion (i.e., if that portion were completely extirpated). In other words, the portion of the range need not be so important that even the species being in danger of extinction in that portion would be sufficient to cause the species in the remainder of the range to be endangered; rather, the complete extirpation (in a hypothetical future) of the species in that portion would be required to cause the species in the remainder of the range to be endangered.

The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that have no reasonable potential to be significant or to analyzing portions of the range in which there is no reasonable potential for the species to be endangered or threatened. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that: (1) The portions may be ''significant,'' and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. Depending on the biology of the species, its range, and the threats it faces, it might be more efficient for us to address the significance question first or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.'' In practice, a key part of the determination that a species is in danger of extinction in a significant portion of its range is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats to the species occurs only in portions of the species' range that clearly would not meet the biologically based definition of ''significant,'' such portions will not warrant further consideration.

We evaluated the current range of the White River Valley skipper to determine if there is any apparent geographic concentration of the primary stressors potentially affecting the subspecies including water and land development, livestock grazing, nonnative species invasion, agriculture, mining and energy development, climate change, and limited range and small population size. On the basis of our review, we found no geographic concentration of potential threats either on public or private lands to suggest that the White River Valley skipper may be in danger of extinction in that portion of its range. We found no area within the range of the White River Valley skipper where the potential threats are significantly concentrated or substantially greater than in other portions of its range. We also found that lost historical range does not constitute a significant portion of the range for the White River Valley skipper because there is no information indicating that there has been a range contraction for this subspecies. Therefore, we find factors affecting the subspecies are essentially uniform throughout its range, indicating no portion of the skipper's range warrants further consideration of possible status as an endangered or threatened species under the Act.

We found no information to indicate that the White River Valley skipper is in danger of extinction now, nor is it likely to become endangered within the foreseeable future, throughout all or a significant portion of its range. Therefore, listing the White River Valley skipper as an endangered or threatened species under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, the White River Valley skipper to our Nevada Fish and Wildlife Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor the White River Valley skipper and encourage its conservation. If an emergency situation develops for the White River Valley skipper or any other species, we will act to provide immediate protection.

Species Information for the Steptoe Valley Crescentspot

Taxonomy and Species Description

We accept the characterization of the Steptoe Valley crescentspot (*Phyciodes cocyta arenacolor*) as a valid subspecies based on its description by Austin (1998b, p. 577) and recent updated nomenclature (NatureServe 2009b, p. 1; A. Warren, pers. comm., cited in WildEarth Guardians 2010, p. 34). This subspecies was described by Austin (1998b, p. 577) from specimens collected in Steptoe Valley at Warm Springs, White Pine County, Nevada. This subspecies is in the Nymphalidae family (Austin 1998a, p. 843). Male wingspan ranges from 0.67 to 0.74 in (17.0–18.8 mm). The upperside is orange and black. The margin is broadly black with a marginal spot. The hindwing has a broad black margin. The submargin (on the wing, just inside marginal zone) has a series of black dots. The fringes of both wings are dark grayish and not distinctly checkered with white. The underside of the forewing is paler (yellower) than the upperside. The margin and submargin are brownish and interrupted with some yellow areas. The hindwing is yellowish. A small brownish patch occurs along the middle of the outer

margin, which also has a distinct submarginal crescent (Austin 1998b, p. 577). Females are slightly larger and range from 0.72 to 0.79 in (18.2–20.0 mm). The upperside is a paler orange than the male's with a forewing that is cream colored postmedian and creamy-orange on the submargin. The black is more extensive than on the male. The hindwing is like that of the male but the black is broader, separating the rows of dots. The underside of the forewing is like that of the male's but the postmedian is pale as on the upperside. The underside of the hindwing is whitish (Austin 1998b, p. 577). Please refer to Austin (1998b, p. 577) for a more detailed description of this subspecies.

Distribution and Habitat

Descriptions of locations where the Steptoe Valley crescentspot has been found are vague. Austin (1993, pp. 8–9) and others (Austin 1998b, p. 577; Austin and Leary 2008, p. 102) found the Steptoe Valley crescentspot in the moist flats adjacent to Duck Creek from Warm Springs (the type locality (Austin 1998b, p. 577)) south to northwest of McGill (in unspecified locations) in Steptoe Valley, White Pine County, Nevada. This is a distance of approximately 18 mi (29 km) where both private and BLM lands occur along Duck Creek. More specific locations include Bassett Lake (private lands) located along Duck Creek Slough (Austin 1993, p. 9; NNHP 2010). Occurrences have been reported by NNHP (2006, p. 42) at Monte Neva Hot Springs (on private and BLM lands) and near McGill (on private and BLM lands), White Pine County, Nevada. Monte Neva Hot Springs is located about 1 mi (1.6 km) west of Warm Springs and about 1 mi (1.6 km) west of Duck Creek. A population may be located near the Ruby Mountains (unspecified locations) (Boyd, pers. comm. 2012a, p. 2). The NNHP (2009, p. 7) indicates three Nevada occurrences, but the locations are not identified. The size of each known occupied site and the extent of this subspecies' host plant, or host plant abundance, has not been reported.

Biology

Adults are known to fly as one brood (Austin 1993, p. 9) during early July to mid-August (Austin 1993, p. 9; 1998b, p. 577). Though adult nectar sources have not been reported, it is possible that they nectar on a variety of plants that are in flower during their flight period. *Aster ascendens* (western aster, longleaf aster), now known as *Symphyotrichum ascendens* (*http://en.wikipedia.org* Web site accessed April 25, 2012), has been documented as a larval host plant (Austin and Leary 2008, p. 102). This perennial forb occurs in most counties in Nevada, including Elko, Eureka, White Pine, Nye, and Lincoln (*http://www.plants.udsa.gov* Web site accessed April 24, 2012). It can be found throughout the western United States (*http://www.plants.udsa.gov* Web site accessed April 24, 2012). It grows in many habitats including meadows and disturbed areas (Hickman 1993, p. 206; *http://en.wikipedia.org* Web site accessed April 25, 2012).

There is little biological information available at the subspecies level, but some inferences can be made from biological information from related species at the species level. Information for the orange crescent (*Phyciodes cocyta=pascoensis*) indicates eggs are pale green and are laid in clusters under host plant leaves (Scott 1986, p. 310; NatureServe 2009b, p. 1). Larvae eat leaves, and no nests are constructed (Scott 1986, p. 311). Adults are local and sip flower nectar and mud, and males patrol during the day near host plants in valley bottoms seeking females (Scott 1986, p. 311).

The best available information does not include surveys documenting this subspecies' population dynamics, its overall abundance, number or size of populations, number of extirpated populations, if any, or population trends.

Five-Factor Evaluation for the Steptoe Valley Crescentspot

Information pertaining to the Steptoe Valley crescentspot in relation to the five factors provided in section 4(a)(1) of the Act is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Potential factors that may affect the habitat or range of the Steptoe Valley crescentspot are discussed in this section, including: (1) Water development, (2) livestock grazing, (3) nonnative plant invasion, (4) agriculture, (5) mining and energy development, and (6) climate change.

Water Development

For general background information on water development, please refer to the Water Development section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

Austin (1993, pp. 9–10) and Austin *et al.* (*in litt.* 2000, p. 2) state that water table changes may impact the Steptoe Valley crescentspot; however, specific information is not provided to support this claim. Since the Steptoe Valley crescentspot is associated with moist flats near wetland areas, potential adverse impacts to aquatic habitat could result in adverse impacts to the butterfly's habitat (e.g., drying of moist habitat and reductions in larval or nectar plant abundance). The NNHP (2007, p. 42) states that various wetland areas in Steptoe Valley have been degraded or converted to other land uses, including water development (including Bassett Lake—25 percent; Duck Creek—30 percent, two of several locations where this subspecies has been observed). The NNHP (2007) does not delineate these various areas in Steptoe Valley on a map or define them in terms of acreage; therefore, the amount of Steptoe Valley crescentspot habitat or the total number of occupied sites that may occur (made difficult because locations where the skipper has been seen are not specific) within these areas and may be impacted are not documented. The extent to which the various land use practices have degraded or converted these various areas is also not individually delineated or quantified by NNHP (2007). Therefore, we cannot determine the amount of overlap between the estimated wetland impacts identified by the NNHP and the distribution of the Steptoe Valley crescentspot.

Bassett Lake is a manmade reservoir (about 10 ac (4 ha) in size) constructed years ago with water control capabilities (Mabey 2012, pers. comm.). The amount of Steptoe Valley crescentspot habitat that may have been impacted at the time of construction is unknown, and it is unknown whether this subspecies' habitat near Bassett Lake and along Duck Creek has been enhanced due to a more consistent water supply provided by Bassett Lake and its flow releases. The Monte Neva Hot Springs is about 5 to 10 ac (2–4 ha) in size with approximately 250 to 300 ac (101–121 ha) of associated habitat; the springs are located on private land. Water from the hot springs has been diverted for at least 40 years (NNHP *in litt.,* 2007, p. 2). The amount of habitat used by the subspecies in this area is not known.

The Steptoe Valley hydrographic area is a ''designated'' basin by the NSE and permitted groundwater rights approach or exceed the estimated average annual recharge of the basin (Table 2). As a ''designated'' basin, the NSE has authority under NRS § 534.120 to establish additional rules, regulations, or orders to protect the basin's water resources (SNWA, *in litt.* 2011, p. 41). If such additional rules, regulations, or orders are established, they may also

provide some protection to species dependent on these water resources, such as the Steptoe Valley crescentspot. A preferred use for industrial (power generation) has been identified for this basin.

The petition raises concerns about the effects of the proposed SNWA water development project in central eastern Nevada on the Steptoe Valley crescentspot (WildEarth Guardians 2010, p. 36). The butterfly could be impacted by the proposed project due to its habitat being impacted by project construction or operation (BLM 2011a, p. 3.6–27). However, the Steptoe Valley crescentspot was not detected during the project's ROW surveys (BLM 2011a, pp. 3.6–18–3.6–19). Based on the groundwater flow model estimate for 200 years post full buildout (BLM 2011a, p. 3.3–102), this butterfly's occupied areas are located outside of the greater than 10-foot (3.0-m) drawdown contour (or any other contour range). While the Service recognizes that uncertainties remain regarding potential impacts to water resources from SNWA's project, within and outside of the 10-foot (3.0-m) drawdown, there are currently no anticipated impacts to the Steptoe Valley crescentspot from SNWA's proposed project.

Human water demands have impacted wetland areas in Steptoe Valley over the decades. However, the best available information does not indicate that impacts due to water development activities are negatively impacting this subspecies. Actions regarding water management in Steptoe Valley crescentspot habitat in the future would be addressed in consideration of Nevada water law. We did not receive any information as a result of our 90-day petition finding notice, nor did we locate information indicating that water development, either in general or specifically from the SNWA proposed project, is impacting the subspecies' habitat. Therefore, the best available information does not indicate that water development is modifying the subspecies' habitat to an extent that it represents a threat to this subspecies now or in the future.

Livestock Grazing

For general background information on livestock grazing, please refer to the Livestock Grazing section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

Austin (1993, pp. 9–10) and Austin *et al.* (*in litt.* 2000, p. 2) state that overgrazing (including trampling) may impact the Steptoe Valley crescentspot; however, specific information is not provided to support this claim. The NNHP (2007, p. 42) states that a portion of wetland areas in Steptoe Valley have been degraded or converted to other land uses, including livestock grazing. A site visit by a BLM employee in 1992 reported cattle grazing on private land west of Duck Creek Slough; the slough did not appear to be heavily impacted by cattle and looked in good condition (Barber *in litt.* 1992a, p. 1). Locations for the Steptoe Valley crescentspot occur on or near BLM's Steptoe Allotment (BLM 2010b, Appendix II, p. 10; Lichtler, 2012, pers. comm.), Duck Creek Flat Allotment (Barber *in litt.* 1993, p. 1; Lichtler, 2012, pers. comm.), and the Heuser Mountain Allotment (Barber *in litt.* 1993, p. 2; Lichtler, 2012, pers. comm.), but also occur on private land. It is not known how livestock grazing is managed on private land, but general knowledge of these areas indicate they are not heavily grazed and habitat conditions are good (Mabey 2012, pers. comm.). Current range conditions on BLM allotments that may support Steptoe Valley crescentspot habitat have improved in the last 5 years through grazing permit renewals with implementation of terms and conditions and lower utilization rates, and this would improve any habitat for the Steptoe Valley crescentspot (Mabey 2012, pers. comm.). Livestock grazing occurs at the Monte Neva Hot Springs area; about 30 head of cattle and a few domestic horses have access to the area, likely year-round (NNHP *in litt.,* 2007, p. 1).

The best available information does not indicate declines in the larval host plant *Aster ascendens* or adult nectar plant species in occupied Steptoe Valley crescentspot habitat due to livestock grazing. The larval host plant is widely distributed in Nevada and other western States and grows in a wide variety of habitats, including disturbed sites (see *Biology* section). One potential adult nectar plant species, *Castilleja salsuginosa* (Monte Neva paintbrush), is thriving at Monte Neva Hot springs and is apparently not being adversely affected by livestock grazing (NNHP *in litt.,* 2007, p. 1). Activities involving grazing management within the Steptoe Valley crescentspot habitat on BLM lands are addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), BLM's authority under Regulations on Grazing Administration Exclusive of Alaska, BLM's 6840 Manual (BLM 2008b), and possibly NEPA, per our discussion of these authorities in our analysis above for the White River Valley skipper. We did not receive any additional information as a result of the 90-day petition finding notice, nor did we locate information indicating that livestock grazing is negatively impacting the habitat or populations of the Steptoe Valley crescentspot. Thus, the best available information does not indicate that livestock grazing is modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Nonnative Plant Invasion

For general background information on nonnative plant invasion, please refer to the Nonnative Plant Invasion section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

The NNHP (2007, p. 42) states that a portion of Steptoe Valley's wetland areas have been degraded or converted to other land uses, including nonnative species invasion. Although they are likely to occur to some extent within the range of the Steptoe valley crescentspot, nonnative invasive plant species are not known to be a problem in Steptoe Valley crescentspot habitat (Mabey 2012, pers. comm.). There is no information indicating that nonnative plants are adversely affecting the Steptoe Valley crescentspot's larval host plant, *Aster ascendens,* or the butterfly's adult nectar plants. Activities involving nonnative plant species management within the Steptoe Valley crescentspot habitat on BLM lands would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), BLM's authority under Regulations on Grazing Administration Exclusive of Alaska, the Plant Protection Act of 2000, BLM's programmatic EIS for vegetation treatments on BLM's administered lands in the western United States (BLM 2007a), BLM's 6840 Manual (BLM 2008b), and possibly NEPA, as these authorities are discussed in our analysis for White River Valley skipper, above. Activities involving nonnative plant species management and control on private lands within the Steptoe Valley crescentspot habitat could also be addressed in consideration of the Plant Protection Act of 2000. We did not receive any further information as a result of our 90-day petition finding notice, nor did we locate information indicating that nonnative or invasive plant species are negatively impacting populations of the Steptoe Valley crescentspot. Thus, the best available information does not indicate that

nonnative plant species are modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Agriculture

For general background information on agriculture, please refer to the Agriculture section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

The NNHP (2007, p. 42) states that a portion of Steptoe Valley's wetland areas have been degraded or converted to other land uses, including agriculture. Although agriculture (hayfields) is known to occur near the Duck Creek-Bassett Lake and Monte Neva sites, agriculture does not occur within Steptoe Valley crescentspot habitat as the soils are not suitable because they are too moist and saline (Mabey 2012, pers. comm.). The best available information does not indicate that agriculture is occurring in areas that are occupied by the Steptoe Valley crescentspot. We did not receive any information as a result of the 90-day petition finding notice, nor did we locate information that indicates agriculture is negatively impacting Steptoe Valley crescentspot populations, host plants, or nectar sources. Therefore, the best available information does not indicate that agriculture is modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Mining and Energy Development

For general background information on mining and energy development, please refer to the Mining and Energy Development section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

The NNHP (2007, p. 42) states that a portion of wetland areas in Steptoe Valley have been degraded or converted to other land uses, including mining and energy development. A copper ore smelter, concentrator, and tailings facility was constructed in McGill in the early 1900s and operated until the early 1980s (*http://www.mii.org* Web site accessed April 26, 2012). It is not known the amount, if any, of Steptoe Valley crescentspot habitat that may have been impacted at the time of the facility's construction. During the late 1980s and early 1990s the site was reclaimed; the tailings area was reclaimed as pasture for livestock grazing (*http://www.mii.org* Web site accessed April 26, 2012).

Though the Steptoe Valley crescentspot is known from the project area for the Southwest Intertie Project, impacts to it were not identified (BLM 1993, pp. 3–75–3–89). This subspecies was also not observed during wildlife surveys conducted for the One Nevada Transmission Line Project (BLM 2010c, Appendix 3D, Table 2, pp. 1–5). Actions involving mineral and energy development within Steptoe Valley crescentspot habitat on BLM-administered lands would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), the FLPMA of 1976, the Mineral Leasing Act of 1920, BLM's 6840 Manual (BLM 2008b), and NEPA, per our analysis of these authorities above for the White River Valley skipper. The best available information does not indicate energy development is impacting Steptoe Valley crescentspot habitat or populations. We did not receive any additional information as a result of our 90-day petition finding notice, nor did we locate information indicating that mining or energy development is negatively impacting the subspecies' habitat. Thus, the best available information does not indicate that mining or energy development is modifying the subspecies' habitat to an extent that they represent a threat to this subspecies now or in the future.

Climate Change

For general background information on climate change, please refer to the Climate Change section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

While the petition asserts that climate change may impact Steptoe Valley crescentspot (WildEarth Guardians 2010, p. 40), it is difficult to predict local climate change impacts, due to substantial uncertainty in trends of hydrological variables, limitations in spatial and temporal coverage of monitoring networks, and differences in the spatial scales of global climate models and hydrological models (Bates *et al.* 2008, p. 3). We found no information on how climate change may impact the Steptoe Valley crescentspot's host plant, *Symphyotrichum ascendens,* or adult nectar sources. In general, increasing temperatures and drought frequency, more winter precipitation in the form of rain, possible decreases in summer rain, and earlier, rapid snowmelt could impact the host plant by causing physiological stress, altering phenology, reducing recruitment events, and reducing seed establishment. However, at this time, it is difficult to predict local climate change impacts to *Symphyotrichum ascendens* or Steptoe Valley crescentspot's adult nectar sources and how individual plant species will react to climate change. Thus, while information indicates that climate change has the potential to affect vegetation and habitats used by the Steptoe Valley crescentspot in the Great Basin, there is much uncertainty regarding which habitat attributes could be affected, and the timing, magnitude, and rate of their change as it relates to this subspecies.

We did not receive any information as a result of our 90-day petition finding notice, nor did we locate specific information that indicates climate change is negatively impacting Steptoe Valley crescentspot populations or their habitats. Therefore, the best available information does not indicate that climate change is modifying the subspecies' habitat to an extent that it represents a threat to this subspecies now or is likely to in the future.

Summary of Factor A

While activities such as water development, livestock grazing, nonnative species invasion, agriculture, and mining and energy development may be impacting a portion of wetland areas in Steptoe Valley, available information does not indicate that these impacts are negatively impacting occupied Steptoe Valley crescentspot habitat. The available information does not indicate that these activities, or climate change, are negatively impacting populations of Steptoe Valley crescentspot. Since the Steptoe Valley crescentspot is associated with wetland areas, impacts from water development could impact the subspecies; however, known occupied locations are outside the greater than 10-foot (3.0-m) drawdown contour for the SNWA proposed project, and impacts are not anticipated. While information indicates that climate change has the potential to affect vegetation used by this subspecies, much uncertainty remains regarding which plant attributes may be affected, and the timing, magnitude, and rate of their change. We conclude based on the best scientific and commercial information available that the present or threatened destruction, modification, or curtailment of its habitat or range does not currently pose a threat to the Steptoe Valley crescentspot, nor is it likely to become a threat to the subspecies in the future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

For general background information on overutilization, please refer to the discussion on collecting under *Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes* in the Five-Factor Evaluation for the White River Valley Skipper.

We are unaware of any studies analyzing impacts of removal of individuals from populations of the Steptoe Valley crescentspot. Austin (1998b, p. 577) indicates 39 males and 10 females were collected between 1981 and 1989 at one site. No additional information is known about the numbers of specimens collected in the past, and we are not aware of any ongoing or current collecting of this subspecies. Given the low number of individuals collected over this 8-year period, the length of time since the collections were made, and the lack of information about the relative impact to the populations, the available information does not indicate that collection may be a threat to this subspecies.

There has been no information presented that documents that overutilization has led to the loss of populations or a significant reduction in numbers of individuals for this subspecies. Therefore, we conclude based on the best scientific and commercial information available that overutilization for commercial, recreational, scientific, or educational purposes does not currently pose a threat to the Steptoe Valley crescentspot, nor is it likely to become a threat to the subspecies in the future.

Factor C. Disease or Predation

We found no information on the incidence of disease in the Steptoe Valley crescentspot.

Predation by other species, such as birds or insects, on eggs, larvae, pupae, or adult Steptoe Valley crescentspots is assumed, but we found no information indicating that predation levels are any greater than naturally occurring levels typical of the biological community in which the Steptoe Valley crescentspot occurs.

Available information does not indicate that there are impacts from disease or predation on the Steptoe Valley crescentspot. Therefore, we conclude that the best scientific and commercial information available does not indicate that disease or predation currently pose a threat to the Steptoe Valley crescentspot, nor is either likely to become a threat to the subspecies in the future.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

The discussion of existing regulatory mechanisms under Factor D for the White River Valley skipper is hereby incorporated into this discussion for the Steptoe Valley crescentspot. As discussed above under Factor D for the White River Valley skipper, Nevada State law pertaining to wildlife does not offer protection to the Steptoe Valley crescentspot specifically because it is an invertebrate species not classified as wildlife. Although not protected by State wildlife law, the best available information, as discussed in Factor B, does not indicate that collection or other forms of overutilization is a threat to the Steptoe Valley crescentspot. In addition, the State's water law may offer some protection to species dependent on water resources such as the Steptoe Valley crescentspot as it occurs in a ''designated'' basin with a preferred use identified.

A portion of habitat for the Steptoe Valley crescentspot occurs on Federal lands administered by BLM. Numerous policies, guidance, and laws have been developed to assist the agency in management of these lands (see Factor D discussion under White River Valley skipper). BLM policies and guidance address species of concern, actions covered by RMPs, and regulatory authority for grazing and oil and gas leasing and operating activities. As discussed under Factor A, the best available information does not indicate that activities such as livestock grazing, nonnative species invasion, and mining and energy development that are regulated by various policies, guidance, and laws on Federal lands are negatively impacting Steptoe Valley crescentspot populations. We conclude based on the best scientific and commercial information available that the inadequacy of existing regulatory mechanisms does not currently pose a threat to the Steptoe Valley crescentspot, nor is it likely to become a threat to the subspecies in the future.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Potential other natural or manmade factors that may affect the continued existence of the Steptoe Valley crescentspot are discussed in this section and include: (1) Limited range and (2) small population size(s).

For general background information on other natural or manmade factors which could affect the Steptoe Valley crescentspot, please refer to the discussion on limited distribution and population size under *Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence* in the Five-Factor Evaluation for the White River Valley Skipper.

As indicated earlier, the Steptoe Valley crescentspot occurs at locations along Duck Creek and at Monte Neva Hot Springs in Steptoe Valley and possibly near the Ruby Mountains. Little information is available related to its distribution and numbers of populations, and no information is available regarding population sizes, loss of populations, if any, or population trends for the Steptoe Valley crescentspot. Information pertaining to the aerial extent of habitat or populations is not available. The best available information does not include comprehensive surveys for this subspecies. Without data to indicate population trends, it is difficult to support claims of adverse impacts to the Steptoe Valley crescentspot. We found no information on connections between chance events and population impacts for the Steptoe Valley crescentspot. Since this subspecies is distributed over different areas, potential impacts due to stochastic events is reduced. In the absence of chance events connected to known populations, we do not consider small population numbers or limited range by themselves to be threats to this subspecies. The best available information does not indicate the Steptoe Valley crescentspot is negatively impacted by limited range or small population numbers. We conclude based on the best scientific and commercial information available that other natural or manmade factors do not currently pose a threat to the Steptoe Valley crescentspot, nor are they likely to become a threat to the subspecies in the future.

Synergistic Interactions Between Threat Factors

We have evaluated individual threats to the Steptoe Valley crescentspot. This subspecies faces potential threats from water development, livestock grazing, nonnative plant invasion, agriculture, mining and energy development, limited range, small population size, and climate change. In considering whether the threats to a species may be so great as to warrant listing under the Act, we must look beyond the possible impacts of potential threats in isolation and consider the potential cumulative impacts of all of the threats facing a species.

In making this finding, we considered whether there may be cumulative effects to the Steptoe Valley crescentspot from the combined impacts of the existing

stressors such that even if each stressor individually does not result in population-level impacts, that cumulatively the effects may be significant. We considered whether the combined effects of water development and mining and energy development may result in a significant impact to the Steptoe Valley crescentspot because these potential impacts have the potential to result in some level of habitat loss. However, we conclude that synergistic effects between water development and mining and energy development are unlikely to result in a significant overall population impact to the Steptoe Valley crescentspot because water development activities have been ongoing in the valley, and the proposed SNWA water development project is not anticipated to cause impacts to this subspecies because sites occupied by the butterfly are located outside of the estimated project impact area. Also, impacts from mining and energy development are not found to be occurring in the butterfly's habitat.

While livestock grazing and nonnative plant invasion could impact the Steptoe Valley crescentspot and its habitat, observations of private land within the subspecies' habitat that are being grazed look to be in good condition; changes in livestock grazing management on BLM sites that may be occupied by the butterfly have improved habitat conditions for this subspecies; and nonnative plant species invasion is not known to be a concern on either private or public lands. We conclude that livestock grazing and nonnative plant species invasion impacts combined with impacts from water development would not be of sufficient severity, frequency, or geographic scope to result in significant habitat impacts or cause population-level impacts to the Steptoe Valley crescentspot. Agriculture and mining and energy development were not found to occur within this subspecies' habitat and, therefore, will not have a cumulative impact on the Steptoe Valley crescentspot.

Limited range and small population size could make the Steptoe Valley crescentspot more vulnerable to potential threats discussed above. However, we cannot conclude that synergistic effects between limited range and small population size and other potential threats are operative threats to the continued existence of the Steptoe Valley crescentspot given the lack of information on the range and population size of this butterfly. There is no information on population size or change in population abundance for the Steptoe Valley crescentspot, and the limited information on occurrence (distribution) is insufficient to define this butterfly's range.

Synergistic interactions are possible between effects of climate change and effects of other potential threats such as livestock grazing and nonnative plant invasion. Increases in carbon dioxide and temperature and changes in precipitation are likely to affect vegetation, and the Steptoe Valley crescentspot is closely associated with the presence of vegetation. However, it is difficult to project how climate change will affect vegetation because certain plant species may increase in cover while other species may decrease. Uncertainty about how different plant species will respond under climate change, combined with uncertainty about how changes in plant species composition would affect suitability of Steptoe Valley crescentspot habitat, make projecting possible synergistic effects of climate change on the Steptoe Valley crescentspot too speculative.

Finding for the Steptoe Valley Crescentspot

As required by the Act, we considered the five factors is assessing whether the Steptoe Valley crescentspot is an endangered or threatened species throughout all of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by this subspecies.

Factors potentially affecting the Steptoe Valley crescentspot, including water development, livestock grazing, nonnative species invasion, agriculture, mining and energy development, or climate change, and limited range and small population size, are either limited in scope or lack documentation that they are occurring in occupied habitat and adversely impacting the subspecies. Though climate change may be affecting the Steptoe Valley crescentspot and its habitats and effects are likely to increase in the future, available information does not support a determination that climate change has or will result in a population-level impact to this subspecies. Available information does not indicate that overutilization, disease, or predation is a threat to the Steptoe Valley crescentspot. Lastly, the available information does not indicate that existing regulatory mechanisms are inadequate to protect the subspecies from potential threats. Furthermore, there is no evidence to indicate that the combined factors acting together are a threat to the Steptoe Valley crescentspot. Based on our review of the best scientific and commercial information available, we find these stressors, either singly or in combination with one another, are not threats to the Steptoe Valley crescentspot or its habitat.

We found no information to indicate that threats are of sufficient imminence, intensity, or magnitude such that the Steptoe Valley crescentspot is in danger of extinction (endangered) or likely to become endangered within the foreseeable future (threatened), throughout all of its range. Therefore, we find that listing the Steptoe Valley crescentspot as an endangered or threatened species is not warranted throughout its range.

Significant Portion of the Range

Having determined that the Steptoe Valley crescentspot does not meet the definition of an endangered or a threatened species, we must next consider whether there are any significant portions of the range where the Steptoe Valley crescentspot is in danger of extinction or is likely to become endangered in the foreseeable future. The Act defines ''endangered species'' as any species which is ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as any species which is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' 16 U.S.C. 1532(6) and 1532(20). The definition of ''species'' is also relevant to this discussion. The Act defines ''species'' as follows: ''The term 'species' includes any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.'' 16 U.S.C. 1532(16). The phrase ''significant portion of its range'' (SPR) is not defined by the statute, and we have never addressed in our regulations: (1) The consequences of a determination that a species is either endangered or likely to become so throughout a significant portion of its range, but not throughout all of its range; or (2) what qualifies a portion of a range as ''significant.''

Two recent district court decisions have addressed whether the SPR language allows the Service to list or protect less than all members of a defined ''species'': *Defenders of Wildlife* v. *Salazar,* 729 F. Supp. 2d 1207 (D. Mont. 2010), concerning the Service's delisting of the Northern Rocky Mountains gray wolf (74 FR 15123, April 2, 2009); and *WildEarth Guardians* v. *Salazar,* 2010 U.S. Dist. LEXIS 105253 (D. Ariz. September 30, 2010), concerning the Service's 2008 finding on a petition to list the

Gunnison's prairie dog (73 FR 6660, February 5, 2008). The Service had asserted in both of these determinations that, under the Act, it had authority, in effect, to protect only some members of a ''species,'' as defined by the Act (i.e., species, subspecies, or DPS). Both courts ruled that the determinations were arbitrary and capricious on the grounds that this approach violated the plain and unambiguous language of the Act. The courts concluded that reading the SPR language to allow protecting only a portion of a species' range is inconsistent with the Act's definition of ''species.'' The courts concluded that once a determination is made that a species (i.e., species, subspecies, or DPS) meets the definition of ''endangered species'' or ''threatened species,'' it must be placed on the list in its entirety and the Act's protections applied consistently to all members of that species throughout its range (subject to modification of protections through special rules under sections 4(d) and 10(j) of the Act).

Consistent with that interpretation, and for the purposes of this finding, we interpret the phrase ''significant portion of its range'' in the Act's definitions of ''endangered species'' and ''threatened species'' to provide an independent basis for listing. Thus there are two situations (or factual bases) under which a species would qualify for listing: A species may be endangered or threatened throughout all of its range, or a species may be endangered or threatened in only a significant portion of its range. If a species is in danger of extinction throughout an SPR, it, the species, is an ''endangered species.'' The same analysis applies to ''threatened species.'' Based on this interpretation and supported by existing case law, the consequence of finding that a species is endangered or threatened in only a significant portion of its range is that the entire species shall be listed as endangered or threatened, respectively, and the Act's protections shall be applied across the species' entire range.

We conclude, for the purposes of this finding, that interpreting the SPR phrase as providing an independent basis for listing is the best interpretation of the Act because it is consistent with the purposes and the plain meaning of the key definitions of the Act; it does not conflict with established past agency practice (i.e., prior to the 2007 Solicitor's Opinion), as no consistent, long-term agency practice has been established; and it is consistent with the judicial opinions that have most closely examined this issue. Having concluded that the phrase ''significant portion of its range'' provides an independent basis for listing and protecting the entire species, we next turn to the meaning of ''significant'' to determine the threshold for when such an independent basis for listing exists.

Although there are potentially many ways to determine whether a portion of a species' range is ''significant,'' we conclude, for the purposes of this finding, that the significance of the portion of the range should be determined based on its biological contribution to the conservation of the species. For this reason, we describe the threshold for ''significant'' in terms of an increase in the risk of extinction for the species. We conclude that a biologically based definition of ''significant'' best conforms to the purposes of the Act, is consistent with judicial interpretations, and best ensures species' conservation. Thus, for the purposes of this finding, and as explained further below, a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction.

We evaluate biological significance based on the principles of conservation biology using the concepts of redundancy, resiliency, and representation. Resiliency describes the characteristics of a species and its habitat that allow it to recover from periodic disturbance. Redundancy (having multiple populations distributed across the landscape) may be needed to provide a margin of safety for the species to withstand catastrophic events. Representation (the range of variation found in a species) ensures that the species' adaptive capabilities are conserved. Redundancy, resiliency, and representation are not independent of each other, and some characteristic of a species or area may contribute to all three. For example, distribution across a wide variety of habitat types is an indicator of representation, but it may also indicate a broad geographic distribution contributing to redundancy (decreasing the chance that any one event affects the entire species), and the likelihood that some habitat types are less susceptible to certain threats, contributing to resiliency (the ability of the species to recover from disturbance). None of these concepts is intended to be mutually exclusive, and a portion of a species' range may be determined to be ''significant'' due to its contributions under any one or more of these concepts.

For the purposes of this finding, we determine if a portion's biological contribution is so important that the portion qualifies as ''significant'' by asking whether, without that portion, the representation, redundancy, or resiliency of the species would be so impaired that the species would have an increased vulnerability to threats to the point that the overall species would be in danger of extinction (i.e., would be ''endangered''). Conversely, we would not consider the portion of the range at issue to be ''significant'' if there is sufficient resiliency, redundancy, and representation elsewhere in the species' range that the species would not be in danger of extinction throughout its range if the population in that portion of the range in question became extirpated (extinct locally).

We recognize that this definition of ''significant'' (a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction) establishes a threshold that is relatively high. On the one hand, given that the consequences of finding a species to be endangered or threatened in an SPR would be listing the species throughout its entire range, it is important to use a threshold for ''significant'' that is robust. It would not be meaningful or appropriate to establish a very low threshold whereby a portion of the range can be considered ''significant'' even if only a negligible increase in extinction risk would result from its loss. Because nearly any portion of a species' range can be said to contribute some increment to a species' viability, use of such a low threshold would require us to impose restrictions and expend conservation resources disproportionately to conservation benefit: Listing would be rangewide, even if only a portion of the range of minor conservation importance to the species is imperiled. On the other hand, it would be inappropriate to establish a threshold for ''significant'' that is too high. This would be the case if the standard were, for example, that a portion of the range can be considered ''significant'' only if threats in that portion result in the entire species' being currently endangered or threatened. Such a high bar would not give the SPR phrase independent meaning, as the Ninth Circuit held in *Defenders of Wildlife* v. *Norton,* 258 F.3d 1136 (9th Cir. 2001).

The definition of ''significant'' used in this finding carefully balances these concerns. By setting a relatively high threshold, we minimize the degree to which restrictions will be imposed or resources expended that do not contribute substantially to species conservation. But we have not set the

threshold so high that the phrase ''in a significant portion of its range'' loses independent meaning. Specifically, we have not set the threshold as high as it was under the interpretation presented by the Service in the *Defenders* litigation. Under that interpretation, the portion of the range would have to be so important that current imperilment there would mean that the species would be currently imperiled everywhere. Under the definition of ''significant'' used in this finding, the portion of the range need not rise to such an exceptionally high level of biological significance. (We recognize that if the species is imperiled in a portion that rises to that level of biological significance, then we should conclude that the species is in fact imperiled throughout all of its range, and that we would not need to rely on the SPR language for such a listing.) Rather, under this interpretation, we ask whether the species would be endangered everywhere without that portion (i.e., if that portion were completely extirpated). In other words, the portion of the range need not be so important that even the species being in danger of extinction in that portion would be sufficient to cause the species in the remainder of the range to be endangered; rather, the complete extirpation (in a hypothetical future) of the species in that portion would be required to cause the species in the remainder of the range to be endangered.

The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that have no reasonable potential to be significant or to analyzing portions of the range in which there is no reasonable potential for the species to be endangered or threatened. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that: (1) The portions may be ''significant,'' and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. Depending on the biology of the species, its range, and the threats it faces, it might be more efficient for us to address the significance question first or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.'' In practice, a key part of the determination that a species is in danger of extinction in a significant portion of its range is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats to the species occurs only in portions of the species' range that clearly would not meet the biologically based definition of ''significant,'' such portions will not warrant further consideration.

We evaluated the current range of the Steptoe Valley crescentspot to determine if there is any apparent geographic concentration of the primary stressors potentially affecting the subspecies, including water development, livestock grazing, nonnative species invasion, agriculture, mining and energy development, climate change, limited range, and small population size. On the basis of our review, we found no geographic concentration of threats either on public or private lands to suggest that the Steptoe Valley crescentspot may be in danger of extinction in that portion of its range. We found no area within the range of the Steptoe Valley crescentspot where the potential threats are significantly concentrated or substantially greater than in other portions of its range. We also found that lost historical range does not constitute a significant portion of the range for the Steptoe Valley crescentspot because there is no information indicating that there has been a range contraction for this subspecies. Therefore, we find factors affecting the subspecies are essentially uniform throughout its range, indicating no portion of the butterfly's range warrants further consideration of possible status as an endangered or threatened species under the Act.

We found no information to indicate that the Steptoe Valley crescentspot is in danger of extinction now, nor is it likely to become endangered within the foreseeable future, throughout all or a significant portion of its range. Therefore, listing the Steptoe Valley crescentspot as an endangered or threatened species under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, the Steptoe Valley crescentspot to our Nevada Fish and Wildlife Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor the Steptoe Valley crescentspot and encourage its conservation. If an emergency situation develops for the Steptoe Valley crescentspot or any other species, we will act to provide immediate protection.

Species Information for Baking Powder Flat Blue Butterfly

Taxonomy and Species Description

We accept the characterization of the Baking Powder Flat blue butterfly (*Euphilotes bernardino minuta*) as a valid subspecies based on its description by Austin (1998c, p. 549). This subspecies is in the Lycaenidae family (Austin 1998c, p. 539; 1998b, p. 841) and was an unnamed segregate of the *E. battoides* complex in Nevada (Austin 1998c, p. 549). The male's wingspan ranges from 0.35 to 0.40 inch (in) (9.0–10.2 mm). The upper side of the male is purplish-blue with a black outer margin (wing edge) of moderate width. Veins are black distally (away from the point of attachment) on both wings. Submarginal orange often occurs in posterior (behind or at the rear) cells on the hindwing. Wing fringes are white and lightly checkered with gray. The underside of the male's wings is grayish-white; there is a slight posterior gray flush on the forewing and the hindwing has an orange aurora (colored marginal band of hindwing) of moderate width (Austin 1998c, p. 549). The female's wingspan ranges from 0.43 to 0.97 in (9.7–11.0 mm). The upper side of the wing is a dark brownish-gray and slightly grayer basally. The hindwing has an orange aurora of moderate width and is outlined with blackish marginal spots distally. Wing fringes and the undersides are like that of the male (Austin 1998c, p. 549). Please refer to Austin (1998c, p. 549) for a more detailed description of this subspecies.

Distribution and Habitat

Descriptions of locations where the Baking Powder Flat blue butterfly has been found are vague, but this subspecies is only known from the Baking Powder Flat area (on BLM lands) in Spring Valley, in Lincoln and White Pine Counties, Nevada, a flat valley bottom with scattered sand dunes (Austin 1998c, p. 550; Austin and Leary 2008, pp. 68–69). The type locality is located approximately 1.0 mi (1.6 km) from Blind Spring in Baking Powder Flat (Spring Valley, White Pine County) (Austin 1998c, p. 550). The Baking Powder Flat area also contains areas of wetland-type habitats (wetlands, springs, seeps). The Baking Powder Flat area contains the largest known contiguous habitat for the Baking Powder Flat blue butterfly (BLM 2009a,

p. 20). In 1993, Austin (1993, p. 5) reported two occupied sites for the Baking Powder Flat blue butterfly in the Baking Powder Flat area in southern Spring Valley, and also suggested that other areas could support the host plant (Austin 1993, pp. 5–6), indicating a possible wider distribution of this butterfly. The only documented host plant, *Eriogonum shockleyi* (Shockley's buckwheat), which the Baking Powder Flat blue butterfly uses for both larval and adult life stages (see *Biology* section below), is a perennial forb (*http://www.plants.usda.gov,* accessed January 6, 2012) and grows on relatively hard and bare areas between the sand dunes in the Baking Powder Flat area (Austin 1993, p. 5; 1998c, p. 550). In this area the plants occur in large, open, loose mats (Kartesz 1987, pp. 282–283).

Throughout its range, *Eriogonum shockleyi* grows mostly on gravelly, clayey, or sandy soils, or on rocky outcrops and ledges, in association with *Sarcobatus* sp. (greasewood), *Atriplex* sp. (shadscale), and *Artemisia* sp. (sagebrush) (Kartesz 1987, p. 282); it is not a wetland-dependent species. The host plant (*E. shockleyi*) is common in Nevada, occurring in Mineral, Esmeralda, Nye, Lincoln, Clark, White Pine, and Elko Counties (Kartesz 1987, p. 282). It is also known to occur in California, Idaho, Utah, Colorado, New Mexico, and Arizona (Kartesz 1987, p. 283; *http://www.plants.usda.gov,* accessed January 6, 2012). Searches of nearby areas in southern Spring Valley did not reveal additional colonies of the subspecies or its host plant (Austin 1993, p. 5; 1998c, p. 550); however, Austin and Leary (2008, pp. 68–69) list what appear to be seven discrete locations in the Baking Powder Flat area where this subspecies (adults and larvae) has been seen between 1969 and 2002.

The NNHP database (2010) also indicates that this subspecies occurs in the Baking Powder Flat area near Blind Spring. The site was visited seven times between 1969 and 2002 (Austin and Leary 2008, pp. 68–69). The other six sites identified by Austin and Leary (2008, pp. 68–69) were visited once (five of the sites) or three times (one site) between the late 1980s and early 2000s. During a general terrestrial invertebrate survey conducted in 2006 at 76 sites in eastern Nevada, including 37 sites in Spring Valley (2 of which could be in or near known locations for this subspecies), the Baking Powder Flat blue butterfly was not encountered (Ecological Sciences, Inc. 2007, pp. 80–82). The aerial extent of each occupied site or the host plant, or host plant abundance, has not been reported. The Baking Powder Flat Area of Critical Environmental Concern (ACEC) encompasses most, if not all, of the known Baking Powder Flat blue butterfly locations. A few of the locations may occur outside of the ACEC as all of the site descriptions are not clear.

Biology

The Baking Powder Flat blue butterfly is associated with *Eriogonum shockleyi* on which both larvae and adults are found (Austin 1993, p. 5; Austin and Leary 2008, pp. 68–69). Larvae of this subspecies are tended by ants (*Formica obtusopilosa*) (Shields 1973 cited by Austin 1993, p. 5). Pupae are likely formed in and protected by litter that is in and beneath the host plant (Austin 1993, p. 5). Adults fly between mid and late June (Austin 1993, p. 6; 1998c, p. 550), and there is one brood (Austin 1993, p. 6).

There is little biological information available at the subspecies level, but some inferences can be made from biological information from related species at the species level. Information for the buckwheat blue (*Euphilotes battoides*) indicates eggs are pale bluish-white, turning white, and they are laid singly on the host plant's flowers (Scott 1986, p. 403). Larvae eat flowers and fruit and are attended by ants (Scott 1986, p. 403). No nests are constructed (Scott 1986, p. 403). Adults sip flower nectar and mud, and males patrol around the host plant during the day seeking females (Scott 1986, p. 403).

The best available information does not include surveys documenting this subspecies' population dynamics, nor its overall abundance, number or size of populations, number of extirpated populations or sites, if any, or population trends.

Five-Factor Evaluation for the Baking Powder Flat Blue Butterfly

Information pertaining to the Baking Powder Flat blue butterfly in relation to the five factors provided in section 4(a)(1) of the Act is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Potential factors that may affect the habitat or range of the Baking Powder Flat blue butterfly are discussed in this section, including: (1) Water development, (2) fire, (3) livestock grazing, (4) nonnative plant invasion, (5) agriculture, (6) recreation (off-highway vehicles), (7) mining and energy development, (8) plant collection, and (9) climate change.

Water Development

For general background information on water development, please refer to the Water Development section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

The NNHP (2007, p. 42) estimates that about 30 percent of the Baking Powder Flat playa/ephemeral pool/spring pool complex has been degraded or converted to other land uses, including by water development. The NNHP (2007) does not delineate this area on a map or define it in terms of acreage; therefore, the amount of Baking Powder Flat blue butterfly habitat that may occur within this area and may be impacted by various land use practices, if any, is not documented. However, it is important to note that the Baking Powder Flat blue butterfly's host plant occurs in dry areas and not within wetland areas. The extent to which the various land use practices have degraded or converted this area is also not individually delineated or quantified by NNHP (2007).

Concerns have been raised regarding SNWA's proposed water development project and its potential impacts to the Baking Powder Flat area and the Baking Powder Flat ACEC (Charlet 2006, p. 19; BLM 2009a, pp. 20–21). During ROWs surveys for various facilities associated with the SNWA project (i.e., powerlines, pipelines), the Baking Powder Flat blue butterfly was not observed (BLM 2011a, pp. 3.6–19; 3.14–4), but all facility locations have not yet been determined (BLM 2011a, p. 2–5). The butterfly has been recorded from Spring Valley within the proposed groundwater development area within the ACEC (BLM 2011a, pp. 3.6–22; 3.14–4); this location is in reference to the site near Blind Spring. The Baking Powder Flat blue butterfly and its habitat could be impacted during construction and facility maintenance activities by direct mortality resulting from construction or vehicles, disruption of breeding success, temporary or permanent loss of habitat, and habitat fragmentation (BLM 2011a, p. 3.6–70). However, BLM mitigation recommendation GW–WL–6 has been included in the proposed project (BLM 2011a, p. 3.6–70). This mitigation recommendation involves pre-construction surveys and the avoidance of Baking Powder Flat blue butterfly occurrence sites and habitat during facility siting to the extent practicable (BLM 2011a, p. 3.6–71). Because the ACEC is large (13,640 ac (5,520 ha)) (72 FR 67748, November 30, 2007), any

facilities constructed, if approved, would impact a small percentage of the ACEC's area. This is in addition to the restoration requirements provided for in the BLM's Ely RMP (BLM 2011a, p. 3.6–70) and BLM's determination for the Baking Powder Flat ACEC that an issuance of a ROW permit will result in minimal conflict with identified resource values and that impacts can be mitigated.

In addition to possible construction impacts, the groundwater flow model estimate for 200 years post full buildout (BLM 2011a, p. 3.3–102) shows Blind Spring within the project's greater than 10-foot (3.0-m) drawdown contour. Blind Spring is located in the ACEC and within 1 mi (1.6 km) of some Baking Powder Flat blue butterfly observations (Austin and Leary 2008, pp. 68–69). As stated earlier, the host plant, described as common in Baking Powder Flat (BLM 2009a, p. 20), grows on relatively hard and bare areas between sand dunes (Austin 1998c, p. 550) and mostly on gravelly, clayey, or sandy soils, or on rocky outcrops and ledges in association with upland plants (Kartesz 1987, p. 282); it is not a wetland-dependent species. Therefore, it is unlikely SNWA's proposed water development project will indirectly impact the Baking Powder Flat blue butterfly in Spring Valley through groundwater drawdowns. The Baking Powder Flat blue butterfly habitat is not specifically considered in the Spring Valley Stipulation because the subspecies and its habitat are not considered to be at risk from groundwater development (SNWA, *in litt.* 2011, p. 36).

Because the Baking Powder Flat blue butterfly's host plant grows in dry areas and not within the Baking Powder Flat wetland areas, it is unlikely that current groundwater rights or SNWA's proposed water development project which have been and are considered under Nevada water law will indirectly impact the butterfly through groundwater drawdowns. The host plant is considered common in the Baking Powder Flat area, and the butterfly has been documented in several areas in the ACEC, and possibly outside it as some butterfly location descriptions are unclear. Any facilities constructed in the ACEC would impact a small percentage (unknown at this time) of the ACEC's total area and would be mitigated by SNWA project mitigations or BLM requirements. At this time, the best available information does not indicate that water development is modifying the subspecies' habitat or that its habitat may be modified through SNWA's proposed project to the extent that it represents a threat to this subspecies now or in the future.

Fire

Butterflies have specialized habitat requirements (Thomas 1984, p. 337). Changes in the structure and composition of vegetation due to natural or other means can threaten butterfly populations as these changes can disrupt specific habitat requirements (Thomas 1984, pp. 337–341). The effects of fire on the landscape depend on the composition of plant species present, and the size, frequency, and intensity of fire. Burning can also allow invasive species, such as *Bromus tectorum,* to increase (Stewart and Hull 1949 and Wright and Britton 1976, cited in Yensen 1982, p. 28).

Fleischman (2000, pp. 688–689) found that a prescribed fire in a watershed in Nevada did not appear to affect butterfly species richness or composition between burned areas and their paired controls. Vogel *et al.* (2007, p. 78) evaluated three restoration practices in prairie habitat on butterfly communities and found that the total butterfly abundance was highest in areas restored through burning and grazing, and was lowest in areas that were only burned. Species richness did not differ among the practices. Species diversity was highest in areas that were only burned. Individual butterfly species responses to the restoration practices were variable.

The petition mentions fire as a potential threat to the Baking Powder Flat blue butterfly (Bruce Boyd, pers. comm. cited in Wild Earth Guardians 2010, p. 14) though it does not provide specific information to support this claim. Fires have occurred in many areas of Nevada over the years and will occur in the future. The best available information does not indicate that fire has occurred in areas that are occupied by the Baking Powder Flat blue butterfly (Podborny 2012, pers. comm.). The Baking Powder Flat area occurs in a valley bottom with sandy soils and widespread vegetation, thus the amount and distribution of vegetation needed to support a fire through this area are not available (Podborny 2012, pers. comm.). In addition, the host plant, *Eriogonum shockleyi,* remains common in the Baking Powder Flat area (BLM 2009a, p. 20). Actions regarding fire management within Baking Powder Flat blue butterfly habitat would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), BLM's 6840 Manual (BLM 2008b) (see our discussion of these authorities in the analysis of the White River Valley skipper), the Emergency Stabilization and Burned Area Rehabilitation Program, Baking Powder Flat ACEC restrictions, and possibly NEPA. We did not receive any information as a result our 90-day petition finding notice, nor did we locate information indicating that fire is impacting the habitat or populations of the Baking Powder Flat blue butterfly. Consequently, the best available information does not indicate that fire is modifying the subspecies' habitat to the extent that it is a threat to this subspecies now or in the future.

Livestock Grazing

For general background information on livestock grazing, please refer to the Livestock Grazing section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

The NNHP (2007, p. 42) indicates that a portion of the Baking Powder Flat playa/ephemeral pool/spring pool complex has been degraded or converted to other land uses, including livestock grazing. The petition indicates that livestock will graze *Eriogonum shockleyi* (WildEarth Guardians 2010, p. 13), but disturbance to this host plant from trampling and soil compaction from livestock was mentioned in the petition and by others as a greater potential threat (Austin 1993, p. 7; Austin *et al., in litt.* 2000, p. 3; NatureServe 2009c, p. 2; B. Boyd, pers. comm. cited in WildEarth 2010, p. 13), though specific information to support this concern is not provided. Injury to or loss of host plant populations would negatively impact larvae and adults as both life stages utilize this plant for food and shelter. Livestock grazing is occurring over widespread general habitat areas where the Baking Powder Flat blue butterfly is either known to occur or could be occurring. In the early 1990s, there were reports of grazing at the site near Blind Spring; in 1992, heavy cattle grazing and trampling was reported (Barber, *in litt.* 1992b, p. 1), while 2 years later, in 1994, light use and minimal trampling by cattle was noted at this one site (Barber, *in litt.* 1994, p. 1). Currently, grazing is authorized within the Baking Powder Flat ACEC and is controlled through grazing permit terms and conditions (BLM 2007c, pp. 2.4–101; 2.4–106). BLM has indicated that some (undefined) areas of the ACEC can be ''heavily impacted'' by livestock grazing (BLM 2009a, p. 21). Over 70 percent of the ACEC is within the South Spring Valley Allotment (SNWA, *in litt.* 2011, p. 37).

However, the host plant is not known to be heavily grazed upon or preferred by livestock within the ACEC (Podborny 2012, pers. comm.). While livestock can and do move through the ACEC, concentrations in the butterfly's habitat do not occur as water is not readily available to them (Podborny 2012, pers. comm.). Thus, trampling of the host plant by livestock is not likely. The best available information indicates that the host plant, *Eriogonum shockleyi,* remains common in the Baking Powder Flat area (BLM 2009a, p. 20), and injury to or declines in the host plant species, larvae, or adults due to livestock grazing practices have not been documented. Activities involving grazing management within the Baking Powder Flat blue butterfly habitat would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), BLM's authority under Regulations on Grazing Administration Exclusive of Alaska, BLM's 6840 Manual (BLM 2008b), Baking Powder Flat ACEC restrictions, and possibly NEPA (see our discussion of these authorities in the above analysis for the White River Valley skipper and below, with respect to the Baking Power Flat ACEC). We did not receive any information as a result of our 90-day petition finding notice, nor did we locate information indicating that livestock grazing is negatively impacting the habitat or populations of the Baking Powder Flat blue butterfly. Thus, the best available information does not indicate that livestock grazing is modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Nonnative Plant Invasion

For general background information on nonnative plant invasion, please refer to the Nonnative Plant Invasion section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

The NNHP (2007, p. 42) indicates that a portion of the Baking Powder Flat playa/ephemeral pool/spring pool complex has been degraded, including by nonnative species invasion. The petition states that nonnative plant species invasion may be a potential threat to the Baking Powder Flat blue butterfly (B. Boyd, pers. comm. cited by WildEarth 2010, p. 14) though specific information to support this claim is not provided. Because numerous nonnative and invasive plant species occur in Nevada, it is likely that nonnative and invasive plant species occur to some extent, though this has not been quantified, within the ACEC and the habitat of the Baking Powder Flat blue butterfly. However, the issue of nonnative plant species invasion is not known to be a concern in the ACEC (Podborny 2012, pers. comm.). Though the Baking Powder Flat blue butterfly is associated with only one plant species for its life-history requirements, nonnative plant species do not appear to be competing with it and causing it to decline, as the host plant remains common in the Baking Powder Flat area and ACEC.

Activities involving nonnative plant species management within the Baking Powder Flat blue butterfly habitat would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), BLM's authority under Regulations on Grazing Administration Exclusive of Alaska, the Plant Protection Act of 2000, BLM's programmatic EIS for vegetation treatments on BLM's administered lands in the western United States (BLM 2007a), BLM's 6840 Manual (BLM 2008b), Baking Powder Flat ACEC restrictions, and possibly NEPA (see our discussion of these authorities above in the analysis of the White River Valley skipper, and below with respect to the Baking Power Flat ACEC). We did not receive any information as a result of our 90-day petition finding notice, nor did we locate information indicating that nonnative or invasive plant species are negatively impacting occupied habitat or populations of the Baking Powder Flat blue butterfly. Therefore, the best available information does not indicate that nonnative plant species are modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Agriculture

The NNHP (2007, p. 42) indicates that a portion of the Baking Powder Flat playa/ephemeral pool/spring pool complex has been degraded or converted to other land uses, including agriculture. Although impacts of agriculture were mentioned in the petition as a potential threat to the Baking Powder Flat blue butterfly (WildEarth Guardians 2010, p. 13), information was not provided to support this claim. Agriculture does not occur in the ACEC (Podborny 2012, pers. comm.). The best available information does not indicate agriculture is occurring in areas occupied by the Baking Powder Flat blue butterfly. We did not receive any information as a result of our 90-day petition finding notice, nor did we locate information that indicates agriculture is impacting occupied habitat or populations of the Baking Powder Flat blue butterfly. Thus, the best available information does not indicate that agriculture is modifying this subspecies' habitat to the extent that it represents a threat to Baking Powder Flat blue butterfly populations, their host plants, or nectar sources, now or in the future.

Recreation (Off-Highway Vehicles)

Off-highway vehicle (OHV) impacts on wildlife can include habitat loss and fragmentation, patch size reduction, and an increase in the ratio of edge to the interior (U.S. Geological Survey (USGS) 2007, p. 16). These effects can influence population dynamics, predator-prey relationships, and animal movements (e.g., dispersal, recolonization, gene flow). Even narrow roads and trails can create a barrier to animal movements. Additionally, OHV roads can facilitate range extensions or invasions of nonnative and opportunistic species, direct mortality through collisions, and nest and burrow damage or destruction, and they create noise. These factors can lead ultimately to reduced survivorship of a species.

One study involving butterflies found wide highways did not affect movement with open populations (immigration and emigration continues to occur), but did slightly impact those with closed populations (Munguira and Thomas 1992, cited in USGS 2007, p. 18). Another study found some butterfly species may not attempt to fly across roads possibly due to the microclimate over roads (van der Zande 1980, cited in USGS 2007, p. 18).

In 2008, BLM designated a portion of Baking Powder Flat (13,640 acres (ac)) (5,520 hectares (ha)) as the Baking Powder Flat ACEC to protect the Baking Powder Flat blue butterfly (72 FR 67748; 73 FR 55867, September 26, 2008; BLM 2009a, p. 20). According to BLM (2009b, p. 20), an ACEC is defined as an area ''within the public lands where special management attention is required (when such areas are developed or used or where no development is required) to protect and prevent irreparable damage to important historic, cultural, or scenic values, fish and wildlife resources, or other natural systems or processes, or to protect life and safety from natural hazards.'' The Baking Powder Flat ACEC is managed as an ''avoidance area [* * *.] [G]ranting rights-of-way (surface, subsurface, aerial) within the area will be avoided, but rights-of-way may be granted if there is minimal conflict with identified resource values and impacts can be mitigated.''

Limited OHV use is authorized within the Baking Powder Flat ACEC on

designated roads and trails (72 FR 67748; BLM 2007c, pp. 2.4–101, 2.4–106). Austin (1993, p. 7) and Austin *et al.* (*in litt.* 2000, p. 3) indicate that soil compaction or direct destruction of host plants from vehicles may impact the Baking Powder Flat blue butterfly, however, no additional information was provided to support this claim. A site visit to the occupied location near Blind Spring found evidence of one motorcycle going through the area as reported by a BLM employee in 1994 (Barber *in litt.* 1994, p. 1). Today, with use limited to designated roads and trails, this recreational activity is not considered a concern in the ACEC (Podborny 2012, pers. comm.). Activities involving OHV use within the Baking Powder Flat blue butterfly habitat would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), BLM's 6840 Manual (BLM 2008b), Baking Powder Flat ACEC restrictions, and possibly NEPA (see also our discussion of several of these authorities in our analysis of the White River Valley skipper, above). We did not receive additional information as a result of our 90-day petition finding notice, nor did we locate information indicating that OHV use is damaging this subspecies' habitat. Consequently, the best available information does not indicate that OHV use is modifying this subspecies' habitat to the extent that it represents a threat to Baking Powder Flat blue butterfly populations or their habitats now or in the future.

Mining and Energy Exploration and Development, Power Lines

The NNHP (2007, p. 42) indicates that a portion of the Baking Powder Flat playa/ephemeral pool/spring pool complex has been degraded or converted to other land uses, including energy development. Baking Powder Flat blue butterfly habitat was not identified within the study area for Southwest Intertie Project (BLM 1993, p. 3–65). The Baking Powder Flat blue butterfly was also not observed during wildlife surveys conducted for the One Nevada Transmission Line Project (BLM 2010c, Appendix 3D, Table 2, pp. 1–5).

There are closures or limits on mineral development within the Baking Powder Flat ACEC to protect the unique cultural values, and special status plants and animals, which includes the Baking Powder Flat blue butterfly (72 FR 67748; BLM 2007c, p. 2.4–101), and these types of projects are not occurring in the ACEC (Podborny 2012, pers. comm.). Additionally, actions involving mineral and energy development within Baking Powder Flat blue butterfly habitat would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), the FLPMA of 1976, the Mineral Leasing Act of 1920, BLM's 6840 Manual (BLM 2008b), and NEPA (see our discussion of these authorities above in our analysis of the White River Valley skipper). The available information does not indicate that mineral and energy development are occurring in areas occupied by the Baking Powder Flat blue butterfly. We did not receive additional information as a result of our 90-day petition finding notice, nor did we locate information that indicates mining or energy development, or transmission line installation is impacting the Baking Powder Flat blue butterfly habitat. Thus, the best available information does not indicate that mining and energy development are modifying the subspecies' habitat or impacting Baking Powder Flat blue butterfly populations to an extent that they represent a threat to this subspecies now or in the future.

Plant Collection

Plant collecting is authorized within the Baking Powder Flat ACEC (72 FR 67748; BLM 2007c, p. 2.4–101). Plant materials, including common species, require a permit to be collected (BLM 2007c, pp. 2.4–101; 2.4–106). There have been no permit requests for collection of the host plant, *Eriogonum shockleyi,* for any purpose (Podborny 2012, pers. comm.). As indicated earlier, this host plant remains common in the Baking Powder Flat area (BLM 2009a, p. 20), and declines in this plant species have not been documented. Actions involving plant collection within Baking Powder Flat blue butterfly habitat would be addressed in consideration of the Ely District Record of Decision and Approved RMP (BLM 2008a), BLM's 6840 Manual (BLM 2008b), the Baking Powder Flat ACEC, and possibly the Plant Protection Act of 2000 and NEPA (see our discussion of these authorities above in the analysis of the White River Valley skipper). We did not receive any information as a result of our 90-day petition finding notice, nor did we locate information that indicates plant collecting in the ACEC, specifically for the host plant or in general, is occurring in occupied Baking Powder Flat blue butterfly habitat. Therefore, the best available information does not indicate that plant collecting is modifying the subspecies' habitat to an extent that it represents a threat to this subspecies now or in the future.

Climate Change

Recent projections of climate change in the Great Basin over the next century include: Increased temperatures, with an increased frequency of extremely hot days in summer; more variable weather patterns and more severe storms; more winter precipitation in the form of rain, with potentially little change or decreases in summer precipitation; and earlier, more rapid snowmelt (U.S. Environmental Protection Agency 1998, pp. 1–4; Chambers and Pellant 2008, pp. 29–33). While the petition asserts that climate change may impact this subspecies (WildEarth Guardians 2010, p. 40), it is difficult to predict local climate change impacts, due to substantial uncertainty in trends of hydrological variables, limitations in spatial and temporal coverage of monitoring networks, and differences in the spatial scales of global climate models and hydrological models (Bates *et al.* 2008, p. 3).

We found no information on how climate change may impact the Baking Powder Flat blue butterfly's host plant, *Eriogonum shockleyi.* In general, increasing temperatures and drought frequency could impact the host plant by causing physiological stress, altering phenology, reducing recruitment events, and reducing seed establishment. However, at this time, it is difficult to predict local climate change impacts to *Eriogonum Shockleyi* and how individual plant species will react to climate change, especially for a species which grows in dry, warm sites and thus has adaptations for such conditions.

Thus, while information indicates that climate change has the potential to affect vegetation and habitats used by the Baking Powder Flat blue butterfly in the Great Basin, there is much uncertainty regarding which habitat attributes could be affected, and the timing, magnitude, and rate of their change as it relates to this subspecies. The available information does not indicate that climate change is affecting occupied Baking Powder Flat blue butterfly habitat. We did not receive any further information as a result of our 90-day petition finding notice, nor did we locate specific information that indicates climate change is impacting Baking Powder Flat blue butterfly populations or their habitats. Thus, the best available information does not indicate that climate change is modifying the subspecies' habitat to an extent that it represents a threat to this subspecies now or in the future.

Summary of Factor A

While several activities such as water development, fire, livestock grazing, nonnative species invasion, agriculture, mining and energy development may be

impacting a portion of the Baking Powder Flat wetland complex according to NNHP (2007 p. 42), available information does not indicate that these impacts are occurring in and negatively impacting occupied Baking Powder Flat blue butterfly habitat, which occurs outside of wetland areas. The available information does not indicate that these activities, or additional activities such as OHV use, plant collecting, or climate change, are negatively impacting Baking Powder Flat blue butterfly habitat or populations. The subspecies' larval host plant and adult nectar source (*Eriogonum shockleyi*) does not occur in wetland areas and is unlikely to be indirectly impacted by current or proposed water development activities. The host plant remains common in the Baking Powder Flat area (BLM 2009a, p. 20). In addition to the larval host plant not being a wetland species, any direct impacts to the plant through proposed SNWA water development facility construction activities, if approved, should be minor due to the commitment to implement avoidance, reduction, and mitigation measures. While information indicates that climate change has the potential to affect vegetation used by this subspecies, much uncertainty remains regarding which plant attributes may be affected, and the timing, magnitude, and rate of their change. We conclude based on the best scientific and commercial information available that the present or threatened destruction, modification, or curtailment of its habitat or range does not currently pose a threat to the Baking Powder Flat blue butterfly, nor is it likely to become a threat to the subspecies in the future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

We are unaware of any studies analyzing impacts of removal of individuals from populations of the Baking Powder Flat blue butterfly. According to Austin (1998c, p. 550), 61 males and 41 females of this subspecies were collected between 1978 and 1980 at one site. No additional information is known about the numbers of specimens collected in the past, and we are not aware of any ongoing or current collecting of this subspecies. Given the relatively low number of individuals collected over this 3-year period, the length of time since the collections were made, and the lack of information about the relative impact to the population, the available information does not indicate that collection may be a threat to this subspecies.

We found no information indicating that overutilization has led to the loss of populations or a significant reduction in numbers of individuals for this subspecies. Therefore, we conclude based on the best scientific and commercial information available that overutilization for commercial, recreational, scientific, or educational purposes does not currently pose a threat to the Baking Powder Flat blue butterfly, nor is it likely to become a threat to the subspecies in the future.

Factor C. Disease or Predation

We found no information on the incidence of disease in the Baking Powder Flat blue butterfly.

Predation by other species, such as birds or insects, on eggs, larvae, pupae, or adult Baking Powder Flat blue butterflies is assumed, but we found no information indicating that predation levels are any greater than naturally occurring levels typical of the biological community in which the Baking Powder Flat blue butterfly occurs.

Available information does not indicate that there are impacts from disease or predation on the Baking Powder Flat blue butterfly. Therefore, we conclude based on the best scientific and commercial information available that disease or predation does not currently pose a threat to the Baking Powder Flat blue butterfly, nor is either likely to become a threat to the subspecies in the future.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

The discussion of existing regulatory mechanisms under Factor D for the White River Valley skipper is hereby incorporated into this discussion for the Baking Power Flat blue butterfly. As discussed above under Factor D for the White River Valley skipper, Nevada State law pertaining to wildlife does not offer protection to the Baking Powder Flat blue butterfly specifically because it is an invertebrate species not classified as wildlife. Although not protected by State wildlife law, the best available information, as discussed in Factor B, does not indicate that collection or other forms of overutilization is a threat to the Baking Powder Flat blue butterfly.

A large portion of habitat for the Baking Powder Flat blue butterfly occurs on Federal lands administered by BLM. Numerous policies, guidance, and laws have been developed to assist the agency in management of these lands (see Factor D discussion under White River Valley skipper). BLM policies and guidance address species of concern, actions covered by RMPs, and regulatory authority for grazing and oil and gas leasing and operating activities. As discussed under Factor A, the best available information does not indicate that activities such as livestock grazing, nonnative plant control, mining and energy exploration and development, and recreational activities that are regulated by various policies, guidance, and laws on Federal lands are impacting Baking Powder Flat blue butterfly populations. After reviewing the best available commercial and scientific information, we conclude that the inadequacy of existing regulatory mechanisms does not currently pose a threat to the Baking Powder Flat blue butterfly, nor is it likely to become a threat to the subspecies in the future.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Potential other natural or manmade factors that may affect the continued existence of the Baking Powder Flat blue butterfly are discussed in this section and include: (1) Limited range and (2) small population size(s).

For general background information on other natural or manmade factors which could affect the Baking Powder Flat blue butterfly, please refer to the discussion on limited range and population size under *Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence* in the Five-Factor Evaluation for the White River Valley Skipper.

The Baking Powder Flat blue butterfly is known from seven discrete areas in the Baking Powder Flat area in Spring Valley, in Lincoln and White Pine Counties, Nevada (Austin 1998c, p. 550; Austin and Leary 2008, pp. 68–69). As indicated earlier, the host plant species, *Eriogonum shockleyi,* is common in Nevada and occurs in several other states. For the Baking Powder Flat blue butterfly, little information is available related to its distribution and numbers of populations, and no information is available about size of populations, loss of populations, if any, or population trends. Information pertaining to the aerial extent of habitat or populations is also not available. Available information does not include comprehensive surveys for this subspecies, though researchers have recommended these surveys to determine if additional populations exist. Without data to indicate population trends, it is difficult to support claims of adverse impacts to the Baking Powder Flat blue butterfly.

We found no information on connections between chance events and population impacts for the Baking Powder Flat blue butterfly. This subspecies is distributed over several

areas in the Baking Powder Flat area, and as mentioned above, recommendations have been made for surveys to determine if it is more widespread than currently known. Potential impacts due to stochastic events are reduced because it occurs in several areas. In the absence of chance events connected to known populations, we do not consider restricted geographic range or small population numbers by themselves to be threats to this subspecies. The best available information does not indicate the Baking Powder Flat blue butterfly is negatively impacted by limited range or small population numbers. Therefore, we conclude based on the best available scientific and commercial information that other natural or manmade factors do not currently pose a threat to the Baking Powder Flat blue butterfly, nor are they likely to become a threat to the subspecies in the future.

Synergistic Interactions Between Threat Factors

We have evaluated individual threats to the Baking Powder Flat blue butterfly. This subspecies faces potential threats from water development, fire, livestock grazing, nonnative plant invasion, agriculture, OHV use, mining and energy development, plant collection, climate change, limited range, and small population size. In considering whether the threats to a species may be so great as to warrant listing under the Act, we must look beyond the possible impacts of potential threats in isolation and consider the potential cumulative impacts of all of the threats facing a species.

In making this finding, we considered whether there may be cumulative effects to the Baking Powder Flat blue butterfly from the combined impacts of the existing stressors such that even if each stressor individually does not result in population-level impacts, that cumulatively the effects may be significant. We considered whether the combined effects of water development and mining and energy development may result in a significant impact to the Baking Powder Flat blue butterfly because these potential impacts have the potential to result in some level of habitat loss. However, we conclude that synergistic effects between water development and mining and energy development are unlikely to result in a significant overall population impact to the Baking Powder Flat blue butterfly because the proposed water development construction footprint would be small, indirect impacts from the water development project are not likely, and BLM policies and mitigation measures ensure that impacts to this subspecies' habitat in the Baking Powder Flat ACEC will be minimized.

Mining and energy development were not found to occur in the butterfly's habitat. If mining and energy development projects are proposed in the future, BLM policies and management offer protection through limitations for these types of activities within the ACEC. Livestock grazing, nonnative plant invasion, and OHV use could impact the Baking Powder Flat blue butterfly and its habitat. However, BLM policies and management provide terms and conditions for livestock grazing to protect resources; nonnative plant species invasion is not known to be a concern in the ACEC; and OHV use is limited to existing roads and trails in the ACEC.

Therefore, we conclude that livestock grazing, nonnative plant species invasion, and OHV use impacts combined with potential impacts from water development and mining and energy development would not be of sufficient severity, frequency, or geographic scope to result in significant habitat impacts or cause population-level impacts to the Baking Powder Flat blue butterfly. Fire is unlikely to occur in Baking Powder Flat blue butterfly habitat due to the sandy soils and widely spaced vegetation being unable to support a fire. Agriculture and collection of the host plant species were not found to occur within this subspecies habitat and, therefore, will not have a cumulative impact on the Baking Powder Flat blue butterfly.

Limited range and small population size could make the Baking Powder Flat blue butterfly more vulnerable to potential threats discussed above. However, we cannot conclude that synergistic effects between limited range and small population size and other potential threats are operative threats to the continued existence of the Baking Powder Flat blue butterfly given the lack of information on the range and population size of this butterfly. There is no information on population size or change in population abundance for the Baking Powder Flat blue butterfly, and the limited information on occurrence (distribution) is insufficient to define this butterfly's range.

Synergistic interactions are possible between effects of climate change and effects of other stressors such as livestock grazing, nonnative plant invasion, and OHV use. Increases in carbon dioxide and temperature and changes in precipitation are likely to affect vegetation, and the Baking Powder Flat blue butterfly is closely associated with the presence of certain types of vegetation. However, it is difficult to project how climate change will affect vegetation because certain plant species may increase in cover while other species may decrease. Uncertainty about how different plant species will respond under climate change, combined with uncertainty about how changes in plant species composition would affect suitability of Baking Powder Flat blue butterfly habitat, make projecting possible synergistic effects of climate change on the Baking Powder Flat blue butterfly too speculative.

Finding for the Baking Powder Flat Blue Butterfly

As required by the Act, we considered the five factors in assessing whether the Baking Powder Flat blue butterfly is an endangered or threatened species throughout all of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by this subspecies.

Factors potentially affecting the Baking Powder Flat blue butterfly, including water development, fire, livestock grazing, nonnative species invasion, agriculture, mining and energy development, OHV, plant collecting, climate change, and limited range and small population size, are either limited in scope or lack documentation that they are occurring in occupied habitat and adversely impacting the subspecies. Though climate change may be affecting the Baking Powder Flat blue butterfly and its habitat and effects are likely to increase in the future, the available information does not support a determination that climate change has or will result in a population-level impact to this subspecies. The available information does not indicate that overutilization, disease, or predation is a threat to the Baking Powder Flat blue butterfly. The available information also does not indicate that existing regulatory mechanisms are inadequate to protect the subspecies from potential threats. Furthermore, there is no evidence to suggest that the combined factors acting together are a threat to the Baking Powder Flat blue butterfly. Based on our review of the best scientific and commercial information available, we find these stressors, either singly or in combination with one another, are not threats to the Baking Powder Flat blue butterfly or its habitat.

We found no information to indicate that threats are of sufficient imminence, intensity, or magnitude such that the Baking Powder Flat blue butterfly is in danger of extinction (endangered) or likely to become endangered within the

foreseeable future (threatened), throughout all of its range. Therefore, we find that listing the Baking Powder Flat blue butterfly as an endangered or threatened species throughout its range is not warranted.

Significant Portion of the Range

Having determined that the Baking Powder Flat blue butterfly does not meet the definition of an endangered or a threatened species, we must next consider whether there are any significant portions of the range where the Baking Powder Flat blue butterfly is in danger of extinction or is likely to become endangered in the foreseeable future. The Act defines ''endangered species'' as any species which is ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as any species which is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' 16 U.S.C. 1532(6) and 1532(20). The definition of ''species'' is also relevant to this discussion. The Act defines ''species'' as follows: ''The term 'species' includes any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.'' 16 U.S.C. 1532(16). The phrase ''significant portion of its range'' (SPR) is not defined by the statute, and we have never addressed in our regulations: (1) The consequences of a determination that a species is either endangered or likely to become so throughout a significant portion of its range, but not throughout all of its range; or (2) what qualifies a portion of a range as ''significant.''

Two recent district court decisions have addressed whether the SPR language allows the Service to list or protect less than all members of a defined ''species'': *Defenders of Wildlife* v. *Salazar,* 729 F. Supp. 2d 1207 (D. Mont. 2010), concerning the Service's delisting of the Northern Rocky Mountains gray wolf (74 FR 15123, April 2, 2009); and *WildEarth Guardians* v. *Salazar,* 2010 U.S. Dist. LEXIS 105253 (D. Ariz. September 30, 2010), concerning the Service's 2008 finding on a petition to list the Gunnison's prairie dog (73 FR 6660, February 5, 2008). The Service had asserted in both of these determinations that, under the Act, it had authority, in effect, to protect only some members of a ''species,'' as defined by the Act (i.e., species, subspecies, or DPS). Both courts ruled that the determinations were arbitrary and capricious on the grounds that this approach violated the plain and unambiguous language of the Act. The courts concluded that reading the SPR language to allow protecting only a portion of a species' range is inconsistent with the Act's definition of ''species.'' The courts concluded that once a determination is made that a species (i.e., species, subspecies, or DPS) meets the definition of ''endangered species'' or ''threatened species,'' it must be placed on the list in its entirety and the Act's protections applied consistently to all members of that species throughout its range (subject to modification of protections through special rules under sections 4(d) and 10(j) of the Act).

Consistent with that interpretation, and for the purposes of this finding, we interpret the phrase ''significant portion of its range'' in the Act's definitions of ''endangered species'' and ''threatened species'' to provide an independent basis for listing. Thus there are two situations (or factual bases) under which a species would qualify for listing: A species may be endangered or threatened throughout all of its range, or a species may be endangered or threatened in only a significant portion of its range. If a species is in danger of extinction throughout an SPR, it, the species, is an ''endangered species.'' The same analysis applies to ''threatened species.'' Based on this interpretation and supported by existing case law, the consequence of finding that a species is endangered or threatened in only a significant portion of its range is that the entire species shall be listed as endangered or threatened, respectively, and the Act's protections shall be applied across the species' entire range.

We conclude, for the purposes of this finding, that interpreting the SPR phrase as providing an independent basis for listing is the best interpretation of the Act because it is consistent with the purposes and the plain meaning of the key definitions of the Act; it does not conflict with established past agency practice (i.e., prior to the 2007 Solicitor's Opinion), as no consistent, long-term agency practice has been established; and it is consistent with the judicial opinions that have most closely examined this issue. Having concluded that the phrase ''significant portion of its range'' provides an independent basis for listing and protecting the entire species, we next turn to the meaning of ''significant'' to determine the threshold for when such an independent basis for listing exists.

Although there are potentially many ways to determine whether a portion of a species' range is ''significant,'' we conclude, for the purposes of this finding, that the significance of the portion of the range should be determined based on its biological contribution to the conservation of the species. For this reason, we describe the threshold for ''significant'' in terms of an increase in the risk of extinction for the species. We conclude that a biologically based definition of ''significant'' best conforms to the purposes of the Act, is consistent with judicial interpretations, and best ensures species' conservation. Thus, for the purposes of this finding, and as explained further below, a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction.

We evaluate biological significance based on the principles of conservation biology using the concepts of redundancy, resiliency, and representation. Resiliency describes the characteristics of a species and its habitat that allow it to recover from periodic disturbance. Redundancy (having multiple populations distributed across the landscape) may be needed to provide a margin of safety for the species to withstand catastrophic events. Representation (the range of variation found in a species) ensures that the species' adaptive capabilities are conserved. Redundancy, resiliency, and representation are not independent of each other, and some characteristic of a species or area may contribute to all three. For example, distribution across a wide variety of habitat types is an indicator of representation, but it may also indicate a broad geographic distribution contributing to redundancy (decreasing the chance that any one event affects the entire species), and the likelihood that some habitat types are less susceptible to certain threats, contributing to resiliency (the ability of the species to recover from disturbance). None of these concepts is intended to be mutually exclusive, and a portion of a species' range may be determined to be ''significant'' due to its contributions under any one or more of these concepts.

For the purposes of this finding, we determine if a portion's biological contribution is so important that the portion qualifies as ''significant'' by asking whether, without that portion, the representation, redundancy, or resiliency of the species would be so impaired that the species would have an increased vulnerability to threats to the point that the overall species would be in danger of extinction (i.e., would be ''endangered''). Conversely, we would

not consider the portion of the range at issue to be ''significant'' if there is sufficient resiliency, redundancy, and representation elsewhere in the species' range that the species would not be in danger of extinction throughout its range if the population in that portion of the range in question became extirpated (extinct locally).

We recognize that this definition of ''significant'' (a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction) establishes a threshold that is relatively high. On the one hand, given that the consequences of finding a species to be endangered or threatened in an SPR would be listing the species throughout its entire range, it is important to use a threshold for ''significant'' that is robust. It would not be meaningful or appropriate to establish a very low threshold whereby a portion of the range can be considered ''significant'' even if only a negligible increase in extinction risk would result from its loss. Because nearly any portion of a species' range can be said to contribute some increment to a species' viability, use of such a low threshold would require us to impose restrictions and expend conservation resources disproportionately to conservation benefit: Listing would be rangewide, even if only a portion of the range of minor conservation importance to the species is imperiled. On the other hand, it would be inappropriate to establish a threshold for ''significant'' that is too high. This would be the case if the standard were, for example, that a portion of the range can be considered ''significant'' only if threats in that portion result in the entire species' being currently endangered or threatened. Such a high bar would not give the SPR phrase independent meaning, as the Ninth Circuit held in *Defenders of Wildlife v. Norton,* 258 F.3d 1136 (9th Cir. 2001).

The definition of ''significant'' used in this finding carefully balances these concerns. By setting a relatively high threshold, we minimize the degree to which restrictions will be imposed or resources expended that do not contribute substantially to species conservation. But we have not set the threshold so high that the phrase ''in a significant portion of its range'' loses independent meaning. Specifically, we have not set the threshold as high as it was under the interpretation presented by the Service in the *Defenders* litigation. Under that interpretation, the portion of the range would have to be so important that current imperilment there would mean that the species would be currently imperiled everywhere. Under the definition of ''significant'' used in this finding, the portion of the range need not rise to such an exceptionally high level of biological significance. (We recognize that if the species is imperiled in a portion that rises to that level of biological significance, then we should conclude that the species is in fact imperiled throughout all of its range, and that we would not need to rely on the SPR language for such a listing.) Rather, under this interpretation, we ask whether the species would be endangered everywhere without that portion (i.e., if that portion were completely extirpated). In other words, the portion of the range need not be so important that even the species being in danger of extinction in that portion would be sufficient to cause the species in the remainder of the range to be endangered; rather, the complete extirpation (in a hypothetical future) of the species in that portion would be required to cause the species in the remainder of the range to be endangered.

The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that have no reasonable potential to be significant or to analyzing portions of the range in which there is no reasonable potential for the species to be endangered or threatened. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that: (1) The portions may be ''significant,'' and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. Depending on the biology of the species, its range, and the threats it faces, it might be more efficient for us to address the significance question first or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.'' In practice, a key part of the determination that a species is in danger of extinction in a significant portion of its range is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats to the species occurs only in portions of the species' range that clearly would not meet the biologically based definition of ''significant,'' such portions will not warrant further consideration.

We evaluated the current range of the Baking Powder Flat blue butterfly to determine if there is any apparent geographic concentration of the primary stressors potentially affecting the subspecies including water development, fire, livestock grazing, nonnative species invasion, agriculture, mining and energy development, OHV, plant collecting, climate change, and limited range and small population size. On the basis of our review, we found no geographic concentration of threats either on public or private lands to suggest that the Baking Powder Flat blue butterfly may be in danger of extinction in that portion of its range. We found no area within the range of the Baking Powder Flat blue butterfly where the potential threats are significantly concentrated or substantially greater than in other portions of its range. We also found that lost historical range does not constitute a significant portion of the range for the Baking Powder Flat blue butterfly because there is no information indicating that there has been a range contraction for this subspecies. Therefore, we find factors affecting the subspecies are essentially uniform throughout its range, indicating no portion of the butterfly's range warrants further consideration of possible status as an endangered or threatened species under the Act.

We found no information to indicate that the Baking Powder Flat blue butterfly is in danger of extinction now, nor is it likely to become endangered within the foreseeable future, throughout all or a significant portion of its range. Therefore, listing the Baking Powder Flat blue butterfly as an endangered or threatened species under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, the Baking Powder Flat blue butterfly to our Nevada Fish and Wildlife Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor the Baking Powder Flat blue butterfly and encourage its conservation. If an emergency situation develops for the Baking Powder Flat blue butterfly or any other species, we will act to provide immediate protection.

Species Information for the Bleached Sandhill Skipper

Taxonomy and Species Description

We accept the characterization of the bleached sandhill skipper (*Polites sabuleti sinemaculata*) as a valid subspecies based on its description by Austin (1987, pp. 7–8). This subspecies is in the Hesperiidae family (Austin 1998a, p. 838). The male's wingspan ranges from 0.47 to 0.53 in (11.9–13.4 mm). The upperside is bright golden-orange with a black stigma on the primaries. The dark margin of the primaries is absent to faint. The terminal line is black. Wing fringes are the same as the wing color. The secondaries do not have an outer marginal border. The black along the costal (leading edge) margin is narrow, and the base of the wing is lightly dusted with black. The terminal line and wing fringes are like they are on the primaries. The underside of the wing is paler than the upperside. The black of the primaries is restricted to the base of the cell and along the posterior margin. The secondaries have a faint cobweb pattern (Austin 1987, pp. 7–8). The female's wingspan ranges from 0.52 to 0.59 in (13.1–15.0 mm). The upperside of the wing is a pale yellow-orange. The postmedial (on the wing, just past the middle) area of the primaries is whitish-yellow. The terminal line is dark gray, and fringes are grayish on the primaries and white on the secondaries. The underside is paler than on the male. The postmedial areas of the primaries and the postmedian band and secondaries are ghostly white (Austin 1987, p. 8). Please refer to Austin (1987, p. 8) for a more detailed description of this subspecies.

Distribution and Habitat

The bleached sandhill skipper is known from one location (Baltazor Hot Spring) located west of Denio Junction, Humboldt County, located in northwestern Nevada (Austin 1987, p. 8; Austin *et al., in litt.* 2000, p. 4; NNHP 2010; B. Boyd, pers. comm. cited in WildEarth Guardians 2010, p. 15) (on BLM and private lands). Austin (1987, p. 8) indicates that other areas of the Baltazor Hot Spring drainage system need to be investigated for possible other populations. The area is a salt flat near a hot spring and is densely covered with *Distichlis spicata* (salt grass) (Austin 1987, p. 8), this subspecies' possible host plant (see *Biology* section). The size of the known occupied site or the extent of this subspecies' host plant(s), or host plant abundance, has not been reported.

Biology

Distichlis spicata may serve as the larval host plant (Austin 1987, p. 8); this species is a perennial grass (*http://www.plants.usda.gov,* accessed April 24, 2012) and is common and widespread in Nevada (Kartesz, 1987, p. 1611). This plant can be found in wetland and non-wetland areas in Nevada (Reed 1988, p. 24). It is common and can be found throughout most of the United States (*http://www.plants.usda.gov,* accessed April 24, 2012). In the western United States, it can be found in Washington, Oregon, California, Idaho, Montana, Nevada, Utah, Arizona, and New Mexico (Kartesz, 1987, p. 1611; *http://www.plants.usda.gov,* accessed April 24, 2012).

Adults have been seen nectaring on white and yellow composites (Asteraceae) (Sunflower family) (Austin 1987, p. 8), but specific nectar plant species are not identified. It is possible that adults nectar on a variety of plants that are in flower during their flight period. Adults are known to fly during late August to mid September, and it is unknown if earlier broods occur (Austin 1987, p. 8; Austin *et al., in litt.* 2000, p. 4).

There is little biological information available at the subspecies level, but some inferences can be made from biological information from related species at the species level. Information for the saltgrass skipper (*Polites sabuleti*) indicates eggs are pale bluish-green, turning cream-colored; eggs are laid singly on the host plant or other nearby plants or soil (Scott 1986, p. 443). Larvae eat leaves, and they live in tied-leaf nests (Scott 1986, p. 443). Males perch in low grassy areas during the day seeking females (Scott 1986, p. 444).

According to the petition, thousands of bleached sandhill skippers have been seen in the past (A. Warren, pers. comm. cited in WildEarth Guardians 2010, p. 15), but the population appears to have declined 2–3 years ago (B. Boyd, pers. comm. cited in WildEarth Guardians 2010, p. 15). The cause or potential cause of this apparent decline is not reported in the petition. The available information does not indicate whether a population decline, if accurate, is unusual or not as butterfly populations are highly dynamic from year to year (Weiss *et al.* 1997, p. 2). The best available information does not include surveys documenting population size, number of extirpated populations or sites, if any, or population trends (other than that mentioned above).

Five-Factor Evaluation for the Bleached Sandhill Skipper

Information pertaining to the bleached sandhill skipper in relation to the five factors provided in section 4(a)(1) of the Act is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Potential factors that may affect the habitat or range of the bleached sandhill skipper are discussed in this section, including: (1) Water development, (2) livestock grazing, (3) energy development, and (4) climate change.

Water Development

For general background information on water development, please refer to the Water Development section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

Austin *et al.* (*in litt.* 2000, p. 4) state that the bleached sandhill skipper could be impacted by water table changes, but specific information is not provided to support this claim. The Baltazor Meadow-Continental Lake wetland area is estimated to have had 20 percent of its wetland area degraded or converted to other land uses, such as by water development (NNHP 2007, p. 36). The Baltazor Meadow-Continental Lake wetland area includes the Baltazor Hot Spring where the bleached sandhill skipper is known to occur and an additional area, Continental Lake, located to the south where the bleached sandhill skipper is not known to occur. The NNHP (2007) does not delineate these wetland areas on a map or define them in terms of acreage; therefore, the amount of bleached sandhill skipper habitat that may occur within these areas and may be impacted by various activities is not indicated. The extent to which the various land use practices have degraded or converted these areas is also not individually delineated or quantified by NNHP (2007). Therefore, we cannot determine the amount of overlap between the estimated wetland impacts identified by the NNHP and the distribution of the bleached sandhill skipper. Bleached sandhill skipper habitat will not be impacted by the SNWA water development project because the project is proposed in southern and eastern Nevada and in groundwater basins not connected to the basin where this skipper occurs.

While it is likely that human water demands have impacted this drainage system over the decades, pumping of

the Baltazor Hot Spring does not currently occur (Lawson 2012, per. comm.). The best available information does not indicate that changes due to water development have occurred in the area occupied by the bleached sandhill skipper and are negatively impacting the habitat of this subspecies. Actions regarding water management in bleached sandhill skipper habitat in the future would be addressed in consideration of Nevada water law. We did not receive any additional information as a result of our 90-day petition finding notice, nor did we locate information that indicates water development is impacting the subspecies' habitat. Therefore, the best available information does not indicate that water development is modifying the subspecies' habitat to an extent that it represents a threat to the bleached sandhill skipper population now or in the future.

Livestock Grazing

For general background information on livestock grazing, please refer to the Livestock Grazing section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

A portion of the Baltazor Meadow–Continental Lake wetland area has been identified as degraded or converted to other land uses, including livestock grazing (NNHP 2007, p. 36). The Baltazor Hot Spring and most of the vegetation associated with bleached sandhill skipper habitat (approximately 100 ac (40.5 ha)) is located within the Continental Pasture of the Pueblo Mountain Allotment on BLM-administered lands (Lawson 2012, pers. comm.). The pasture is on a 3-year rotation with cattle grazing occurring 2 out of every 3 years for 1 month in August; the permittee usually does not graze the entire month (Lawson 2012, pers. comm.). The area is not heavily grazed, and the habitat looks to be in good condition (Lawson 2012, pers. comm.). The possible larval host plant, *Distichlis spicata,* is common here and widespread in Nevada. The Asteraceae Family is a large plant family comprising numerous species, several of which the adults may be using as nectar sources. The best available information does not indicate a decline in either the possible larval host plant or probable adult nectar source populations within the bleached sandhill skipper's habitat due to livestock grazing.

Actions involving livestock grazing within bleached sandhill skipper habitat are addressed in consideration of the Winnemucca District Record of Decision and Approved RMP (BLM 2010a) (see Factor D discussion under White River Valley skipper), BLM's authority under Regulations on Grazing Administration Exclusive of Alaska, BLM's 6840 Manual (BLM 2008b), and possibly NEPA (see our discussion of these authorities above, under White River Valley skipper). We did not receive any information as a result of our 90-day petition finding notice, nor did we locate information indicating that livestock grazing is negatively impacting the habitat or the known population of the bleached sandhill skipper. Thus, the best available information does not indicate that livestock grazing is modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Energy Development

For general background information on energy development, please refer to the Energy Development section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

A portion of the Baltazor Meadow–Continental Lake wetland area has been identified as degraded or converted to other land uses, including energy development (NNHP 2007, p. 36). Energy development is not occurring within the bleached sandhill skipper habitat (Lawson 2012, pers. comm.). Any actions involving energy development within bleached sandhill skipper habitat would be addressed in consideration of the Winnemucca District Record of Decision and Approved RMP (BLM 2010a), the FLPMA of 1976, BLM's 6840 Manual (BLM 2008b), and NEPA (see our discussion of these authorities above under White River Valley skipper). We did not receive any information as a result of our 90-day petition finding notice, nor did we locate information indicating that energy development is negatively impacting the bleached sandhill skipper population or its habitat. Thus, the best available information does not indicate that energy development is modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Climate Change

For general background information on climate change, please refer to the Climate Change section under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range* in the Five-Factor Evaluation for the White River Valley Skipper.

It is difficult to predict local climate change impacts, due to substantial uncertainty in trends of hydrological variables, limitations in spatial and temporal coverage of monitoring networks, and differences in the spatial scales of global climate models and hydrological models (Bates *et al.* 2008, p. 3). We found no information on how climate change may impact the bleached sandhill skipper's potential host plant, *Distichlis spicata,* or adult nectar sources. In general, increasing temperatures and drought frequency, more winter precipitation in the form of rain, possible decreases in summer rain, and earlier, rapid snowmelt could impact the host plant by causing physiological stress, altering phenology, reducing recruitment events, and reducing seed establishment. However, at this time, it is difficult to predict local climate change impacts to *Distichlis spicata* and how individual plant species will react to climate change, especially for a species which is common and grows in both wet and dry areas. Thus, while information indicates that climate change has the potential to affect vegetation and habitats used by the bleached sandhill skipper in the Great Basin, there is much uncertainty regarding which habitat attributes could be affected, and the timing, magnitude, and rate of their change as it relates to this subspecies.

The best available information does not indicate that climate change is impacting occupied bleached sandhill skipper habitat. We did not receive any information as a result of our 90-day petition finding notice, nor did we locate specific information that indicates climate change is negatively impacting bleached sandhill skipper habitat. Therefore, the best available information does not indicate that climate change is modifying the subspecies' habitat to the extent that it represents a threat to this subspecies now or in the future.

Summary of Factor A

While a few activities such as water development and livestock grazing may be impacting a portion of the Baltazor Meadow-Continental Lake wetland area, the available information does not indicate that these activities or climate change are negatively impacting the bleached sandhill skipper population or its habitat. Therefore, we conclude based on the best scientific and commercial information available that the present or threatened destruction, modification, or curtailment of its habitat or range does not currently pose

a threat to the bleached sandhill skipper, now or is it likely to become a threat to the subspecies in the future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

For general background information on overutilization, please refer to the discussion on collecting under *Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes* in the Five-Factor Evaluation for the White River Valley Skipper.

We are unaware of any studies analyzing impacts of removal of individuals from populations of the bleached sandhill skipper. According to Austin (1987, p. 8), 27 males and 14 females were collected between 1984 and 1985 at one site. No additional information is known about the numbers of specimens collected in the past, and we are not aware of any ongoing or current collecting of this subspecies. Given the low number of individuals collected over this 2-year period, the length of time since the collections were made, and the lack of information about the relative impact to the populations, the available information does not indicate that collection may be a threat to this subspecies.

We found no information indicating that overutilization has led to the loss of populations or a significant reduction in numbers of individuals for this subspecies. Therefore, we conclude based on the best scientific and commercial information available that overutilization for commercial, recreational, scientific, or educational purposes does not currently pose a threat to the bleached sandhill skipper, nor is it likely to become a threat to the subspecies in the future.

Factor C. Disease or Predation

We found no information on the incidence of disease in the bleached sandhill skipper.

We assume that predation by other species, such as birds or insects, on eggs, larvae, pupae, or adult bleached sandhill skippers occurs, but we found no information indicating that predation levels are any greater than naturally occurring levels typical of the biological community in which the bleached sandhill skipper occurs.

Available information does not indicate that there are impacts from disease or predation on the bleached sandhill skipper. Therefore, we conclude based on the best scientific and commercial information available that disease or predation does not currently pose a threat to the bleached sandhill skipper, nor is either likely to become a threat to the subspecies in the future.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

The discussion of existing regulatory mechanisms under Factor D for the White River Valley skipper is hereby incorporated into this discussion for the bleached sandhill skipper. As discussed above under Factor D for the White River Valley skipper, Nevada State law pertaining to wildlife does not offer protection to the bleached sandhill skipper specifically because it is an invertebrate species not classified as wildlife. Although not protected by State wildlife law, the best available information, as discussed in Factor B, does not indicate that collection or other forms of overutilization is a threat to the bleached sandhill skipper.

A large portion of habitat for the bleached sandhill skipper occurs on Federal lands administered by BLM. Numerous policies, guidance, and laws have been developed to assist the agency in management of these lands (see Factor D discussion under White River Valley skipper). BLM policies and guidance address species of concern, actions covered by RMPs, and regulatory authority for grazing and oil and gas leasing and operating activities. As discussed under Factor A, the best available information does not indicate that activities such as livestock grazing and mining and energy development that are regulated by various policies, guidance, and laws on Federal lands are impacting the habitat of the bleached sandhill skipper. We conclude based on the best available commercial and scientific information that the inadequacy of existing regulatory mechanisms does not pose a threat to the bleached sandhill skipper, nor is it likely to become a threat to the subspecies in the future.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Potential other natural or manmade factors that may affect the continued existence of the bleached sandhill skipper are discussed in this section and include: (1) Limited range and (2) small population size(s).

For general background information on other natural or manmade factors which could affect the bleached sandhill skipper, please refer to the discussion on limited distribution and population size under *Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence* in the Five-Factor Evaluation for the White River Valley Skipper.

The bleached sandhill skipper is currently known from only one area (Baltazor Hot Spring) near Denio Junction, Humboldt County, Nevada (see *Distribution and Habitat* section). However, Austin (1987, p. 8) indicates that other areas of the Baltazor Hot Springs drainage system need to be investigated for possible other populations. The petition reports that although thousands had been seen in the past, a decline appears to have occurred 2–3 years ago (A. Warren, pers. comm. and B. Boyd, pers. comm., cited in WildEarth Guardians 2010, p. 15), but details regarding this decline or a reason(s) for it are not provided in the petition. It is unknown whether or not this decline, if accurate, can be attributed to the normal natural fluctuations of butterfly populations. Butterfly populations are highly dynamic, and numbers and distribution can be highly variable year to year (Weiss *et al.* 1997, p. 2).

Little information is available related to population numbers, size, or trends for the bleached sandhill skipper. Information pertaining to the aerial extent of habitat or populations is not available. The available information does not include comprehensive surveys for this subspecies though researchers have recommended these surveys to determine if additional populations exist. Without data to indicate population trends, it is difficult to support claims of adverse impacts to the bleached sandhill skipper. We found no information on connections between chance events and population impacts for the bleached sandhill skipper. In the absence of chance events connected to known populations, we do not consider restricted geographic range or small population numbers by themselves to be threats to a species. The best available information does not indicate that the bleached sandhill skipper is negatively impacted by limited range or small population numbers. Therefore, we conclude based on the best available scientific and commercial information that other natural or manmade factors do not currently pose a threat to the bleached sandhill skipper, nor are they likely to become a threat to the subspecies in the future.

Synergistic Interactions Between Threat Factors

We have evaluated individual threats to the bleached sandhill skipper. This subspecies faces potential threats from water development, livestock grazing, energy development, climate change, limited range, and small population

size. In considering whether the threats to a species may be so great as to warrant listing under the Act, we must look beyond the possible impacts of potential threats in isolation and consider the potential cumulative impacts of all of the threats facing a species.

In making this finding, we considered whether there may be cumulative effects to the bleached sandhill skipper from the combined impacts of the existing stressors such that even if each stressor individually does not result in population-level impacts, that cumulatively the effects may be significant. We considered whether the combined effects of water development and energy development may result in a significant impact to the bleached sandhill skipper because these potential impacts have the potential to result in some level of habitat loss. However, we conclude that synergistic effects between water development and energy development will not result in a significant overall population impact to the bleached sandhill skipper because these activities have not been found to occur within this subspecies' habitat. While livestock grazing could impact habitat of the bleached sandhill skipper, BLM policies and management provide terms and conditions for livestock grazing to protect resources, and we conclude that livestock grazing is not of sufficient severity, frequency, or geographic scope to result in significant habitat impacts or cause population-level impacts to the bleached sandhill skipper.

Limited range and small population size could make the bleached sandhill skipper more vulnerable to potential threats discussed above. However, we cannot conclude that synergistic effects between limited range and small population size and other potential threats are operative threats to the continued existence of the bleached sandhill skipper given the lack of information on the range and population size of this butterfly. There is no information on population size or change in population abundance for the bleached sandhill skipper, and the limited information on occurrence (distribution) is insufficient to define this skipper's range.

Synergistic interactions are possible between effects of climate change and effects of other stressors such as livestock grazing. Increases in carbon dioxide and temperature and changes in precipitation are likely to affect vegetation, and the bleached sandhill skipper is closely associated with the presence of vegetation. However, it is difficult to project how climate change will affect vegetation because certain plant species may increase in cover while other species may decrease. Uncertainty about how different plant species will respond under climate change, combined with uncertainty about how changes in plant species composition would affect suitability of bleached sandhill skipper habitat, make projecting possible synergistic effects of climate change on the bleached sandhill skipper too speculative.

Finding for the Bleached Sandhill Skipper

As required by the Act, we considered the five factors in assessing whether the bleached sandhill skipper is an endangered or threatened species throughout all of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by this subspecies.

Factors potentially affecting the bleached sandhill skipper including water development, livestock grazing, energy development, or climate change, and limited range and small population size, are either limited in scope or lack documentation that they are occurring in occupied habitat and adversely impacting the subspecies. Though climate change may be affecting the bleached sandhill skipper and its habitats, and effects are likely to increase in the future, the available information does not support a determination that climate change will have a population-level impact on this subspecies. The available information also does not indicate that overutilization, disease, or predation is negatively impacting the bleached sandhill skipper. There is also no indication that existing regulatory mechanisms are inadequate to protect the subspecies from potential threats. Furthermore, there is no evidence to suggest that the combined stressors acting together are a threat to the bleached sandhill skipper. Based on our review of the best scientific and commercial information available, we find these stressors, either singly or in combination with one another, are not threats to the bleached sandhill skipper.

We found no information to indicate that threats are of sufficient imminence, intensity, or magnitude such that the bleached sandhill skipper is in danger of extinction (endangered) or likely to become endangered within the foreseeable future (threatened), throughout all of its range. Therefore, we find that listing the bleached sandhill skipper as an endangered or threatened species is not warranted throughout its range.

Significant Portion of the Range

Having determined that the bleached sandhill skipper does not meet the definition of an endangered or a threatened species, we must next consider whether there are any significant portions of the range where the bleached sandhill skipper is in danger of extinction or is likely to become endangered in the foreseeable future. The Act defines ''endangered species'' as any species which is ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as any species which is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' 16 U.S.C. 1532(6) and 1532(20). The definition of ''species'' is also relevant to this discussion. The Act defines ''species'' as follows: ''The term 'species' includes any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.'' 16 U.S.C. 1532(16). The phrase ''significant portion of its range'' (SPR) is not defined by the statute, and we have never addressed in our regulations: (1) The consequences of a determination that a species is either endangered or likely to become so throughout a significant portion of its range, but not throughout all of its range; or (2) what qualifies a portion of a range as ''significant.''

Two recent district court decisions have addressed whether the SPR language allows the Service to list or protect less than all members of a defined ''species'': *Defenders of Wildlife* v. *Salazar,* 729 F. Supp. 2d 1207 (D. Mont. 2010), concerning the Service's delisting of the Northern Rocky Mountains gray wolf (74 FR 15123, April 2, 2009); and *WildEarth Guardians* v. *Salazar,* 2010 U.S. Dist. LEXIS 105253 (D. Ariz. September 30, 2010), concerning the Service's 2008 finding on a petition to list the Gunnison's prairie dog (73 FR 6660, February 5, 2008). The Service had asserted in both of these determinations that, under the Act, it had authority, in effect, to protect only some members of a ''species,'' as defined by the Act (i.e., species, subspecies, or DPS). Both courts ruled that the determinations were arbitrary and capricious on the grounds that this approach violated the plain and unambiguous language of the Act. The courts concluded that reading the SPR language to allow protecting only a portion of a species' range is inconsistent with the Act's definition of

''species.'' The courts concluded that once a determination is made that a species (i.e., species, subspecies, or DPS) meets the definition of ''endangered species'' or ''threatened species,'' it must be placed on the list in its entirety and the Act's protections applied consistently to all members of that species throughout its range (subject to modification of protections through special rules under sections 4(d) and 10(j) of the Act).

Consistent with that interpretation, and for the purposes of this finding, we interpret the phrase ''significant portion of its range'' in the Act's definitions of ''endangered species'' and ''threatened species'' to provide an independent basis for listing. Thus there are two situations (or factual bases) under which a species would qualify for listing: A species may be endangered or threatened throughout all of its range, or a species may be endangered or threatened in only a significant portion of its range. If a species is in danger of extinction throughout an SPR, it, the species, is an ''endangered species.'' The same analysis applies to ''threatened species.'' Based on this interpretation and supported by existing case law, the consequence of finding that a species is endangered or threatened in only a significant portion of its range is that the entire species shall be listed as endangered or threatened, respectively, and the Act's protections shall be applied across the species' entire range.

We conclude, for the purposes of this finding, that interpreting the SPR phrase as providing an independent basis for listing is the best interpretation of the Act because it is consistent with the purposes and the plain meaning of the key definitions of the Act; it does not conflict with established past agency practice (i.e., prior to the 2007 Solicitor's Opinion), as no consistent, long-term agency practice has been established; and it is consistent with the judicial opinions that have most closely examined this issue. Having concluded that the phrase ''significant portion of its range'' provides an independent basis for listing and protecting the entire species, we next turn to the meaning of ''significant'' to determine the threshold for when such an independent basis for listing exists.

Although there are potentially many ways to determine whether a portion of a species' range is ''significant,'' we conclude, for the purposes of this finding, that the significance of the portion of the range should be determined based on its biological contribution to the conservation of the species. For this reason, we describe the threshold for ''significant'' in terms of an increase in the risk of extinction for the species. We conclude that a biologically based definition of ''significant'' best conforms to the purposes of the Act, is consistent with judicial interpretations, and best ensures species' conservation. Thus, for the purposes of this finding, and as explained further below, a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction.

We evaluate biological significance based on the principles of conservation biology using the concepts of redundancy, resiliency, and representation. Resiliency describes the characteristics of a species and its habitat that allow it to recover from periodic disturbance. Redundancy (having multiple populations distributed across the landscape) may be needed to provide a margin of safety for the species to withstand catastrophic events. Representation (the range of variation found in a species) ensures that the species' adaptive capabilities are conserved. Redundancy, resiliency, and representation are not independent of each other, and some characteristic of a species or area may contribute to all three. For example, distribution across a wide variety of habitat types is an indicator of representation, but it may also indicate a broad geographic distribution contributing to redundancy (decreasing the chance that any one event affects the entire species), and the likelihood that some habitat types are less susceptible to certain threats, contributing to resiliency (the ability of the species to recover from disturbance). None of these concepts is intended to be mutually exclusive, and a portion of a species' range may be determined to be ''significant'' due to its contributions under any one or more of these concepts.

For the purposes of this finding, we determine if a portion's biological contribution is so important that the portion qualifies as ''significant'' by asking whether, without that portion, the representation, redundancy, or resiliency of the species would be so impaired that the species would have an increased vulnerability to threats to the point that the overall species would be in danger of extinction (i.e., would be ''endangered''). Conversely, we would not consider the portion of the range at issue to be ''significant'' if there is sufficient resiliency, redundancy, and representation elsewhere in the species' range that the species would not be in danger of extinction throughout its range if the population in that portion of the range in question became extirpated (extinct locally).

We recognize that this definition of ''significant'' (a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction) establishes a threshold that is relatively high. On the one hand, given that the consequences of finding a species to be endangered or threatened in an SPR would be listing the species throughout its entire range, it is important to use a threshold for ''significant'' that is robust. It would not be meaningful or appropriate to establish a very low threshold whereby a portion of the range can be considered ''significant'' even if only a negligible increase in extinction risk would result from its loss. Because nearly any portion of a species' range can be said to contribute some increment to a species' viability, use of such a low threshold would require us to impose restrictions and expend conservation resources disproportionately to conservation benefit: Listing would be rangewide, even if only a portion of the range of minor conservation importance to the species is imperiled. On the other hand, it would be inappropriate to establish a threshold for ''significant'' that is too high. This would be the case if the standard were, for example, that a portion of the range can be considered ''significant'' only if threats in that portion result in the entire species' being currently endangered or threatened. Such a high bar would not give the SPR phrase independent meaning, as the Ninth Circuit held in *Defenders of Wildlife* v. *Norton,* 258 F.3d 1136 (9th Cir. 2001).

The definition of ''significant'' used in this finding carefully balances these concerns. By setting a relatively high threshold, we minimize the degree to which restrictions will be imposed or resources expended that do not contribute substantially to species conservation. But we have not set the threshold so high that the phrase ''in a significant portion of its range'' loses independent meaning. Specifically, we have not set the threshold as high as it was under the interpretation presented by the Service in the *Defenders* litigation. Under that interpretation, the portion of the range would have to be so important that current imperilment there would mean that the species would be currently imperiled everywhere. Under the definition of ''significant'' used in this finding, the portion of the range need not rise to such an exceptionally high level of

biological significance. (We recognize that if the species is imperiled in a portion that rises to that level of biological significance, then we should conclude that the species is in fact imperiled throughout all of its range, and that we would not need to rely on the SPR language for such a listing.) Rather, under this interpretation, we ask whether the species would be endangered everywhere without that portion (i.e., if that portion were completely extirpated). In other words, the portion of the range need not be so important that even the species being in danger of extinction in that portion would be sufficient to cause the species in the remainder of the range to be endangered; rather, the complete extirpation (in a hypothetical future) of the species in that portion would be required to cause the species in the remainder of the range to be endangered.

The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that have no reasonable potential to be significant or to analyzing portions of the range in which there is no reasonable potential for the species to be endangered or threatened. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that: (1) The portions may be ''significant,'' and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. Depending on the biology of the species, its range, and the threats it faces, it might be more efficient for us to address the significance question first or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.'' In practice, a key part of the determination that a species is in danger of extinction in a significant portion of its range is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats to the species occurs only in portions of the species' range that clearly would not meet the biologically based definition of ''significant,'' such portions will not warrant further consideration.

We evaluated the current range of the bleached sandhill skipper to determine if there is any apparent geographic concentration of the primary stressors potentially affecting the subspecies including water development, livestock grazing, energy development, climate change, and limited range and small population size. On the basis of our review, we found no geographic concentration of threats either on public or private lands to suggest that the bleached sandhill skipper may be in danger of extinction in that portion of its range. We found no area within the range of the bleached sandhill skipper where the potential threats are significantly concentrated or substantially greater than in other portions of its range. We also found that lost historical range does not constitute a significant portion of the range for the bleached sandhill skipper because there is no information indicating that there has been a range contraction for this subspecies. Therefore, we find factors affecting the subspecies are essentially uniform throughout its range, indicating no portion of the skipper's range warrants further consideration of possible status as an endangered or threatened species under the Act.

We found no information to indicate that the bleached sandhill skipper is in danger of extinction now, nor is it likely to become endangered within the foreseeable future, throughout all or a significant portion of its range. Therefore, listing the bleached sandhill skipper as an endangered or threatened species under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, the bleached sandhill skipper to our Nevada Fish and Wildlife Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor the bleached sandhill skipper and encourage its conservation. If an emergency situation develops for the bleached sandhill skipper or any other species, we will act to provide immediate protection.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Nevada Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this notice are the staff members of the Nevada Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: August 20, 2012.

Benjamin N. Tuggle,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2012–21243 Filed 8–31–12; 8:45 am]

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Part IV

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Mardon Skipper as Threatened or Endangered; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2012–0060; 4500030113]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Mardon Skipper as Threatened or Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on a petition to list the mardon skipper (*Polites mardon*) as a threatened or endangered species under the Endangered Species Act of 1973, as amended (Act). After review of the best available scientific and commercial information, we find that listing the mardon skipper is not warranted at this time. However, we ask the public to submit to us any new information that becomes available concerning the threats to the mardon skipper or its habitat at any time. At our discretion, after additional review of the subspecies *Polites mardon mardon* and *Polites mardon klamathensis,* we find that listing for these subspecies is also not warranted at this time.

DATES: The finding announced in this document was made on September 4, 2012.

ADDRESSES: This finding is available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R1–ES–2012–0060. Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Washington Fish and Wildlife Office, 510 Desmond Drive SE., Suite 102, Lacey, WA 98503. Please submit any new information, materials, comments, or questions concerning this finding to the above address.

FOR FURTHER INFORMATION CONTACT: Ken Berg, Field Supervisor, Washington Fish and Wildlife Office (see **ADDRESSES**); by telephone at 360–753–9440; facsimile at 360–753–9008; or Paul Henson, Field Supervisor, Oregon Fish and Wildlife Office, 2600 SE 98th Avenue, Suite 100, Portland, OR 97266; by telephone at 503–231–6179; facsimile at 503–231–6195 mailto:. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), requires that, for any petition to revise the Federal Lists of Endangered and Threatened Wildlife and Plants that contains substantial scientific or commercial information that listing the species may be warranted, we make a finding within 12 months of the date of receipt of the petition. In this finding, we will determine that the petitioned action is: (1) Not warranted, (2) warranted, or (3) warranted, but the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are threatened or endangered species, and expeditious progress is being made to add or remove qualified species from the Federal Lists of Endangered and Threatened Wildlife and Plants. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register**.

Previous Federal Actions

On October 25, 1999, the Service identified the mardon skipper (*Polites mardon*) as a candidate species for listing under the Act (64 FR 57539). The identification of the mardon skipper as a candidate species was based on information compiled in the Washington State Status Report for the Mardon Skipper (Potter *et al.* 1999, entire).

On December 11, 2002, we received a petition dated December 10, 2002, from The Xerces Society, Gifford Pinchot Task Force, The Northwest Environmental Defense Center, Center for Biological Diversity, Oregon Natural Resources Council, Friends of the San Juans, and Northwest Ecosystem Alliance (petitioners), requesting that the mardon skipper be listed as an endangered species, and that critical habitat be designated under the Act (Black *et al.* 2002, entire). Included in the petition was supporting information regarding the species' taxonomy and ecology, historical and current distribution, present status, and actual and potential causes of decline. We acknowledged the receipt of the petition in a letter to the petitioners, dated January 22, 2003. In that letter we also stated that the Service considered the mardon skipper as having been subject to both a positive 90-day finding and a ''warranted but precluded'' 12-month finding, with the Candidate Notice of Review constituting publication of these required findings. The Service's ''warranted but precluded'' finding was based on limited funding that was dedicated to court-ordered or other higher-priority listings.

From 2003 to 2011, the Service continued to work with Federal, State, and private parties to compile information on the status and distribution of the mardon skipper, which is documented in the Service's candidate species assessment forms for those years. Substantial new information was collected regarding mardon skipper populations, distribution, and habitat requirements. In 2009, we changed the listing priority number for the mardon skipper from 5 to 8 (lower priority) due to the documentation of many new populations and increased protections for the species and its habitat provided by State and Federal special status species programs.

In a settlement agreement with plaintiff WildEarth Guardians, on May 10, 2011, the Service submitted a workplan to the U.S. District Court for the District of Columbia in *re Endangered Species Act Section 4 Deadline Litigation,* No. 10–377 (EGS), MDL Docket No. 2165 (D. DC May 10, 2011), and obtained the court's approval to systematically, over a period of 6 years, review and address the needs of more than 250 candidate species to determine if they should be added to the Federal Lists of Endangered and Threatened Wildlife and Plants. The mardon skipper is one of 251 candidate species identified in the May 2011 workplan. On October 26, 2011, the Service published the intent to develop a proposed listing for several candidate species in the Puget Sound prairie region (including the mardon skipper) with funding allocated in Fiscal Year 2011 (76 FR 66830). We have since determined that, as the distribution of the mardon skipper includes additional habitat other than prairie, the public would be better served evaluating this information and the species, separately.

This notice constitutes our 12-month finding on the mardon skipper. Substantial new information regarding the mardon skipper has been compiled since we originally advanced the species to candidacy. Therefore, this finding considers information presented in the 2002 petition, as well as new information compiled over the past decade.

Species Information

The mardon skipper is a small (20 to 24 millimeters; less than 1 inch), tawny-orange butterfly with a stout, hairy body. The upper surface of the forewings and hindwings is orange with broad dark-brown borders, and the ventral hindwings have a distinctive pattern of light yellow to white rectangular spots (Pyle 2002, p. 88). Males are smaller than females, and have a small, dark-brown, slender and branched streak (stigma) on the upper surface of the forewing. Females have a more distinct ventral hindwing pattern. The mardon skipper is differentiated from other closely related *Polites* species by its short, rounded wings, reduced stigmal elements, and other distinctive morphological features (MacNeill 1993, p. 179). Like most Hesperiinae butterflies, mardon skippers have bent antennae clubs and a characteristic basking posture in which the forewings are held at a 45-degree angle and the hind wings are fully spread (Potter *et al.* 1999, p. 1).

Taxonomy and Species Description

The mardon skipper is a butterfly in the Order Lepidoptera (butterflies and moths), superfamily Hesperioidae, and family Hesperiidae (skippers), subfamily Hesperiinae (grass skippers). It was originally described by W. H. Edwards (1881, pp. 47–48) as *Pamphila mardon* from three males and three females collected by H.K. Morrison in 1880. The original type locality, stated by W.H. Edwards as Mount Hood, Oregon, was later correctly designated as small prairies near Puget Sound, Washington (Morrison 1883, p. 43). This type location was further defined as ''Tenino Prairie, Thurston County, Washington'' by Brown and Miller (1980, p. 53). The mardon skipper is a rare species that occurs in four disjunct areas that include locations near the coast in northwestern California and southwestern Oregon, the southern Oregon Cascades, the southern Washington Cascades, and prairies in the south Puget Sound region (James and Nunallee 2011, p. 388).

In 1998, Mattoon *et al.* (p. 768) proposed that the Oregon Cascade populations be given subspecies status as *Polites mardon klamathensis,* and the Washington and northern California populations be given subspecies status as *Polites mardon mardon.* Adults of P.m. klamathensis are described as having a consistently tawnier dorsal and ventral coloration when compared to adults from other populations (Mattoon *et al.* 1998, pp.771–772).

The distinction between *Polites mardon klamathensis* and *P.m. mardon* was based largely on comparisons between specimens collected in northwestern California and the southern Oregon Cascades. According to Warren (2005, p. 49), the use of the name *P.m. mardon* for California populations should be considered tentative because the series of *P.m. mardon* from the northwestern California (and coastal southwestern Oregon) populations have not yet been carefully compared to the series of *P.m. mardon* from Washington due to the small number of specimens available for evaluation (Mattoon *et al.* 1998, p. 771). The Catalogue of the Butterflies of the United States and Canada (Pelham 2008, p. 78) lists the full species followed by both subspecies. However, in the introduction of his Catalogue, Pelham (2008, p. VII) notes that the subspecies category is used without regard to its validity. No additional taxonomic work or genetic analyses have been done to clarify the subspecific designations described above (Kerwin 2011, p. 10). *Polites mardon* is recognized as a valid species by the Integrated Taxonomic Information System (ITIS) while *P.m. klamathensis* and *P.m. mardon* are recognized as valid subspecies (ITIS 2011, *P. mardon,* entire). For the purposes of this finding, we first analyzed the threats to the species *Polites mardon* as a whole. We then, at our initiative, further considered the threats to each of the currently recognized subspecies: *P.m. mardon* and *P.m. klamathensis.*

Distribution

The mardon skipper is a rare northwestern butterfly with a remarkably disjunct range. The species' current range is known from four widely separated locations: the south Puget Sound region of Washington, the southern Washington Cascades, the Cascade Mountains of southern Oregon, and coastal hills in northwestern California and southwestern Oregon (Kerwin 2011, pp. 8–9). The historical range and abundance of mardon skippers are unknown. The species was originally described from specimens collected at a south Puget Sound prairie site in 1880 (Morrison 1883, p. 43), but there are few historical records or museum collections of this species (Potter *et al.* 1999, p. 3). No estimates of abundance are available from any site prior to 1980 (Potter *et al.* 1999, p. 5).

The mardon skipper's disjunct distribution and strong association with early-seral, semi-mesic grassland habitats in the Pacific Northwest suggest a relict distribution that was likely much more widespread in the past. Both Pyle (2002, p. 89) and Runquist (2004a, p. 6) suggest that the mardon skipper is an ancient species. The species' short, rounded wing morphology is not adapted to long-distance dispersal. The apparent lack of intervening populations between the distinct geographic areas suggests the species probably evolved under more open, contiguous environmental conditions (Runquist 2004a, p. 6). Populations in each disjunct geographic region have likely become isolated over long geologic time scales, as evidenced by the subspecies distinction between *Polites mardon mardon* and *P. m. klamathensis.* It is likely that mardon skippers were historically more widespread within each disjunct geographic region prior to the widespread loss of grassland and montane meadow habitats due to fire suppression, invasive species, and development over the past century (Potter *et al.* 1999, p. 5, Beyer and Schultz 2010, p. 863; Schultz *et al.* 2011, p. 370).

In this assessment we use the term ''site'' to indicate a specific location with species presence. Sites are usually mapped as distinct habitat patches, such as individual meadows in summary reports (e.g., Black *et al.* 2010, p. 25). Sites may include locations with a single mardon skipper observation, or locations that support many mardon skippers observed over multiple years. Sites are variable, and not all reports define sites the same way. For purposes of estimating the number of populations, occupied meadows can be considered to belong to the same population if the sites are within the annual dispersal distance for the species, generally assumed to be 0.5 mi (0.8 km) or less (Potter and Fleckenstein 2001, p.6). In this assessment we use the term ''populations'' to represent local clusters of sites that we assume are likely to be associated and function as a local population.

Summary of Mardon Skipper Current Range and Distribution

In 1999, the mardon skipper was known from approximately 14 extant sites located in four distinct geographic areas (Potter *et al.* 1999, p.5). Targeted surveys from 2000 through 2011 have documented a total of 165 sites with mardon skipper presence representing approximately 66 populations (Table 1). New sites or populations have been documented in each year that surveys have been completed. For example, five new sites were documented in 2011, including four sites in the Washington Cascades, and one site in the southern

Oregon Cascades. It is very likely that additional undocumented sites exist, particularly in the Washington Cascades and possibly in southwestern Oregon or northwestern California, because not all of the potential habitat areas have been surveyed. The increase in known populations since 1999 is due to increased survey effort in areas not previously surveyed, rather than to increased habitat or expanding populations (Kerwin 2011, p. 18). The majority (76 percent) of the sites throughout the species' range occur on Federal lands managed by the Forest Service, Bureau of Land Management (BLM), National Park Service, Fish and Wildlife Service, and the Department of Defense, as well as Tribal lands owned by the Yakama Indian Reservation (17 percent). Due to the species' disjunct distribution, the populations in different geographic regions are relatively isolated, with two recognized subspecies *Polites mardon mardon* and *P.m. klamathensis,* occurring within the species' range.

Geographic region	Site ownership	Approximate number of documented sites with species presence (2000–2011)	Approximate number of populations (local clusters of sites)
Polites mardon mardon			
Washington—South Puget Sound Prairies (Pierce and Thurston Counties).	Joint Base Lewis McChord—Dept. of Defense	4	1
	Washington Dept. of Fish & Wildlife	2	2
Washington—South Cascades (Yakima, Klickitat, and Skamania Counties).	Wenatchee National Forest	36	15
	Gifford Pinchot National Forest	43	13
	Conboy Lake National Wildlife Refuge	3	3
	Yakama Indian Reservation	23	11
	Private ownership	6	4
Southwest Oregon—Curry County	BLM—Coos Bay District	2	1
	Rogue River Siskiyou National Forest	3	1
	Oregon State Parks	1	
Northwest California—Del Norte County	Six Rivers National Forest	8	2
	Redwood National Park	9	1
	Private ownership	3	1
Polites mardon klamathensis			
Oregon—South Cascades Jackson County	BLM Medford District	15	9
	Rogue River Siskiyou National Forest	4	2
	Private ownership	3	
Totals		165	66

Note: In this assessment we use the term "sites" for specific locations with documented species presence (some of which are single observations) and "populations" to represent local clusters of sites that we assume are likely to be closely associated and function as a local population.

Summary of Mardon Skipper Population Estimates and Trends

Estimates of population sizes or population trends over time for mardon skippers are generally not available. Surveys to estimate relative abundance of mardon skippers are conducted by systematically walking transects through a site and counting the number of adult mardon skippers encountered (Seitz *et al.* 2007, p. 11). The majority of survey efforts have been 1-day counts, so it is not known if they were conducted early or late in the adult flight period. Multiple surveys during the flight season and across a number of years are required to assess population sizes because the timing and length of adult flight periods can vary widely from year to year (Kerwin 2011, p. 19).

A few surveyors have used line-transect distance-sampling methods to estimate mardon skipper populations, but these techniques have generally failed to provide statistically reliable estimates at sites with small populations (Runquist 2004b, p. 4, Arnold 2006, p. 6). Runquist (2004a, pp. 4–5) used both line-transect sampling and mark-recapture sampling techniques to estimate a mardon skipper population in a small complex of three meadows in the Oregon Cascades. Researchers counted a total of 172 mardon skippers on all line-transects over all days, compared with a total of 238 mardon skippers that were captured and marked in the same meadows during the same period (Runquist 2004a, p. 5). No statistically reliable estimates of the actual population size were derived from this effort, but the author opines that a total population estimate of 350–400 individuals would be reasonable at this site based on his observations (Runquist 2004a, p. 5).

Line-transect distance sampling was used to census mardon skippers across approximately 800 acres (ac) (324 hectares (ha)) of Puget prairie habitat in 2009, and provided the first statistically reliable estimates of the mardon skipper populations at these sites (Potter 2010, p. 4). At the Scatter Creek Wildlife Area in 2009, the population estimate during the peak of the adult flight period was 801 mardon skippers at the South Unit (95 percent confidence interval = 399–1,286 skippers) and 204 at the North Unit (95 percent confidence interval = 84–360) (Potter 2010, p. 4). These estimates were derived from actual counts of 312 skippers on the South Unit and 93 skippers on the North Unit (Potter 2009, p. 1). This was the most comprehensive survey effort at this site to date, so the results of the survey are not directly comparable to previous monitoring efforts at this site (Potter 2009, p. 2), but this population appears to be relatively stable based on counts conducted between 1997 and 2009 (Potter *et al.* 1999, p. 6; Harke 2001, p. 12; Potter 2009, p. 1).

Only one site (in Washington) has had a full spectrum of censuses that have covered the entire adult flight period (Beyer and Black 2007, p. 8). In 2006, the counts at this site (Grapefern Meadow) went from 0 mardon skippers counted on July 6, to 135 on July 9; 345

on July 16; 128 on July 23; and 2 on August 4 (Beyer and Black 2007, p. 8). These counts demonstrate that the number of mardon skippers present at a site can fluctuate significantly over a few days. The observed mardon skipper population at this site has fluctuated greatly over the past decade, with peak counts ranging from 420 butterflies in 2004 to 34 in 2011. Although there have been high counts of butterflies from time to time, overall the populations on the Wenatchee National Forest and Gifford Pinchot National Forest appear to be relatively stable. Data from the Wenatchee National Forest show some evidence of trends related to elevation, with lower elevation population sites (less than 3,300 feet (ft) [1,000 meters (m)]) appearing to be stable, and mid-elevation sites (3,500–4000 ft [1,067–1,220 m]) showing some local declines, likely associated with cool, wet summer conditions (St. Hilaire *et al.* 2010, p. 2).

In the Oregon Cascades, limited population information for *Polites mardon klamathensis* is available, as few multiple-day surveys have been conducted here. Black *et al.* (2010, Appendix 1) report single-day counts for multiple *P.m. klamathensis* sites over a 5-year period, spanning 2005–2010 (there were no counts for most sites in 2008). In 2011, one new *P.m. klamathensis* site was located on Bureau of Reclamation Lands managed by BLM (Black 2012, pers. comm.). Although several of the *P.m. klamathensis* sites appear to be small in size (fewer than 20 individuals), only a handful of these sites had counts on more than a single day in a year, and even in these few cases there were never more than 2 days of counts in any single year (Black *et al.* 2010, Appendix 1). Furthermore, the dates for these counts range quite widely from one year to the next, from early or mid-June through the first week of July, so whether these counts occurred within the peak flight period is unclear. For example, as described above for Grapefern Meadow in Washington, the only site where we have data from mardon skipper counts over the entire adult flight period, the numbers of skippers counted on any single day ranged anywhere from 0 to 345 over a 10-day period (Beyer and Black 2007, p. 8). This high variability in potential counts shows why single-day counts are not a credible means of determining population abundance or trend. Of the known sites for the subspecies, most have had relatively few individuals counted on any single day over the period 2005 through 2010, but it is not known whether the observed numbers may represent an increase or decrease over historical levels. One site, Pumpchance 125 Meadow, has generally had relatively high numbers of *P.m. klamathensis* over 5 years of single-day counts (up to 304 individuals counted in 2009); historical abundance of mardon skippers is not known at this site. On the other hand, the three sites that make up the Hobart Peak complex, the one site where historical abundance information is available, appear to have lower numbers of *P. m. klamathensis* than observed in the past (Black *et al.* 2010, Appendix 1). In general, however, based on the lack of historical abundance information and the uncertainty accompanying individual day counts, we are unable to determine population trends for *P.m. klamathensis*.

Recent monitoring at Coon Mountain in California found lower numbers of mardon skippers in areas treated with prescribed burning compared to unburned areas in 2008. Three years after the burn event, mardon skipper numbers were still lower in burned areas than in unburned areas, but the overall population at this site appears to be stable (Black *et al.* 2011, p. 13). Monitoring efforts at other sites in California have been inconsistent, but the limited data for the historical sites at High Divide Ridge indicate this population is potentially stable within the limited suitable habitat areas present at these sites.

Mardon skippers can be locally abundant where the species is present (Pyle 1989, p. 28) with day counts of greater than 100 individuals documented at several sites across the species' geographic range (Black *et al.* 2010, pp. 70–71; St. Hilaire *et al.* 2010, pp. 10–12; Black *et al.* 2011, p. 13). Conversely, populations at many locations within the species' range are apparently persisting at very low levels with consistent peak counts of fewer than 20 individuals.

Documented extirpations occurred at five Puget Prairies sites from 1985 through 1999, resulting in a local contraction of the species' range in that region (Potter *et al.* 1999, p. 6). Extirpation at one historical site in the Washington Cascades has been documented (Potter *et al.* 1999, p. 4), but there are at least three other extant populations in the vicinity of this historical site at the Conboy Lake National Wildlife Refuge, including a newly documented population in 2011 (USFWS unpublished data). Black *et al.* (2010, p. 7) state that some *Polites mardon klamathensis* sites in the Oregon Cascades may possibly be extirpated; however, they also stress that more monitoring is needed to confirm this supposition. No historical data is available at these sites prior to 2005, and many of these sites appear to have always had very low numbers of individuals according to single-day counts (Black *et al.* 2010, pp. 70–72). Black *et al.* (2010, p. 7) additionally note that there are cases where one individual mardon skipper may have been found in past years but not in subsequent surveys, but such instances may represent errant findings and are not indicative of sites or popultions that have become extirpated.

With the apparent exception of a few *Polites mardon klamathensis* populations where more monitoring is needed, and a few higher-elevation *P. m. mardon* sites in the Washington Cascades, most mardon skipper populations now appear to be stable across the species' range.

Habitat

Mardon skippers are grass skippers in the subfamily Hesperiinae, meaning the larvae feed strictly on graminoids (grasses and sedges) (Scott 1986, p. 424). The mardon skipper's habitat requirements include food resources for adults (flower nectar), larval host plants (grasses and sedges), and site-specific environmental and structural conditions that support successful reproduction and survival. This includes patches of early-seral open grassland habitat that are dominated by short-statured grasses or sedges and forbs that are generally free of overstory trees and shrubs. Mardon skippers generally avoid areas with tall grasses, shrubs, or trees (Henry 2010, p. 44). Grassland patches that are as small as 0.5 ac [0.2 ha] are capable of supporting small populations of mardon skippers. However, most areas that support populations of mardon skippers consist of mixed forest-grassland complexes that support multiple occupied ''sites'' with some connectivity between habitat patches for successful dispersal and movement of individuals among sites.

The species' larval development is prolonged, lasting for 3 months or more prior to diapause (Newcomer 1966a, p. 246; Henry 2010, p. 5). During this time the larvae require succulent grasses for successful development. Occupied sites retain sufficient moisture to maintain host plant palatability (green leaves) for larval development (Beyer and Black 2007, p. 18; Kerwin 2011, p. 21). Meadows that are too wet or too dry do not support mardon skippers. Site conditions and host plants selected by mardon skippers vary across sites, indicating the species is capable of using multiple graminoids as larval food (Beyer and Schultz 2010, p. 867).

Although mardon skippers are not selective for a specific grass species, they do exhibit host plant specificity within some localities (Beyer and Schultz 2010, p. 869; Henry 2010, p. 15).

South Puget Sound Prairies

In the south Puget Sound region of Washington, mardon skippers are found in low-elevation (200–300 ft [60–90 m]), glacial outwash grasslands (prairies) with abundant *Festuca roemeri* (Roemer's fescue) interspersed with *Viola adunca* (early blue violet) (Potter et al. 1999, p. 5). Occupied prairies range in size from 300 to greater than 1,000 ac [120 to more than 400 ha]. Mardon skippers oviposit (lay eggs) on Roemer's fescue almost exclusively at Puget prairie sites, indicating a very strong association with this grass species (Henry 2010, p. 13). Roemer's fescue is a perennial bunchgrass native to the Pacific Northwest. Although Roemer's fescue accounted for 50 percent of the total grass cover at the sampled locations, mardon skippers selected this species in 86 out of 88 observed ovipositions (Henry 2010, p. 13.). In addition to the presence of the host plants, the structure of the surrounding plant community is also important for oviposition selection (Henry 2010, p. 16). Mardon skippers selected small, green (live) fescue tufts in areas with at least 50 percent open moss cover on the surrounding ground (Henry 2010, p. 16). Mardon skippers avoid areas that are heavily invaded with *Arrhenatherum elatius* (tall oatgrass) and *Cytisus scoparius* (Scot's broom) (Henry 2010, p. 44). The oviposition habitat requirements of mardon skippers in Puget prairies are distinct from those of populations in the southern Washington Cascades (Henry 2010, p. 19).

At Puget prairie sites, early blue violet and *Vicia sativa* (common vetch) are strongly preferred as nectar sources, and Scot's broom is strongly avoided (Hays *et al.* 2000, p. 14). Nectaring was also observed on *Camassia quamash* (common camas), *Lomatium utriculatum* (fine-leaved desert parsley), *Teesdalia nudicaulis* (barestem teesdalia), and *Ranunculus occidentalis* (western buttercup) (Hays *et al.* 2000, p. 24).

Southern Washington Cascades

In the southern Washington Cascades, the mardon skipper is found in open grasslands and small montane meadows within *Abies grandis* (Grand fir), *Psuedotsuga menziesii* (Douglas-fir), or *Pinus contorta* (lodgepole pine)/mixed-conifer woodlands at mid to high elevations (1,800 to 5,600 ft [549 to 1,707 m]) (Potter *et al.* 2002, p. 12). Occupied sites in the Washington Cascades vary in size from small (0.5 ac [0.2 ha]) meadows to large forest/meadow complexes encompassing hundreds of acres. Site conditions range from relatively dry, ridgetop meadows to small montane meadows associated with wetlands, springs, or riparian habitat (Potter *et al.* 2002, p. 13). Wetland areas that are perennially submerged do not support mardon skippers, but the species is often found in dry transitional zones along the margins of wetlands. Water features such as small streams or wetlands are common at many Washington Cascades sites (Kerwin 2011, p. 20). Alpine meadows (more than approximately 6,000 ft [1,829 m] elevation) apparently do not support this species, perhaps due to the relatively short season these areas are free from snow cover. Sites with grassland vegetation, including grassy forest openings, roadside meadows, and young, grass-dominated tree plantations support mardon skipper populations (Potter *et al.* 2002, pp. 12–13).

In the Washington Cascades, oviposition has been documented on 23 different graminoid species (Beyer and Schultz 2010, p. 866). However, this analysis indicated that mardon skippers are selective for certain grass species within different meadows. The most frequently used oviposition plants include *Festuca idahoensis* (Idaho fescue), *Poa pratensis* (Kentucky bluegrass), *Danthonia intermedia* (timber oatgrass), *Carex inops* (long-stolen sedge), and *Festuca rubra* (red fescue) (Beyer and Schultz 2010, p. 866). *Danthonia unispecta* (one-spiked oatgrass) appears to be an important grass species at sites on the Wenatchee National Forest. Females have been observed ovipositing on this species (Jepsen *et al.* 2008, p. 3), and higher densities of adult butterflies are commonly associated with patches of *D. unispecta* (St. Hilaire *et al.* 2009, p. 7). The variety of identified oviposition plants suggests that females may not always oviposit on specific host plants, but within a community of possible species that can be used by the larvae (Beyer and Black 2007, p. 5). These findings are significantly different from the observations at Puget prairies sites, which indicated mardon skippers were strongly associated with a single grass species (Henry 2010, p. 19).

Due to the range of plant communities present at Washington Cascades sites, there were no common habitat features across all study sites other than the presence of short-statured grasses and sedges (Beyer and Schultz 2010, pp. 869–870). Mardon skippers selected for larger graminoids with greater total cover and less bare ground selection was also negatively influenced by the presence of trees, indicating a preference for selecting oviposition sites away from trees and forest edges (Beyer and Schultz, p. 869). Studies of mardon skipper densities within individual meadows also demonstrated that mardon skippers are patchily distributed within occupied sites, with the highest densities tending to occur near the center of a meadow away from forested edges (Beyer and Black 2007, p. 18).

In the Washington Cascades, adults have most frequently been observed nectaring on vetch, *Fragaria* spp. (strawberry), and *Trifolium* spp. (clover) (Beyer and Black 2007, p. 15). *Erysimum asperum* (wallflower), *Erigeron peregrinus* (fleabane), *Calochortus* spp. (sego lily), and *Achillea millefolium* (yarrow) are also reported as nectar sources from this region (Beyer and Black 2007, p. 15; Potter and Fleckenstein 2001, p. 6).

Southern Oregon Cascades

Populations of *Polites mardon klamathensis* in southern Oregon occupy small (0.5 to10 ac [0.25 to 4 ha]), high-elevation (4,500 to 5,100 ft [1,372 to 1,555 m]) grassy meadows within mixed-conifer forests that are associated with an ephemeral or permanent water source such as a stream or wetland (Black *et al.* 2010, pp. 6–7). As seen at many sites in Washington, mardon skippers in the Oregon Cascades are typically found along the margins of forest wetlands in the narrow transitional zone along the edge of a water feature and the adjacent dry uplands (Kerwin 2011, p. 21).

Occupied sites are dominated by short-statured grass/sedge communities. In the Oregon Cascades, the most common oviposition plant was *Danthonia californica* (California oatgrass) (Beyer and Black 2007, p. 6). Other species selected for oviposition were red fescue, Roemer's fescue, Kentucky bluegrass, *Deschampsia cespitosa* (tufted hairgrass), and *Carex* spp. (sedges) (Beyer and Black 2007, p. 6). The primary nectar plants being utilized are *Potentilla diversifolia* (diverse-leaved cinquefoil), *Wyethia angustifolia* (narrow-leaved mule's ears), *Penstemon procerus* (small-flowered penstemon), and *Plectritis congesta* (sea blush) (Beyer and Black 2007, p. 16).

Coastal Northwest California/Southwest Oregon

The coastal populations of *Polites mardon mardon* are found in small meadows (0.5–5 ac [0.2–2 ha]) dominated by Idaho fescue in sparse *Pinus jeffreyi* (Jeffrey pine) forests in extreme northwestern California and southwestern Oregon. Sites are located in coastal hills approximately 7 to 15 miles (11 to 24 km) inland from the Pacific coast, at elevations ranging from approximately 1,500 to 3,000 ft (427 to 854 m). These sites are within the coastal fog belt (Mattoon *et al.* 1998, p. 771). Meadow habitats at these sites are associated with the western extent of serpentine-based soils in the region (Imper 2003, p. 4), and are more mesic (moist) than typical serpentine grasslands found in northwestern California (Imper 2003, p. 4). Ross (2010, p. 1) notes that the coastal Oregon mardon skipper sites are associated with serpentine-based soils supporting moist-to-dry transitional meadow habitats with abundant bunchgrasses.

The most detailed description of vegetation for sites in this area is for the High Divide Ridge sites (Imper 2003, pp. 4–5). Both Idaho fescue and California oatgrass are common at these sites (Imper 2003, p. 5) and are likely used as host plants for oviposition and larval food. No oviposition or habitat selection studies have been completed for these populations, but Runquist (2004b, p. 2) observed females ovipositing on Festuca spp. at High Divide sites. The most commonly selected nectar plants at California sites are *Phlox diffusa* (spreading phlox) and *Viola adunca* (early blue violet; Arnold 2006, pp. 6–7). Detailed observations of mardon skipper behavior including oviposition, plant selection, and adult nectar species have not been reported for the coastal Oregon sites. Ross (2008, p. 9) noted observing mardon skippers nectaring on *Viola* spp. and *Calochortus* spp. at a coastal Oregon site.

Biology

Mardon skippers are univoltine, completing one life cycle annually (i.e., egg–larva–pupa–adult). Adults typically emerge between May and July, depending upon location and elevation of the site, with adults in higher elevation sites emerging later. Adults do not all emerge on the same date, so flight period duration at any given site depends in part on the number of skippers present. In 2007, at one Washington site, Beyer and Black (2007, p. 8) note that adult emergence went from 0 adults on July 6 to 135 adults on July 9. In large populations the flight period may extend for over a month, while small populations may have adults present for only 10 or fewer days (Potter *et al.* 2002, p. 11). Within the same geographic area, emergence dates vary with elevation, with emergence occurring earlier at lower elevations. Weather influences emergence and flight period duration. Wet or cold conditions delay emergence; conversely, warm, dry conditions promote earlier emergence, and both may affect the duration of the adult flight period (Potter *et al.* 2002, p. 11).

Mark-recapture experiments indicate adults can live up to 3 weeks (Runquist 2004a, p. 5), but most adults live only 7 to 9 days (Scott 1986, p. 25). During their brief life as adult butterflies, mardon skippers feed on flower nectar, mate, and lay eggs on grasses or sedges (see Habitat Requirements for details). As with many butterfly species, males are often observed ''puddling'' or congregating on wet soils (Scott 1986, p. 68). During periods of adverse weather, mardon skippers seek shelter low in the vegetation, under grass or forbs. Mardon skippers generally fly low to the ground, often hovering over low grasses and forbs, or darting from place to place with a fast skipping flight. Mardon skippers are non–migratory. Adults generally disperse distances of up to 0.25 mile (mi) (0.4 kilometers [km]) over relatively short periods, but there appears to be very little dispersal beyond their natal meadow complexes (Runquist 2004a, p. 5). On occasion, individual males have been detected up to 1 mi (1.6 km) away from their original location (Runquist 2004a, p. 5). Mardon skippers have not been observed flying through closed-canopy forest, but they have been observed along open corridors such as powerlines or roads with nectar sources (Potter and Fleckenstein 2001, p. 6).

After mating, females deposit their eggs (oviposit) singly into tufts of low-growing grasses or sedges (host plants) (James and Nunnalle 2011, p. 388). The total number of eggs laid in the wild is unknown, but Newcomer (1966a, p. 243) observed about 25 eggs per female for captive *Polites,* and James and Nunnallee (2011, p. 388) note that two captive females produced 21 eggs total. Eggs hatch in 7 to 10 days (Newcomer 1966a, p. 244; Henry 2010, p. 5). After hatching, the larvae feed on host grasses or sedges throughout the summer and into the fall months (Beyer and Black 2007, p. 19, Henry 2010, p. 14). Larvae use silk to construct a grass ''nest'' and emerge from this shelter to feed on the tender edges or leaf tips of host grasses (James and Nunallee 2011, p. 388). These nests are tube-like structures up to 0.78 inches (in) (2 centimeters [cm]) long that are oriented either vertically or horizontally at the base of the host plant (Beyer and Black 2007, p. 17). It does not appear that the larvae disperse away from the oviposit location (Beyer and Black 2007, p. 17). Henry (2010, p. 14) found six larvae at a Puget prairie site in September 2009, confirming that larvae feed on the same plants that the females had selected during oviposition (Henry 2010, p. 14). There are five instars (stages) of larval development, followed by the formation of a pupa and emergence as an adult butterfly (James and Nunallee 2011, p. 388).

Captive-rearing efforts suggest that mardon skipper larvae overwinter as pupae (Newcomer 1966a, p. 246; James and Nunalle 2011, p. 388), but field observations indicate that the larvae overwinter in diapause, and feed again in the spring before pupating (Henry 2009, p. 2; Henry 2010, p. 5). Beyer and Black (2007, p. 19) found larvae present at a Washington Cascades site as late as October 21, and Henry (2009, p. 2) found larvae at a Puget prairie site in November and February. This aspect of mardon skipper life history is not well understood. Some captive-reared larvae developed quickly, forming a pupa and eclosing (emerging) as adults in the fall (which is not known to occur in the wild), while other captive-reared larvae overwintered as pupa (James and Nunallee 2011, p. 388). Other *Polites* species have been recorded as overwintering as larvae (*P. mystic*), pupae (*P. sabuleti*), or both (P. peckius) (Scott, 1986, pp. 443–445).

Conservation Measures

When the mardon skipper was first identified as a Federal candidate for listing in 1999 (64 FR 57539; October 25, 1999), the species was known from approximately 14 extant sites located in 4 distinct geographic areas—south Puget Sound prairies, the southern Washington Cascades, the southern Oregon Cascades, and northwestern California (Potter *et al.* 1999, p. 5). At that time, the species was not afforded any special status or protections from existing regulatory mechanisms (Potter *et al.* 1999, p. 15). However, the subsequent designation of the mardon skipper as a State-listed endangered species in Washington and as a Federal candidate species has raised awareness of the need for the species' conservation. The species is now designated as a Sensitive Species or Special Status Species on Federal lands within its range (discussed below), and State natural resource agencies have

identified mardon skippers as a priority species for conservation.

State Laws and Conservation Plans

The mardon skipper is listed as an endangered species in the State of Washington by the Washington Fish and Wildlife Commission (Washington Administrative Codes 232–12–014, Endangered Species; 232–12–011, Threatened Species, Appendix D). The Washington Department of Fish and Wildlife (WDFW) has prepared a Comprehensive Wildlife Conservation Strategy (CWCS) (WDFW 2005). The CWCS identifies the mardon skipper as a ''species of greatest conservation need'' and identifies specific conservation actions for the species, including the protection of known sites and potential habitats and the investigation of limiting factors, and identifies development of a recovery plan for the species as a priority (WDFW 2005, p. 326). The conservation plan provides recommended management actions that have contributed to the amelioration of threats to the mardon skipper where they are found on State lands. Ongoing management for mardon skipper habitat on State lands in the Puget Prairie region is occurring through partnerships between the Department of Defense, The Nature Conservancy (now Center for Natural Lands Management), Washington State Department of Natural Resources, Washington Department of Fish and Wildlife, and U.S. Fish and Wildlife Service among others. These treatments have been effective for restoring or maintaining mardon skipper habitat at managed sites. Mardon skippers have been documented using many areas that were previously unsuitable due to the presence of invasive weeds after the habitat was restored with herbicides to eliminate tall oat grass, followed by management (mowing, pulling) to control Scot's broom (Hays 2008, pp 1–2).

There are also a number of small Prairie sites in the region that are currently in protected status and are actively being managed to maintain butterfly habitats that may serve as potential future reintroduction sites for mardon skippers (Anderson 2008, p. 2, Henry 2010, pp.3–4). Beginning in 2007, the Fort Lewis Army Compatible Use Buffer (ACUB) initiative has supported the convening of a cooperative, interdisciplinary and interagency Butterfly Habitat Enhancement Team to develop and implement habitat improvements for mardon skipper and other rare butterflies on formerly occupied sites off of the Fort Lewis reservation (Anderson 2008, p. 1). This interagency team is a source of funding for mardon skipper habitat management, population assessments, and mardon skipper life history research at Puget prairie sites. These projects continue to maintain habitat and mardon skipper populations at the Scatter Creek Wildlife Area through prescribed fire, direct seeding of native species, mowing, and herbicide control of Scotch broom (*Cytisus scoparius*) and exotic grasses and forbs (WDFW 2011, p.79). The ongoing management to maintain mardon skipper populations and habitat at Puget prairie sites afford the species a high level of protection against further losses of habitat or populations.

Oregon has a State Endangered Species Act, but the law does not cover invertebrate species. The Oregon Department of Fish and Wildlife (ODFW) has prepared a Comprehensive Conservation Strategy (ODFW 2006). The strategy identifies the mardon skipper as a ''strategy species.'' Strategy species are found in low numbers at few locations and are considered to be at-risk species. The plan targets conservation actions for the most at-risk species. The strategy generally identifies special habitat needs, limiting factors, and data gaps for the mardon skipper (ODFW 2006, p. 351).

California has a State Endangered Species Act, but the law does not apply to insects. The State Comprehensive Wildlife Action Plan (CDFG 2006) does not specifically address the conservation needs of the mardon skipper, but the plan emphasizes conservation of invertebrate species listed on the State ''special animal'' list.

Special Status Species Policies on National Forest and BLM Lands

The mardon skipper is listed as a Sensitive Species by the U.S. Forest Service in Washington and Oregon (Forest Service Region 6), and in California (Forest Service Region 5), and as a Special Status Species by the Bureau of Land Management (BLM) in Oregon and Washington. For Oregon and Washington BLM-administered lands, Special Status Species policy (BLM 6840) details the need to conserve those species and the ecosystems on which they depend. Conservation is defined as the use of all methods and procedures which are necessary to improve the condition of Special Status Species and their habitats to a point where their Special Status recognition is no longer warranted. Policy objectives also state that actions authorized or approved by the BLM do not contribute to the need to list Special Status Species under the Endangered Species Act (Interagency Special Status/Sensitive Species Program [ISSSSP] 2011, entire).

On National Forest lands, Sensitive Species are defined as those plant and animal species identified by a Regional Forester for which population viability is a concern, as evidenced by significant current or predicted downward trends in population numbers or density and habitat capability that would reduce a species' existing distribution (Forest Service Manual [FSM] 2670.5). Management of Sensitive Species ''must not result in a loss of species viability or create significant trends toward federal listing'' (FSM 2670.32). The Regional Forester is responsible for identifying Sensitive Species and is directed by policy to coordinate with Federal and State agencies and other sources, as appropriate, in order to focus conservation management strategies and to avert the need for Federal or State listing as a result of National Forest management activities (ISSSSP 2011, entire).

The Pacific Northwest Regional Office of the Forest Service and Oregon/Washington State Office of the BLM established the Interagency Special Status/Sensitive Species Program (ISSSSP) to facilitate the conservation and management of rare species on Federal lands. This interagency collaboration focuses on regional-level conservation approaches for Sensitive and Special Status Species lists (ISSSSP 2011, entire).

With dedicated funding from the ISSSSP, the Forest Service/BLM have:

(1) Formed the inter agency Mardon Skipper Work Group, which meets semi annually to share information and ideas and to plan future conservation work for mardon skippers;

(2) Developed a mardon skipper survey protocol (Seitz *et al.* 2007, entire);

(3) Funded multiple seasons of mardon skipper surveys across Forest Service, BLM, and other lands in Oregon and Washington;

(4) Funded an oviposition habitat study in cooperation with the Xerces Society and Washington State University to determine plants that mardon skippers choose for egg laying and larval hosts (Beyer 2009, entire);

(5) Contracted with the Xerces Society to develop site-specific management plans for all mardon skipper sites on BLM lands in the southern Oregon Cascades (Black *et al.* 2010, entire);

(6) Completed a Conservation Assessment for the mardon skipper in 2007 (Kerwin and Huff 2007, entire); and

(7) Revised and updated the Conservation Assessment in 2011 (Kerwin 2011, entire).

Additional site-management plans are currently under development in 2012 with dedicated funding from the ISSSSP for Forest Service mardon skipper sites on the Wenatchee, Gifford Pinchot, and Rogue River—Siskiyou National Forests, as well as additional sites on the Coos Bay BLM District.

The Forest Service/BLM Conservation Assessment is a comprehensive review of the mardon skipper's status, threats, and conservation needs, and provides specific management guidance and recommendations for protecting and maintaining the species' habitat on Federal lands (Kerwin 2011, pp. 30–35). The management considerations in the Conservation Assessment provide general guidance to Forest Service/BLM administrative units for managing mardon skipper sites and addressing potential threats such as conifer encroachment, invasive weeds, livestock grazing, and off-road vehicles (Kerwin 2011, pp. 31–33). The listing of the mardon skipper as a Forest Service Sensitive/BLM Special Status species ensures that the species is considered and addressed during the planning and implementation of Forest Service and BLM land management activities. The Sensitive/Special Species status has resulted in direct protection or restoration of mardon skipper habitat at many sites on Federal lands across the species range. Examples include conifer removal projects and placement of boulders to block off-road vehicle access (Kogut 2008, pp. 4–9), building grazing exclosures to exclude cattle from mardon skipper habitat (e.g., USFS 2003, p. 185); or eliminating grazing impacts by closing grazing allotments or reducing use (e.g., BLM 2008, p. 6). In California, both the Forest Service and the National Park Service have included mardon skipper habitat protections in the planning and implementation of prescribed burn projects (e.g., Black *et al.* 2011, p. 3; NPS 2010, pp. 26–27).

In summary, the majority of the known occurrences of the mardon skipper throughout its range are located on Federal or State lands where the species is assured a high level of protection through existing regulations or conservation management associated with special status species programs. Federal and State agencies have been proactive in implementing effective conservation measures for the mardon skipper throughout its range. These protective measures are currently in place and are not dependent upon the species being listed under the Act.

Summary of Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1533) and implementing regulations (50 CFR 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, a species may be determined to be an endangered or threatened species based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In making this finding, information pertaining to the mardon skipper in relation to the five factors provided in section 4(a)(1) of the Act is discussed below. In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat and we then attempt to determine how significant a threat it is. If the threat is significant, it may drive or contribute to the risk of extinction of the species such that the species warrants listing as a threatened or endangered species as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors are operative threats that act on the species to the point that the species meets the definition of a threatened or endangered species under the Act.

In making our 12-month finding on the petition, we considered and evaluated the best available scientific and commercial information. Here we evaluate the factors affecting the petitioned species *Polites mardon.* In addition, the Service has elected, at our own discretion, to additionally evaluate the two subspecies *Polites mardon mardon* and *Polites mardon klamathensis.* For the sake of brevity, we analyze the subspecies separately from the species rangewide only in those cases where the factors affecting the subspecies are unique, or where potential threats to the subspecies differ in severity or scope of impact from those affecting the species in the remainder of its range. The evaluation of the five factors, below, should thus be interpreted as applying equally to the species as a whole as well as to its constituent subspecies, unless indicated otherwise.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Pyle (1989, p. 28) characterized threats to the mardon skipper as any factor that degrades its obligate grassland habitats, including development or land conversion, overgrazing, the use of herbicides and pesticides, encroachment by native and invasive nonnative vegetation, and succession from grassland to forest. In addition to the threats listed above, Black and others (2010, p. 12) identify climate change, stochastic weather events, and small, isolated populations as threats for *Polites mardon klamathensis.* Here we discuss the potential threats associated with habitat loss or degradation; the additional threats identified by Black *et al.* (2010, p. 12) are discussed under Factor E, below.

Habitat Loss Associated With Land Conversion

Prairies, which historically covered over 145,000 ac (60,000 ha) of the south Puget Sound region, have largely been lost over the past 150 years (Crawford and Hall 1997, p. 11). The primary causes of historical prairie habitat loss in the region are attributed to the conversion of prairie habitat to urban development and agricultural uses (over 60 percent of losses), and succession to Douglas-fir forest (32 percent) (Crawford and Hall 1997, p. 11). Today approximately 8 percent of the original prairies in the south Puget Sound area remain, but only about 3 percent contain native prairie vegetation (Crawford and Hall 1997, p. 11). Today approximately 8 percent of the original prairies in the south Puget Sound area remain, but only about 3 percent contain native prairie vegetation.

Puget prairie sites with extant populations of mardon skippers are protected from further development through either State or Federal ownership. Habitats at these sites have

been degraded by invasive species and competing uses such as recreation or military training (Schultz *et al.* 2011, pp. 370–371), but these threats are now being addressed through active management, as referenced above under ''Conservation Measures'' and as discussed further below.

Remaining prairie habitats in the south Puget Sound region are relatively small, isolated patches with little potential connectivity between patches (Schultz *et al.* 2011, p. 371). Because of this, historical prairie sites where mardon skippers have been extirpated are unlikely to be re colonized naturally due to isolation from extant populations (Schultz *et al.* 2011, p. 371). However, there are a number of small prairie sites in the region that are currently in protected status and are actively managed to maintain butterfly habitats that may serve as potential future reintroduction sites for mardon skippers (Anderson 2008, p. 2; Henry 2010, pp. 3–4).

In other portions of the mardon skipper's range, outside of the south Puget prairie region, habitat loss due to urban development or land conversion has not been a significant threat due to their locations primarily on Federal or Tribal lands, in remote areas that have historically been managed for grazing, timber production, or recreation. There have been minor historical losses of mardon skipper habitat from the placement of roads, trails, or buildings in occupied meadow sites (Potter *et al.* 1999, p. 12), but these losses have not been quantified and are relatively small. There are no reported examples of recent habitat loss from new road construction or developments in mardon skipper habitats on Federal lands. Because of the protections the mardon skipper receives as a Federal special status/sensitive species (described above under ''*Conservation Measures''*) the threat of additional habitat loss due to land conversion on Forest Service or BLM lands is very low. Twelve out of the 165 sites known for mardon skipper are found on private lands; the potential for future development at these privately owned sites is unknown. However, most of these sites on private lands are located near other extant populations on neighboring Federal lands, indicating that private lands sites are likely subpopulations of these larger populations on Federal lands. It is therefore unlikely that any of the few mardon skipper sites on private lands support source populations of the species.

Summary: The historical loss of native prairie habitats to urban development and agriculture in the south Puget Sound region has likely resulted in a contraction of the species' distribution within that portion of the species' range. However, Puget prairie sites currently occupied by mardon skippers are protected from further loss due to development by State or Federal ownership. Land conversion for roads and other uses has historically resulted in only minor losses of mardon skipper habitat on Federal lands in all other portions of the species' range. Additional habitat losses due to land conversion or development on Federal lands that support populations of *Polites mardon mardon* and *Polite mardon klamathensis* are not anticipated. Very few of the known mardon skipper sites are found on private lands, and most of these sites are believed to be subpopulations of larger populations found on Federal lands that are protected from conversion or development. Therefore, continued habitat loss due to land conversion is not a significant threat to the mardon skipper at the species or subspecies levels.

Habitat Loss and Fragmentation Associated With Forest Succession

Throughout the Pacific Northwest the invasion of meadow or grassland habitats by conifers represents a recent and widespread phenomenon potentially triggered by changes in climate, the cessation of intensive grazing, and wildfire suppression (Haugo and Halpern 2007, pp. 285–286). In Redwood National Park in California, meadow habitats have declined due to forest encroachment over the past century (NPS 2010, pp. 44–45). At Joint Base Lewis-McChord in Washington, approximately 39 percent (over 16,200 ac [6,560 ha]) of the original prairie habitat has transitioned to Douglas-fir forest, and only a fraction of the original prairie habitat remains as small, isolated prairies (Tveten 1997, p. 124)

The loss of meadow habitats in the Cascades is also well documented. At one study site in the Oregon Cascades, the area associated with mesic meadows declined from 328 ac (133 ha) to 163 ac (66 ha) during the period from 1946 to 2000 (Takaoka and Swanson 2008, p. 521). This represents a loss of approximately 50 percent of the mesic meadow habitat over a period of 54 years. Most xeric (dry) meadows were fairly stable over the study period, indicating that patterns of forest succession in montane meadows are complex and that diverse factors influence these processes (Takaoka and Swanson 2008, p. 521). The contraction of mesic meadow habitats was strongly associated with a lack of fire disturbance over the past half century (Takaoka and Swanson 2008, p. 538).

Aerial photographs taken on the Gifford Pinchot National Forest in the southern Washington Cascades indicate that the mardon skipper sites located within a historical (1918–1919) burn area were larger with much greater potential for connectivity between sites than exists today (Foster 2010, p. 3). Forest succession over the past 60 years has reduced the meadow habitats in this landscape to a few isolated patches ranging in size from 2 to 8 ac (0.8 to 3.2 ha) (Foster 2010, p. 2).

The loss of meadow habitats from forest succession not only reduces the amount of suitable grassland habitat available for mardon skippers, it also closes off potential dispersal corridors between meadows, potentially resulting in remnant, isolated populations (Beyer and Schultz 2010, p. 870). In addition to natural meadow habitats, many mardon skipper sites in the Washington Cascades are located in areas that were clearcut for timber harvest in 1960s through 1980s (Price and Mendez-Treneman 2000, p. 6; St. Hilaire *et al.* 2008, p. 5), and subsequently were colonized by mardon skippers. Open grass habitats in many of these old clearcuts are now rapidly declining. Because the mardon skipper requires early seral habitats, conifer encroachment is a potential threat at all mardon skipper sites located on National Forest or BLM lands in Washington, Oregon, and California. However, actual habitat degradation as a result of this threat is ranked as high at only a few mardon skipper sites, primarily on the Wenatchee National Forest, and a few in the range of *P.m. klamathensis* (Kerwin 2011, pp. 49–60).

Land managers across the range of the mardon skipper recognize conifer encroachment as impacting meadow habitats, and many local districts have undertaken projects to reduce conifer encroachment at mardon skipper meadows. For example, Kerwin (2011, p. 31) notes the implementation of ''considerable meadow restoration efforts for mardon skippers'' on the Gifford-Pinchot National Forest. Examples of restoration activities range from hand-cutting and removal of small conifers on the Gifford Pinchot National Forest in Washington (Kogut 2008, pp. 4–7) to prescribed burning projects on the Six Rivers National Forest in California (Black *et al.* 2011, p. 3). Some level of grazing is also recognized as a potential management tool for reducing conifer encroachment (Kerwin 2011, p. 27). Habitat management activities can be beneficial to the species, although

site disturbance from these actions can result in negative impacts to mardon skipper populations if they are not carefully planned and implemented (Black 2011, p. 385).

Although conifer encroachment has the potential to negatively impact meadow habitats required by the mardon skipper, Federal land managers are actively managing sites to reduce conifer encroachment and maintain meadows to improve habitat for the mardon skipper throughout its range, as outlined in the management provisions in the revised Forest Service/BLM Conservation Assessment for the Mardon Skipper (Kerwin 2011, pp. 30–33), and in Management Plans for all Southern Oregon Cascades Mardon Skipper (*Polites mardon klamathensis*) Sites on BLM Lands (Black *et al.* 2010, pp. 15–17). Therefore, the impacts of conifer encroachment do not presently represent a threat to the mardon skipper across its range, and continued active management is expected to control this threat in the future.

Discussion Specific to *Polites mardon klamathensis*

Little information exists about vegetation change over time in the grasslands, shrublands, and woodlands of southwestern Oregon (Hosten *et al.* 2007b, p. 1). A comparison of historical and current photos shows a general loss of high-elevation grassland to woody shrub and tree domination, and transition from shrubland and woodland to conifer domination (Hosten *et al.* 2007b, p. 31). The encroachment of shade-tolerant conifers into non-conifer vegetation, reduced reproduction by pine, and the loss of meadows support the generally accepted belief that fire suppression has negatively impacted historically open vegetation types in the southern Oregon Cascades (Hosten *et al.* 2007b, p. 1). Historical anecdotes also identify livestock grazing as playing a role in the depletion of native perennial bunchgrasses and subsequent invasion of woody species (Hosten *et al.* 2007b, p. 31).

The loss of open grassland habitats from conifer succession has the potential to impact populations of *Polites mardon klamathensis* through the gradual reduction and loss of suitable habitat patches and by closing off corridors between meadows, reducing the potential for successful dispersal to suitable habitat patches. Studies with other butterfly species have demonstrated that conifer encroachment reduces dispersal between populations and reduces gene flow, resulting in small, isolated populations with a greater risk of local extirpation (Roland and Matter 2007, p. 13702). Although identified as a potential threat at some sites, conifer encroachment within meadows is currently being addressed through management plans developed for *P.m. klamat*hensis sites on BLM lands (Black *et al.* 2010, pp. 21–61). In 2011, the BLM staff at the Medford District implemented small conifer removal projects at most of the sites identified for this work, which has reduced the imminency of continued habitat loss within meadows (Mardon Skipper Work Group [MSWG] 2011, in litt.). Present management of these areas to reduce conifer encroachment and enhance meadow habitats appears to have ameliorated this threat for *P.m. klamathensis.*

Summary: The potential loss of meadow habitats due to forest succession is a concern at most mardon skipper sites across the species' range. However, habitat loss due to succession is a gradual process that occurs on a scale of decades and can be checked with appropriate low-impact management methods, which is presently occurring at many key sites across the species' and subspecies' range. Because Federal managers have implemented actions to substantially ameliorate this threat, forest succession, while still affecting habitat, is no longer considered to be a threat to the mardon skipper at the species or subspecies levels.

Habitat Modifications Associated With Fire

Fire is an important source of disturbance that reduces conifer encroachment and maintains meadow and grassland habitats. Prescribed fire is a tool that is often used by land managers to maintain meadows or other fire-adapted habitats (e.g., NPS 2010, p. 4). Although mardon skippers occur in landscapes that have historically burned, mardon skipper populations may be vulnerable to local extirpation if a fire burns all of the occupied habitats at a population site (Black 2011, p. 384). The use of prescribed fire is implicated in the extirpation of mardon skippers from one historical Puget Prairie site in 1992 (Stinson 2005, p. 10).

In California, the Coon Mountain mardon skipper site on the Six Rivers National Forest is being managed with prescribed fire to maintain the meadow habitat at the site and, consequently, mardon skipper habitat. Working in cooperation with the Xerces Society, the Forest Service modified their original plans to burn the entire site, and established four experimental burn plots with corresponding unburned areas. The experimental plots were burned in the fall of 2008 (Black *et al.* 2011, pp. 3–4). Monitoring at the site in 2009 indicated mardon skippers were 3–27 times more abundant in unburned areas compared to burned areas (Black 2011, p. 384). Continued monitoring at the site in 2010 and 2011 indicate that mardon skipper densities in unburned patches were consistently higher than in burned patches (Black *et al.* 2011, p. 14); however, mardon skippers are gradually recolonizing the burned patches from the adjacent unburned areas at the site as their preferred habitat increases (Black 2011, p. 384). Although peak counts of mardon skippers in subsequent years after the burn have not been as high as they were prior to burning in 2008, the authors note that the overall population appears to be stable, and is still considered the largest known population in California (Black *et al.* 2011, p. 13). As their preferred habitat increases at these sites, the mardon skipper population may expand into the burned areas and increase over time. Continued monitoring is needed to fully assess the population response at Coon Mountain.

A large wildfire burned over 8,000 ac (3,238 ha) at Mt. Adams in Washington in 2008, including burning the forest around at least one known mardon skipper site (Eureka Meadow). Although the fire burned the surrounding forest, the meadow itself did not burn (likely because it was still snow-covered at the time of the fire), and 135 mardon skippers were counted at the site in 2010 (Wainwright 2010, p. 1). The Windy Valley site on the Rogue River-Siskiyou National Forest in southwestern Oregon is another example of a mardon skipper population surviving a recent wildfire event. Much of the forest around this meadow/wetland complex burned as part of the Biscuit Fire in 2002, but the site continues to support a large population of mardon skippers that was discovered in 2010 (Kerwin 2011, p. 51). Wildfires are likely to have beneficial effects for mardon skippers due to resultant increases in early seral habitat, although large wildfires also pose a risk to mardon skippers if all occupied habitat in a local area is burned. Because wildfires typically result in a mosaic of burned and unburned areas, it is unlikely that wildfires would result in the loss of multiple populations across large areas within the species' or subspecies' range.

Assessing whether wildfires or prescribed fire used to manage mardon skipper habitats poses a threat to the species is a complex undertaking. Fire disturbance is an integral process in

natural ecosystems (Agee 1993, p. 3), and has certainly played a pivotal role in maintaining mardon skipper habitats. Conservation scientists as well as Federal land managers recognize that the habitat benefits gained from using prescribed fire to maintain mardon skipper habitat must balance the lethal effects fire can pose to mardon skippers (Black 2011, p. 384; Kerwin 2011, p. 33). The Coon Mountain experiment demonstrates that prescribed fire can be used to restore mardon skipper meadow habitat and maintain a population at the site, but the fire must be carefully managed so that only a portion of the occupied areas at a site is burned (Black 2011, p. 384).

Summary: Wildfires or prescribed fires that maintain and restore meadow habitats can be either beneficial or lethal to mardon skippers, depending on the timing and severity of the fire and the condition of the habitat. Fire is an important disturbance agent for maintaining the early-seral habitats mardon skippers require. Managers using fire to restore habitat can and have modified burn plans to meet both fire objectives and protect mardon skippers, which greatly reduces the potential threat associated with prescribed fires. Therefore, the use of prescribed fires for habitat management is not considered to be a threat to mardon skippers at either the species or subspecies level. Wildfires are also a potential threat on a local scale, but it is unlikely that wildfires would result in the loss of multiple populations across large areas within the species' or subspecies' range; therefore, we do not consider it to be a threat to mardon skippers at the species or subspecies level.

Habitat Loss Associated With Invasive, Nonnative Plants

The invasion and subsequent dominance of nonnative plant species in native grassland habitats is common and has occurred rapidly at several current and historical mardon skipper locations associated with Puget prairies (Potter *et al.* 1999, p. 10). Invasive grasses such as tall oatgrass and the invasive shrub Scot's broom drastically alter the short-grass/forb habitat structure that mardon skippers select for oviposition or nectaring sites (Hays *et al.* 2000, p. 28; Schultz *et al.* 2011, p. 371). Habitat utilization studies have demonstrated that mardon skippers actively avoid areas invaded by these species (Hays *et al.* 2000, p. 28; Henry 2010, p. 44), but will recolonize sites where these invasive species have been removed (Hays *et al.* 2000, p. 16). Scot's broom and tall oatgrass are present at south Puget Sound prairie sites occupied by mardon skippers, but significant portions of these sites are managed annually to control these species (Hays 2010, p. 1). The Washington State Department of Natural Resources, for example, recommends restoration techniques including mowing, hand pulling, herbicide application, and prescribed burning to restore or maintain prairie habitats for the mardon skipper (Potter *et al.* 1999, p. 8) . Mardon skippers have been documented using many areas that were previously unsuitable due to the presence of invasive weeds after the habitat was restored with herbicides to eliminate tall oatgrass, followed by management (mowing, pulling) to control Scot's broom (Hays 2008, pp. 1–2).

Continued site management is required to maintain mardon skipper habitat and populations at south Puget prairie sites (Schultz *et al.* 2011, p. 375). Ongoing management for mardon skipper habitat is occurring through partnerships between the Department of Defense, The Nature Conservancy (now Center for Natural Lands Management), Washington State Department of Natural Resources, Washington Department of Fish and Wildlife, and U.S. Fish and Wildlife Service among others. The prairie sites with extant populations of mardon skippers also support a number of other high-priority prairie species, including Taylor's checkerspot butterfly (*Euphydryas editha taylorii*), a candidate for listing under the Act (Stinson 2005, p. 6). Based on the importance of these sites for multiple prairie-associated species, we expect that State, Federal, and nongovernmental organizations will continue to place a high priority on maintaining prairie habitats at these sites for the benefit of mardon skippers and other prairie species.

Not all mardon skipper sites have been evaluated for the presence of invasive, nonnative plants; however, the problem is increasingly common (Potter *et al.* 1999, p. 10). At least two sites (Cave Creek and Lost Meadows) on the Gifford Pinchot National Forest are being actively managed to reduce invasive *Cirsium arvense* (Canada thistle) which has formed dense patches and has been spreading throughout the mardon skipper habitat (Kogut 2008, p. 9). Managing for invasive species is required at a number of sites to maintain mardon skipper habitat, but, as with managing for conifer removal, the management must be carefully planned to avoid negative impacts to local butterfly populations (Schultz *et al.* 2011, p. 373). We expect that Federal land managers will continue to manage sites to control invasive weeds and will do so in a way that improves habitat for the mardon skipper, while minimizing impacts to local populations as outlined in the revised Forest Service/BLM Conservation Assessment for the Mardon Skipper (Kerwin 2011, pp. 30–33), and in site-specific plans such as those developed on the Gifford Pinchot National Forest (USFS 2008, p. 57).

Summary: Invasive nonnative plants have historically resulted in habitat loss and degradation at a number of mardon skipper sites, primarily in the Puget prairies. Federal, State, and private land managers have been actively managing invasive weeds at the most degraded sites to restore and maintain mardon skipper habitat, and are likely to continue to do so under their current management plans, which substantially reduces this potential threat. Based on the ongoing partnership and commitment of private, State, and Federal entities to manage invasive nonnative plants and restore prairie habitats, the impact of invasive nonnative plants appears to have been sufficiently ameliorated throughout the range of the mardon skipper such that it does not pose a threat to the species or either subspecies.

Habitat Modifications Associated With Livestock Grazing

Current or historical livestock grazing has occurred at essentially all mardon skipper sites in the Washington and Oregon Cascades. Historically (1900–1930s), many areas in the Cascades were intensively grazed by sheep (Miller and Halpern 1998, p. 267), including several known mardon skipper sites on the Gifford Pinchot National Forest (USFS 2007a, p. 30; Foster 2010, p. 2). Sheep grazing was largely replaced by cattle grazing after the 1930s. Grazing allotments at Mt. Adams in Washington have been grazed for over 100 years (USFS 2007a, pp. 30–31).

Long-term grazing can alter both the structure and composition of plant communities, rendering them unsuitable to some butterfly species (Dana 1991, p. 54; Ellis 2003, p. 292), while benefiting other species, depending on the specific habitat requirements of each species (Kruess and Tshcharntke 2002, p. 1575; Poyry *et al.* 2005, p. 469; Vogel *et al.* 2007, pp. 81–82). Grazing can impact mardon skipper populations by (1) direct trampling of eggs, larvae, pupae, and adults (Potter *et al.* 1999, p. 13; Black *et al.* 2010, pp. 13–14); (2) removal of both larval and adult food sources, and (3) disturbing the soil, which allows weeds to invade (Ellis 2003, pp. 292–293; Schtickzelle *et al.* 2007, p. 657). One grazing study found that both the

abundance and recruitment of the bog fritillary butterfly (*Proclossiana eunomia*) were reduced by as much as 74 percent in grazed areas compared to ungrazed sites (Schtickzelle *et al.* 2007, p. 657). Dana (1991, p. 54) notes that both the Dakota skipper (*Hesperia dacotae*) and the ottoe skipper (*Hesperia ottoe*) apparently decline or can be extirpated in response to intensive grazing, likely due to changes in the composition and structure of the plant communities at intensively grazed sites.

Although intensive livestock grazing can be detrimental to many butterfly species, moderate to light grazing can be a useful method for halting succession and maintaining butterfly habitats where other habitat management methods are impractical (Schtickzelle *et al.* 2007, p. 658; Ellis 2003, p. 293). The silver-spotted skipper (*Hesperia comma*) is one species that has shown a positive response to moderate grazing, and depends on continued grazing to maintain the short-statured grassland habitats the species requires (Thomas and Jones 1993, p. 473).

The impact of cattle grazing to mardon skipper populations is likely relative to the timing, duration, and magnitude of the grazing at the site (Black *et al.* 2010, p. 13). Large mardon skipper populations are able to persist in some heavily grazed habitats. Conrad Meadows on the Wenatchee National Forest is subjected to native ungulate (deer and elk) grazing in the spring, and then intensive cattle grazing during the summer months. Conrad Meadows is a large system of interconnected meadows, wetlands, and forested areas with complex vegetative structure and site conditions. The meadow complex supports the largest known population of mardon skippers, with minimum population counts of over 1,000 mardon skippers in some years (St. Hilaire *et al.* 2010, p. 11). Conrad Meadows has been in an active cattle grazing allotment for 80 years, and there continues to be a robust population of mardon skippers at this site (St. Hilaire *et al.* 2008, p. 15). Because the timing of the onset of livestock grazing tends to occur towards the end or after the adult flight period at Conrad Meadows, the grazing at this site may not affect mardon skipper populations to the same degree as sites that are grazed throughout the flight period (St. Hilaire *et al.* 2008, p. 14).

Ongoing monitoring at grazing exclosures (2007–2010) on the Wenatchee National Forest has shown no clear pattern between mardon skipper populations in grazed versus ungrazed areas (St. Hilaire *et al.* 2010, p. 7). The authors note that there are a number of confounding variables associated with this monitoring project and more research at these sites is recommended. Anecdotal observations within grazing exclosures indicate a much higher abundance and diversity of flowering forbs (adult nectar sources) compared to outside the exclosures (Jepsen *et al.* 2007, p. 17), but there appears to be no clear pattern in the number of mardon skippers within exclosures versus outside exclosures (St. Hilaire *et al.* 2010, p. 7). Mardon skipper densities at sites grazed by cattle on the Wenatchee National Forest are comparable or higher than densities observed at sites on the adjacent Gifford Pinchot National Forest that are subjected only to light native ungulate grazing.

Because mardon skippers have specific habitat requirements related to graminoid cover, composition, and structure (Beyer and Schultz 2010, pp. 867–868), it appears likely that intensive livestock grazing that occurs before or during the adult flight period would have a negative effect on mardon skipper reproductive success and larval survival due to the loss of adult nectar sources and larval host plants, and the introduction of nonnative grasses, forbs, or shrubs that do not meet the structural requirements of mardon skippers. The grasses most commonly used by mardon skippers for oviposition and larval food (e.g., Roemer's fescue, California oatgrass, Kentucky bluegrass (nonnative), and sedges) (Beyer and Black 2007, p. 6) are also some of the most preferred forage species used by cattle (Hosten *et al.* 2007, p. 20). These effects are likely to be most profound at sites where grazing impacts are intensified due to the presence of surface water or wet soils that attract livestock (Hosten and Whitridge 2007, p. 1), and the grazing use entirely overlaps the adult flight period (Black *et al.* 2010, p. 13). However, the removal of livestock from sites that have historically been grazed for decades does not automatically restore degraded habitats or improve mardon skipper populations.

There are a number of sites that are no longer in active grazing allotments that continue to have chronically low or declining populations of mardon skippers, most likely due to degraded habitat conditions associated with the plant community composition (Black *et al.* 2010, pp. 60–63; USFWS unpublished data). The short-grass/forb habitats preferred by mardon skippers can become quickly degraded in the absence of livestock grazing due to presence of tall-structured nonnative grasses and shrubs (Black *et al.* 2010, p. 61). The use of short-duration, low-intensity grazing may prove to be beneficial or necessary for maintaining mardon skipper habitat in some situations (e.g., Black *et al.* 2010, p. 38).

Over the past 5 years, a number of grazing allotments on both Forest Service and BLM lands in both Oregon and Washington have been retired. Grazing allotments at most of the southern Oregon Cascades BLM mardon skipper sites for *Polites mardon klamathensis* were retired in 2009 (Black *et al.* 2011, pp. 14–15). A major grazing allotment (Ice Caves) on the Gifford Pinchot National Forest was discontinued in 2009, and was officially closed in 2011. On the Wenatchee National Forest, the Forest Service has installed a number of grazing exclosures to reduce grazing impacts and protect key mardon skipper habitat areas (St. Hilaire *et al.* 2010, p. 5). In general, grazing impacts on Federal lands are decreasing, with fewer animals being allowed onto grazing allotments, with shorter grazing periods, and placement of exclosures in key locations to protect sensitive habitats (e.g., USFS 2007b, p. 2). Active grazing allotments are still present at several mardon skipper sites within the range of the species, and continued monitoring is needed to assess the impact that grazing has on these populations. Under current management conditions, light to moderate grazing can be potentially beneficial in maintaining the habitat structure preferred by mardon skippers, and based on the most recent conservation assessment for the mardon skipper, intensive grazing does not appear to be a significant factor in habitat degradation for the species across its range (Kerwin 2011, Appendix A).

Summary: Cattle grazing can have either negative or beneficial effects to mardon skippers depending upon the timing, duration, and intensity of the grazing. Robust mardon skipper populations are able to persist in some heavily grazed habitats, while other areas that have been heavily grazed have generally poor habitat conditions and support only low numbers of mardon skippers. Grazing is likely to be beneficial for maintaining mardon skipper habitat at sites that are vegetated with tall-statured nonnative grasses and shrubs. Potential negative impacts from grazing on Federal lands have been substantially reduced due to the closure of a number of grazing allotments in key areas, as well as changes in management practices to reduce grazing intensity and protect key habitat areas. Therefore, livestock grazing does not represent a threat to the mardon skipper at the species level at this time, nor is it likely

to be so in the future due to current management efforts. We have no information to indicate that it is a threat to the subspecies *Polites mardon mardon.*

Discussion specific to *Polites mardon klamathensis:*

Current or historical livestock grazing has occurred at all *Polites mardon klamathensis* sites in the Oregon Cascades for over 100 years (Hosten *et al.* 2007, p. 13), and habitat conditions at some sites have been excessively degraded by grazing (Black *et al.* 2010, pp. 22–23). Until recently all of the occupied sites were located in active grazing allotments. With the recent designation of the Cascades-Siskiyou National Monument (Monument) in 2000, the BLM initiated a review of grazing impacts on Federal lands within the Monument. This review determined that four grazing allotments within the Monument failed to meet BLM standards for maintaining populations of threatened and endangered and other locally important species (BLM 2008, p. 6). The major reasons for not meeting this standard included the threat to special status species including the mardon skipper, the favoring of noxious weeds (e.g., Canada thistle at high elevations) over native plants; and the invasion of the nonnative *Poa bulbosa* (bulbous bluegrass) (BLM 2008, p. 6). Although overgrazing is considered to have had negative impacts on several *P.m. klamathensis* sites in the past (Black. 2010, p. 14), some of these sites have now been retired from grazing, and others are now being managed in accordance with a management plan developed by The Xerces Society for Invertebrate Conservation for all *P.m. klamathensis* sites on BLM lands in southern Oregon, including provisions specific to grazing, such as avoiding grazing during the flight period of adults and keeping grazing periods short and interspersed with long recovery period for the habitat (Black *et al.* 2010, entire).

In 2009, grazing allotments at 10 mardon skipper sites located on BLM lands within the Monument were retired (Black *et al.* 2010, pp. 14). The remaining sites on BLM lands that are still within active grazing allotments have existing or planned grazing exclosures to protect core mardon skipper habitat areas (Black *et al.* 2010, pp. 23–61). Four *Polites mardon klamathensis* sites located on the Rogue River–Siskiyou National Forest are in active grazing allotments, and Jepsen *et al.* (2007b, pp. 24–25) reported that grazing had degraded habitat at three of these sites. However, more recently Kerwin (2011, pp. 49–60) reviewed the *P.m. klamathensis* sites in his conservation assessment and found that none faced a serious threat from grazing (with exception of Hobart Peak, where effects from grazing were considered ''unknown''), and additionally noting that several of the grazed sites are in excellent condition. Remaining sites in active grazing allotments on Federal lands are expected to continue to exhibit reduced grazing impacts due to the placement of existing or planned grazing exclosures around core habitat areas (Black *et al.* 2010, pp. 23–61; Kerwin 2011, p. 32).

Summary: The threats from active livestock grazing have been substantially reduced from all Federal lands sites within the range of *Polites mardon klamathensis.* Planned or existing grazing exclosures are likely to protect core habitat areas at some key sites, but the effectiveness of grazing exclosures for maintaining mardon skipper habitat structure and populations remains unknown. We expect that mardon skipper habitat conditions within exclosures will generally improve with the removal of livestock grazing, but these areas will require monitoring and possible management actions to insure that invasive weeds or tall-statured nonnative grasses do not become a secondary threat in the absence of grazing, as recommended in the revised Forest Service/BLM Conservation Assessment for the Mardon Skipper (Kerwin 2011, pp. 30–33), and in Management Plans for all Southern Oregon Cascades Mardon Skipper (*Polites mardon klamathensis*) Sites on BLM Lands (Black *et al.* 2010, pp. 15–17). The potential negative impacts of grazing on Federal lands within the range of *P.m.klamathensis* have been substantially reduced due to the closure of a number of grazing allotments in key areas, as well as changes in management practices to reduce grazing intensity and protect key habitat areas. Therefore, we do not consider the effects of livestock grazing to be a threat to *P.m. klamathensis.*

Habitat Loss Associated With Off-Road Vehicles and Recreation

Recreational activities, including off-trail walking, off-trail horseback riding, and off-road vehicle use, may directly kill some mardon skippers by trampling and crushing larvae (Potter *et al.* 1999, p. 12). Off-road vehicle use has the greatest impact on mardon skipper habitat because vehicle tires can destroy native plants and disturb soils, leading to invasion by weeds. Small, roadside meadows are vulnerable to damage or destruction associated with off-road vehicle use. Currently, this threat applies to a few locations across the range of the species (Kerwin 2011, pp. 37–41). In 2008, a mardon skipper site located on private lands in Del Norte County, California, was partially destroyed when the site was used as a dump for logging slash and debris (Ross 2008a, p. 5; Devlin 2009, pers. comm.). At least one historical locale in the southern Washington Cascades was destroyed by this practice in 1997 or 1998 (Potter *et al.* 1999, p. 11). Military training activities at Joint Base Lewis-McChord have also resulted in damage to mardon skipper habitat (Potter *et al.* 1999, p. 12), but the majority of the prairie habitat at this site is protected from vehicle damage due to the presence of unexploded ordnance (Stinson 2005, p. 12). Over the past 10 years, Federal land managers have installed access barriers (e.g., placement of road-side boulders, gates, or exclosures) and posted educational signs in attempts to reduce illegal off-road vehicles and other recreational uses at almost all mardon skipper sites where these problems have been noted (Kogut 2008, p. 8). These measures have substantially reduced these threats on Federal lands, which constitutes the majority of the range occupied by the species. Therefore, habitat loss associated with off-road vehicles and recreation is not a significant concern for the mardon skipper at the species level at this time, nor is it likely to become so. In addition, we have no information to indicate that it has a significant impact on the subspecies *Polites mardon mardon.*

Discussion specific to *Polites mardon klamathensis:*

Management plans developed for *Polites mardon klamathensis* sites on BLM lands identified off-road vehicle use and recreation (camping) within meadows as a potential threat at several sites (Black *et al.* 2010, pp. 21–61). In 2011, both BLM staff at Medford District and Forest Service staff on the Rogue River–Siskiyou National Forest implemented a number of projects to reduce these impacts at *P.m. klamathensis* sites through the strategic placement of boulders to block vehicle access, and by posting signs at most of the sites identified for this work (MSWG 2011, in litt.). These measures are expected to substantially reduce any potential impacts from off-road vehicles and other recreational uses.

Summary: Off-road vehicles and other recreational activities have historically resulted in minor habitat losses and degradation at a number of sites across the range of the mardon skipper. However, this threat has been substantially reduced on Federal lands

where the majority of these activities occur through the placement of access barriers and signs. Because private lands comprise an insubstantial portion of the species' range, we do not consider any such activities on private lands, if they should occur, to pose a threat to the mardon skipper. Therefore, habitat loss or degradation as a consequence of off-road vehicles and other recreational uses is not considered to be a threat at either the species or subspecies levels.

Summary of Factor A

In summary, the potential negative impacts to mardon skipper habitat associated with forest succession, fire, invasive nonnative plants, livestock grazing, and off-road vehicle use have been substantially reduced or eliminated on Federal and State lands through the development and implementation of conservation plans and habitat restoration projects. Habitat degradation associated with intensive livestock grazing continues to occur at a few sites, but grazing impacts have been substantially reduced or eliminated at many key sites across the species' range with recent closures of Federal grazing allotments and the implementation of site-specific conservation plans for the benefit of the mardon skipper. Habitat degradation from off-road vehicle use has been reduced or eliminated at many sites by installing vehicle barriers or closing roads. Meadow habitat restoration activities (prescribed burning, herbicide treatments) can be lethal to mardon skippers, but careful planning and implementation of habitat restoration projects designed with these concerns in mind have minimized the risks associated with these positive efforts for skipper conservation. Because the vast majority of mardon skipper sites are found on Federal or State lands, and most of the sites that are found on private lands are subpopulations of larger populations on Federal lands, we do not consider habitat degradation that may occur on private lands to pose a threat to the mardon skipper. Based on these ongoing conservation actions on Federal and State lands, we do not consider Factor A, the present or threatened destruction, modification, or curtailment of its habitat or range, to pose a threat to the mardon skipper as a species now or in the future, nor do we have any information to indicate that it is a threat to either subspecies *Polites mardon mardon* or *Polites mardon klamathensis,* now or in the future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Insect collecting is a valuable component of research, including systematics work, and is often necessary for documenting the existence of populations (Potter *et al.* 1999, p. 14). Rare butterflies, such as the mardon skipper, could be potentially desirable. Most mardon skipper populations are easily accessible and could be vulnerable to collectors (Potter *et al.* 1999, p.14). However, we currently have no information indicating that mardon skipper populations at either the species or subspecies level have been negatively affected by collection or scientific research activities (Kerwin 2011, p. 26), and therefore have determined that overutilization for commercial, recreational, scientific, or educational purposes is not a threat to the mardon skipper at the species or subspecies level now or in the future.

Factor C. Disease or Predation

Disease and predation are usually naturally occurring factors that may pose a heightened threat to populations that are vulnerable due to other factors, but no specific examples are known for the mardon skipper. Predatory insects (ants, wasps, spiders, etc.) commonly prey on butterfly eggs, larvae, and pupae (Scott, 1986, p. 70), but no studies have specifically researched this aspect of mardon skipper ecology. At Puget Prairie sites, mardon skipper larvae were found only in the smallest tufts of bunchgrass, while potential larval predators (spiders, ants) were commonly observed in larger clumps of bunchgrass (Henry 2010, p. 18). The author suggests that larval survival rates from predation are likely influenced by the fine-scale structure of individual host plants and the density of vegetation surrounding host plants, but acknowledged that more research is needed to understand how these factors influence mardon skipper survival rates (Henry 2010, p. 18). We currently have no information indicating mardon skipper populations have been negatively affected by disease or predation outside the normal range of variability; therefore, we do not consider disease or predation to pose a threat to the mardon skipper at the species or subspecies levels.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

State Laws

The mardon skipper is listed as an endangered species in the State of Washington by the Washington Fish and Wildlife Commission (Washington Administrative Codes 232–12–014, Endangered Species; 232–12–011, Threatened Species, Appendix D). This designation provides protection from directly harming the species (e.g., collecting) (Black *et al.* 2002, p. 19).

State regulatory mechanisms in the States of Oregon and California do not apply to the mardon skipper, as Oregon's State Endangered Species Act does not cover invertebrate species, and California's State Endangered Species Act does not apply to insects.

We have no information to indicate that the inadequacy of existing State regulatory mechanisms may pose a threat to the mardon skipper, rangewide or at the subspecies level.

Special Status Species Policies on National Forest and BLM Lands

As discussed above under ''Conservation Measures,'' the mardon skipper is listed as a Sensitive Species by the U.S. Forest Service in Washington, Oregon (Forest Service Region 6), and California (Forest Service Region 5) and as a Special Status Species by the Bureau of Land Management (BLM) in Oregon and Washington. We have no information to indicate that the inadequacy of existing Federal regulatory mechanisms may pose a threat to the mardon skipper, rangewide or at the subspecies level.

Summary of the Inadequacy of Existing Regulatory Mechanisms

When the mardon skipper was originally identified as a Federal candidate in 1999, the species had no protection mechanisms under the auspices of either State or Federal agencies. Since that time, both Federal and State land managers have developed conservation plans and policies that provide a high level of protection for the species. Existing laws and regulations do not protect mardon skipper habitats where they occur on private land. However, there are few mardon skipper populations known to occur on private lands. The majority of the species' occurrences are on Federal or State lands where the species is assured a high level of protection through its recognition as a Sensitive Species or Special Status Species (Federal lands) or through State Conservation Plans (California, Oregon, and Washington). We did not identify any threats to the mardon skipper at either the species or subspecies levels that existing regulatory mechanisms have failed to address. Therefore, we have no information to indicate that the inadequacy of existing regulatory mechanisms is a threat to the mardon

skipper at either the species or subspecies levels.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Application of Pesticides and Herbicides

Aerial applications of pesticide pose a potential threat to mardon skippers. The lepidopteran-specific insecticide, *Bacillus thuringiensis* var. *kurstaki* (Btk), has been aerially applied to control the Asian gypsy moth (*Lymantria dispar*) in the Puget Sound region, and in the Washington Cascades to control spruce budworm (*Choristoneura occidentalis*) (Potter *et al.* 1999, p. 13). Although grasslands are not targeted for application, small meadows may receive aerial applications due to the location of these habitats within the wooded target area or from aerial drift. Drift from aerial applications can be lethal to non target butterflies up to 1.8 miles (3 km) away from the target area in steep, mountainous terrain (Whaley *et al.* 1998, p. 539). Lepidoptera, such as the mardon skipper, that are single-brooded, spring-active species with caterpillars actively feeding during the application period of Btk are especially vulnerable (Wagner and Miller 1995, p. 21).

Several of the southern Washington Cascade mardon skipper sites are located in areas where widespread applications of Btk were used on State, tribal, and private lands to control spruce budworm outbreaks in the late 1990s (Potter *et al.* 1999, p. 13). Btk application is implicated in the local decline of at least one mardon skipper population on non-Federal lands from 1998 to 2000 (Potter and Fleckenstein 2001, pp. 7–8). The use of Btk has diminished in the southern Cascades over the past decade as spruce budworm populations have declined. There have been no reported applications of Btk on Federal lands in close proximity to mardon skipper sites. The risks associated with Btk application can be greatly reduced with adequate buffers to avoid pesticide drift into sensitive habitats (Black *et al.* 2010, p. 19). Although Btk application poses a potential threat to mardon skipper populations, we are not aware of any Btk applications over the past 10 years that would have had the potential to affect mardon skipper populations. The aerial application of pesticides remains a potential threat, but any local application of lepidopteran-specific pesticides on Federal lands will be subject to environmental review consistent with National Environmental Policy Act procedures, and existing special status/sensitive species policies of the Forest Service and BLM are likely to provide for a high level of protection.

Herbicides are commonly used to manage mardon skipper habitat and control invasive nonnative plants in south Puget Sound prairies (Schultz *et al.* 2011, p. 373); and have been used at mardon skipper sites on the Gifford Pinchot National Forest. Herbicide use may affect mardon skippers by damaging larval or adult food sources, or through the direct ingestion of a toxic substance. Loss of non target plants can be avoided by using grass-specific herbicides, such as sethoxydim, which has been used effectively to control invasive grasses such as tall oatgrass, while having minimal impacts on native bunchgrasses and forbs (Schultz *et al.* 2011, p. 373).

There are currently dozens of herbicide formulations that are available for general use. The toxicity of an herbicide to butterflies varies from non toxic to potentially lethal depending upon the compounds used. All herbicides are required to be tested on honeybees (*Apis* spp.) as part of registration requirements (USFS 2005, p. 252), but there are relatively few studies that evaluate the effects of herbicides on butterflies (Russell and Schultz 2010, p. 53). One study with the Karner blue butterfly (*Lycaeides melissa samuelis*) found that direct applications of some herbicide compounds with glyphosate had no apparent effect on egg survival and larval development (Sucoff *et al.* 2001, p. 18). However, treatments with a glyphosate-triclopyr mix did significantly lower egg hatching rates (Sucoff, *et al.* 2001, p. 18). Use of the grass-specific herbicide compounds sethoxydim or fluazifop-p-butyl with the non-ionic surfactant Preference can stress butterflies, resulting in reduced survival and increased rates of development from larvae to adult, as well as decreased wing area in some species of butterflies (Russell and Schultz 2010, p. 53). Stark and others (2012, pp. 26–27) found that Behr's metalmark butterfly (*Apodemia virgulti*) exposed to field rates of triclopyr, sethoxydim, and imazapyr reduced the number of adults that emerged from pupation, perhaps due to effects from inert ingredients or indirect effects on food plant quality. These studies indicate that direct applications of herbicides can result in reduced survival in some butterfly species, emphasizing the need for careful management using selective applications in habitats occupied by mardon skippers.

Herbicides are recognized as an important tool for managing invasive plants and maintaining habitat for butterflies. Potential adverse effects of herbicides to mardon skippers can be minimized through selective applications. Federal and State land managers currently using herbicides to manage invasive plants at mardon skipper sites are using best management practices to minimize effects to non target plant species and to butterflies (Hays 2010, p. 1; USFS 2008, p. 57). These methods include using selective herbicide treatments and only treating a small portion of the habitat area within the site in any given year (USFS 2008, p. 57; Schultz *et al.* 2011, p. 373). We expect Federal and State land managers will continue to manage sites to control invasive weeds and to do so in a way that improves habitat for the mardon skipper, while minimizing impacts to local populations as outlined in the revised Forest Service/BLM Conservation Assessment for the Mardon Skipper (Kerwin 2011, pp. 30–33), and in site-specific plans such as those developed on the Gifford Pinchot National Forest (USFS 2008, p. 57). Based on this information, we do not consider the use of herbicides to be a threat to mardon skipper at either the species level or subspecies levels.

Summary: The widespread application of pesticides and herbicides may affect the mardon skipper and its habitat. However, there are no documented instances of Btk applications occurring on Federal lands in close proximity to mardon skipper sites. Further, Federal and State land managers have successfully used herbicides to restore and maintain mardon skipper habitat at a number of sites in Washington. Based on this information, we do not consider the use of pesticides or herbicides to be a threat to the species or either subspecies.

Climate Change

Over the next century, climate change at global and regional scales is predicted to result in changes in butterfly species distributions and altered life histories (McLaughlin *et al.* 2002, p. 6074; Hill *et al.* 2002, p. 2163; Singer and Parmesan 2010, p. 3161). Rare butterflies, including the mardon skipper, may be vulnerable to climate change, as their populations are often fragmented due to habitat losses that restrict the species' ability to adapt to changing environmental conditions (Schultz *et al.* 2011, p. 375). Likewise, butterflies with limited dispersal capability, such as the mardon skipper, may be vulnerable to climate change if suitable alternative

habitats are not located within the dispersal distance for the species.

Changes in regional climate can benefit some butterfly species. The habitat-generalist Sachem skipper (*Atalopedes campestris*) has expanded its range more than 435 mi (700 km) northward from California into central Washington in the last 50 years (Crozier 2004, p. 231). Crozier's (2004, p. 231) study suggested that the range expansion has been due to a warming trend, and each step in the range expansion coincided with warmer winters (which affects larval survival rates). Similarly, populations of the silver-spotted skipper (*Hesperia comma*) in southern England have increased over the past 20 years, due in part to warmer summer temperatures, which have increased the availability of thermally suitable habitats for the species (Davies *et al.* 2006, p. 247). Recent butterfly range expansions linked to climate change are generally limited to highly mobile, habitat-generalist species, while many habitat-specialist butterfly species have declined due to complex interactions of climate, habitat loss, and fragmentation (Warren *et al.* 2001, p. 65; Hill *et al.* 2002, p. 2170).

In the Pacific Northwest, mean annual temperatures rose 0.8 °Celsius (° C) (1.5 °Fahrenheit (° F)) in the 20th century and are expected to continue to warm from 0.1 to 0.6 °C (0.2 to 1 °F) per decade (Mote and Salathe 2010, p. 29). Global climate models project an increase of 1 to 2 percent in annual average precipitation, with some models predicting wetter autumns and winters with drier summers (Mote and Salathe 2010, p. 29). Regional models of potential climate changes are much more variable, but the models generally indicate a warming trend in mean annual temperature, reduced snowpack, and increased frequency of extreme weather events (Salathe *et al.* 2010, pp. 72–73). Downscaled regional climate models, such as those presented by *http://www.climatewizard.org* have tremendous variation in projections for annual changes in temperature or precipitation depending upon the climate model or scenario. Averaged values across large areas generally indicate a general warming trend in mean annual temperature consistent with the climate projections reported by Salathe and others (2010, pp. 72–73).

Predicted climate changes in the Pacific Northwest have implications for forest disturbances that are important for maintaining montane meadow habitats. Both the frequency and intensity of wildfires and mountain pine beetle (*Dendroctonus ponderosae*) outbreaks are expected to increase over the next century in the Pacific Northwest (Littell *et al.* 2010, p. 130). The gradual loss of montane meadow habitats over the past century is linked to fire suppression and lack of disturbance. One study in the Cascades found that the majority of mesic meadow habitats that were historically burned (1880–1946) have contracted over the past half century (Takaoka and Swanson 2008, p. 539). Increased fires over the next century are likely to result in increased meadow habitat and improved connectivity between meadows occupied by mardon skippers. Similarly, mountain pine beetle outbreaks can result in the widespread mortality of lodgepole pine trees, a common tree species that is invading meadow habitats at many mardon skipper sites. Where invading trees are killed, marginal areas along the edges of existing meadows are likely to revert rapidly back to dominance by meadow species (Haugo *et al.* 2011, p. 17).

Climate change is also likely to affect the rate of conifer succession in montane meadow habitats. A decrease in summer precipitation and soil moisture may reduce the rate of conifer encroachment in montane meadows at mesic sites (Haugo *et al.* 2011, p. 17), which may prove beneficial to mardon skippers by increasing available meadow habitats. Increased wildfire or insect disturbances associated with climate change are likely to have beneficial effects for mardon skippers due to increases in early seral habitat, although large wildfires also pose a risk to mardon skippers if all occupied habitat in a local area is burned. Because wildfires typically result in a mosaic of burned and unburned areas, it is unlikely that increased incidence of wildfires associated with climate change would result in the loss of multiple populations across large areas within the species' or subspecies' range.

How mardon skipper populations will respond to future climate change is unknown. There are no retrospective studies for the species that have examined how annual weather patterns such as annual or seasonal precipitation, snowpack, and temperature have influenced mardon skipper populations from year to year. We do know that prolonged periods of cool, wet weather during the spring or summer months can delay adult emergence and reduce the abundance of mardon skippers. Because the mardon skipper at the species level is distributed across a broad range of elevations and habitat types, and has documented use of several host-plant species, it may not be as vulnerable to climate change as some other narrowly distributed butterfly species. In the Washington Cascades the majority of mardon skipper sites occur in the mid-elevation montane zone, where there is a potential for upslope movement and colonization of higher elevation habitats in response to climate change over time. Based on the above information, we do not have data to suggest that climate change poses a threat to the species *Polites mardon,* or the subspecies *Polites mardon mardon.*

Discussion specific to *Polites mardon klamathensis*

Populations of *Polites mardon klamathensis* may be vulnerable to the effects of climate change due to the subspecies' limited distribution, apparently smaller populations, and limited dispersal capability. All *P.m. klamathensis* sites are located in the high-elevation montane zone of the southern Oregon Cascades, where there is little potential for upslope movement or colonization of higher elevation habitats in response to climate change over time. Regional models of potential climate changes in the Pacific Northwest are variable, but the models generally indicate a warming trend in mean temperature, reduced snowpack, and increased frequency of extreme weather events (Salathe *et al.* 2010, pp. 72–73). All *P.m. klamathensis* sites are associated with mesic soils and permanent or ephemeral water sources (Black *et al.* 2010, p. 12).

Black *et al.* (2010, p. 60) notes that habitat within portions of the meadow complex are marginal for *P.m. klamathensis* because the sites are currently too dry, but the habitat may have been wetter in the past. Runquist (2004a, p. 5) observed over 200 skippers at this complex in 2002. Although multi day surveys have not been completed here, the population at this meadow complex appears to have declined (Black *et al.* 2010, pp. 60–61).

Given the restricted distribution of *P.m. klamathensis,* and the strong association of the subspecies with mesic sites, a projected warming trend in regional climate is a potential concern for *P.m. klamathensis,* depending on the changes in the environment that may manifest as a result. We acknowledge this concern and the need for monitoring of these populations in the face of climate change. However, at the present time, due to the multiple uncertainties associated with regional climate models, the actual changes that may be realized and how they would impact the species, the timeframes involved, and the questions surrounding *P.m. klamathensis* abundance information, we can not conclude that

climate change is a threat to *P.m. klamathensis* or likely to become so.

Summary: Because the mardon skipper is distributed across a range of elevations and habitat types, and has documented use of several host-plant species, it may not be as vulnerable to climate change as some other narrowly distributed species. Despite the potential for future climate change in the Pacific Northwest as discussed above, we have not identified, nor are we aware of, any data on an appropriate scale to evaluate habitat or population trends for the mardon skipper or to make reliable predictions about future trends and whether the species will be significantly impacted. Due to the uncertainty associated with regional climate models and how any potential environmental changes may possibly impact the species, we conclude that climate change is not a threat to mardon skippers at the species or subspecies levels or likely to become so.

Stochastic Weather Events and Small, Isolated Populations

Adverse weather (freezing temperatures, heavy rain events, or prolonged drought) can extirpate local butterfly populations by killing adults, larvae, or larval food plants (Guppy and Shephard 2001, p. 59). Even large populations of butterflies (greater than 5,000 individuals) can rapidly decline in response to successive seasons of unfavorable weather conditions during reproduction and larval development (Ehrlich *et al.* 1980, pp. 102–103). The decline in mardon skipper numbers at some Washington Cascades sites in 2009 is an example of how variations in seasonal weather can have a profound effect on local mardon skipper populations. The exact weather event that caused the decline is unknown, but unseasonably warm weather in May and June caused a rapid snowmelt to occur in these high-elevation meadows, followed by at least 4 days of freezing temperatures in late June during the period when mardon skipper adults typically emerge (Kogut 2009, p. 1). The adult flight period in 2009 occurred later, in mid-July, and was very brief, and the total numbers of adults were approximately 80 to 95 percent less than what had typically been counted at these sites during the previous 6 years (Kogut 2009, p. 1).

The weather effect was not limited to mardon skippers; other butterfly species were also affected, including the closely related Sonora skipper (*Polites sonora*), which was apparently absent from all sites where the species commonly co-occurs with mardon skippers at Cowlitz Valley (Kogut 2009, p. 1). The apparent weather-related effect was also noted at sites on the adjacent Wenatchee-Okanogan National Forest, where the emergence of adults occurred later, and the adult flight period was shorter than in previous years (St. Hilaire *et al.* 2009, p. 2), although the effect to the populations was not as severe as that seen on the Gifford Pinchot National Forest. Populations at lower elevation sites did not appear to be affected by these same weather events (St. Hilaire *et al.* 2009, p. 3). Subsequent years (2010 and 2011) have generally been cool and wet during the mardon skipper flight season, so the populations at the Cowlitz Valley sites have not recovered and have continued to gradually decline since 2009, but populations at other locations in the Washington Cascades have not shown a similar pattern of decline and are apparently stable. It is evident that adverse weather conditions can profoundly impact local mardon skipper populations. Because the species occurs across a broad range of elevations and habitat types, it is unlikely that a stochastic weather event is likely to affect all populations simultaneously.

Butterfly populations with very low numbers of individuals (e.g., fewer than 20 butterflies) are vulnerable to extirpation from random events such as inclement weather, wildfire, or other potential threats identified above (e.g., Schtickzelle *et al.* 2005, p. 578). There are a number of studies that demonstrate that habitat patch size, local population size, and proximity to adjacent populations have important implications for the long-term persistence of butterfly populations with limited dispersal capabilities (e.g., Thomas and Jones, 1993, p. 472; Hanski *et al.* 1995, p. 618; Saccheri *et al.* 1998, p. 492; Maes *et al.* 2004, pp. 234–235). Studies that examined butterfly population dynamics generally define ''small'' populations as having fewer than 500 adults and ''very small'' as having fewer than 100 adults at peak emergence (e.g., Maes *et al.* 2004, p. 232; Davies *et al.* 2005, p. 192). (As described below, for mardon skippers, counts of at least 100 individuals are generally considered to be large). Extremely small butterfly populations (fewer than 20 individuals) are not only highly vulnerable to environmental factors such as adverse weather conditions (Schtickzelle *et al.* 2005, p. 578), but such small populations are also at increased risk of extinction due to genetic effects associated with inbreeding (Saccheri *et al.* 1998, p. 491; Nieminen *et al.* 2001, p. 243). Inbreeding in small populations of the Glanville fritillary butterfly (*Melitaea cinxia*) resulted in reduced egg hatching rates, larval survival, and adult longevity (Nieminen *et al.* 2001, p. 243).

Long-term studies of the silver-spotted skipper (*Hesperia comma*) in England have documented a series of local population extinctions and colonizations over a 20-year period (Thomas and Jones 1993, p. 472; Davies *et al.* 2005, p. 189). These studies found that large habitat patches tended to support large populations of skippers, and that no extinctions occurred in habitat patches that supported populations of greater than 225 individuals; sites with 10 populations of fewer than 225 skippers, however, went extinct and the probability of extinction increased with isolation from the nearest population (Thomas and Jones 1993, pp. 476–478). Populations of silver-spotted skipper have expanded in recent years, and most of the sites that had documented extinctions in 1991 have subsequently been recolonized by dispersing individuals from adjacent sites (Davies *et al.* 2005, p. 195).

Most populations of mardon skippers consist of a series of one or more occupied meadows located within close proximity to each other. These populations or local ''clusters'' of sites likely function as small metapopulations with some dispersal of individuals between local sites (Kerwin 2011, pp. 21–23). Mardon skipper ''metapopulations'' likely experience local site-scale extinctions and recolonizations as local populations expand and contract in response to changing climate or habitat conditions, such as with the silver-spotted skipper in England (Davies *et al.* 2005, p. 195), although on a smaller scale, as silver-spotted skippers likely have greater dispersal capability than mardon skippers (Kerwin 2011, p. 23). However, there is strong evidence that mardon skippers exhibit similar metapopulation dynamics. The large number of mardon skipper sites in the Washington Cascades that are located in young clearcuts or roadside areas that were previously forested demonstrate that the species is capable of dispersing away from their core habitats and colonizing adjacent early-seral habitats that support host grasses and forbs (e.g., Kerwin 2011, p. 14).

Mardon skippers can be locally abundant where the species is present (Pyle 1989, p. 28) with single-day counts of greater than 100 individuals documented at many sites across the species' entire geographic range (for the mardon skipper, populations in the hundreds are relatively large) (Black *et al.* 2010, pp. 70–71; St. Hilaire *et al.*

2010, pp.10–12; Black *et al.* 2011, p. 13). Conversely, there are a number of apparently very small populations within the species' range with peak counts of fewer than 20 individuals. Because the number of mardon skippers present at a site can vary tremendously over the course of a few days (Beyer and Black 2007, p. 8), and the timing of the flight period can vary due to a variety of conditions, including elevation and weather conditions, there is little certainty of actual population sizes associated with these individual day counts. A single day, peak count of 100 skippers potentially represents a total population of more than 200 skippers based on observations during an experimental mark-recapture study (Runquist 2004a, p. 5), because not all butterflies emerge on the same date, and not all butterflies present at a site are likely to be counted during a survey.

Since 1999, mardon skippers have been documented at approximately 165 sites across the species' range. Considering that local clusters of sites likely function as small metapopulations, there are approximately 66 populations of mardon skippers currently known, and, with the exception of the Puget prairies, it is likely that there are additional undocumented populations present in all portions of the species' range because not all suitable habitats have been searched for mardon skippers (Kerwin 2011, p. 18). Each region within the species' range supports one or more ''large'' populations of mardon skippers (in the case of the mardon skipper, ''large'' is defined as single-day counts of more than 100 individuals, which likely represents a much larger total population).

All extant Puget prairie sites likely support total populations from more than 100 up to 1,000 individuals (Schultz *et al.* 2011, p. 370). The largest mardon skipper populations occur in the Washington Cascades, with at least 2 populations of greater than 1,000 individuals, and at least 11 other populations that have supported populations from 100 to 400 skippers over the past decade (unpublished data). In the Oregon Cascades, there are 2 populations that number from 100 to 300 individuals, and in the coastal areas of northwest California/southwestern Oregon, there are at least 3 populations with more than 100 individuals. In total, at least 22 of the approximately 66 populations rangewide support large populations of mardon skippers, and these sites represent the majority of the species' total populations.

Conversely, there are many individual ''sites'' with single-day counts of fewer than 20 individuals. Most of these sites are closely associated with larger local populations. A few sites may represent small, isolated populations that are vulnerable to local extirpation associated with stochastic weather events, but these generally represent only a small portion of the total species' populations. Because the mardon skipper has presumably limited dispersal capabilities, if an isolated population were to become extirpated, some isolated sites are unlikely to be reestablished due to long distances or physical barriers (e.g., extensive forested areas) between extant populations (Kerwin 2011, p. 23).

The mardon skipper is a naturally rare species across its disjunct range. Given the limited information concerning mardon skipper population trends rangewide, and the presence of multiple ''large'' populations in each distinct region within the species range, the majority of the species' total populations appear to be relatively secure from threats associated with small populations.

Discussion specific to *Polites mardon klamathensis:*

The distribution of *Polites mardon klamathensis* appears to be restricted to 22 sites likely representing approximately 11 populations in the southern Oregon Cascades. Surveys in recent years have searched over 200 sites in the vicinity of these known populations and have failed to detect the species, indicating the subspecies is highly restricted in its distribution to a few small meadow complexes within a small geographic area (Black *et al.* 2010, p. 7). However, one small site was documented on Bureau of Reclamation lands managed by BLM in 2011 (Black 2012, pers. comm.), indicating it is possible that additional undocumented *P.m. klamathensis* sites may exist in the area. Although populations of *P.m. klamathensis* appear to be relatively small, it is difficult to draw any reliable conclusions on population sizes based on the limited data available, since the majority of sites have only been visited once during the flight season in recent years (Black *et al.* 2010, pp. 70–72). Additional multiple-day surveys are needed to confirm if populations are as small as they appear based on the limited survey data collected thus far, or whether past single-day counts may have just missed the peak flight period. As discussed earlier, due to the variability of mardon flight periods between sites and years, as well as extreme fluctuations in numbers of individuals that may be present from day to day, a single-day survey in a year is insufficient to indicate trends or abundance.

In summary, total population sizes at all *Polites mardon klamathensis* sites are unknown due to limited surveys, although counts at most sites indicate that populations of this subspecies may be relatively small. Unfortunately the high variability in potential counts from day to day for this subspecies undermines the credibility of any single-day counts for the purpose of determining population status or trend, and raises questions as to whether counts of zero or few individuals on any one day accurately reflect population numbers or abundance. Based on the lack of historical abundance information and the uncertainty accompanying the numbers of individuals associated with individual day counts, we do not have reliable information to suggest that *P.m. klamathensis* is such a small isolated population that stochastic weather events would pose a significant threat to the subspecies as a whole.

Summary: Prolonged periods of cool wet weather during the spring and summer months are known to negatively affect mardon skipper populations. Small butterfly populations are particularly vulnerable to these effects. Given the limited information concerning mardon skipper population trends rangewide, and the presence of multiple ''large'' populations in each distinct region within the species' range, the majority of the species' total populations and those of the subspecies *Polites mardon mardon* appear to be relatively secure from threats associated with small populations. Additionally, due to the limited population and abundance information we have for the the subspecies *Polites mardon klamathensis,* we conclude that we do not have reliable information to indicate that populations of this subspecies are so small or isolated as to represent a threat to *P.m. klamathensis as a whole.*

Finding

As required by the Act, we considered the five factors in assessing whether the mardon skipper is a threatened or endangered species throughout all of its range. We additionally considered whether either of the two recognized subspecies comprising the species mardon skipper may be a threatened or endangered species throughout all or a significant portion of their ranges. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by the mardon skipper and its subspecies. We reviewed the petition, information available in our

files, other available published and unpublished information, and consulted with recognized mardon skipper experts and other Federal, State, and tribal agencies.

The Species Mardon Skipper (Polites mardon)

The mardon skipper is a little-studied species; however, the species has received considerable attention and funding for surveys since becoming a Federal candidate species in 1999. The number of documented locations of mardon skippers has expanded from fewer than 10 in 1998 to 165 in 2011; this increase in known occurrences of the species is largely due to increased survey effort. Since 1999, new site locations have been documented each year that targeted surveys have been conducted. In the past 5 years, significant new populations have been located in the Washington Cascades and in coastal areas of Oregon and California, with local sites supporting populations of hundreds of mardon skippers. It is likely that there are additional, undocumented populations, particularly in the Washington Cascades, and possibly in southwestern Oregon and northern California because not all available habitat for the species has yet been surveyed. The majority of the sites throughout the species' range occur on Federal lands managed by the Forest Service, Bureau of Land Management, National Park Service, Fish and Wildlife Service, and the Department of Defense (76 percent).

Current management actions, policies, and protections associated with State and Federal special-status-species programs now afford the species a high level of security from habitat loss or destruction across the species' range. Potential threats to mardon skipper habitat associated with forest succession, fire, invasive nonnative plants, livestock grazing, and off-road vehicle use have been substantially reduced or eliminated on State and Federal lands through the development of conservations plans and implementation of habitat restoration projects. Habitat degradation associated with intensive livestock grazing continues to occur at some sites, but grazing impacts have been substantially reduced or eliminated at many key sites across the species' range with recent closures of Federal grazing allotments. Habitat degradation from off-road vehicle use has been reduced or eliminated at many sites by installing vehicle barriers or closing roads. Meadow habitat restoration activities (prescribed burning, herbicide treatments) can be lethal to mardon skippers if not conducted properly, but these risks have been minimized through careful planning and implementation of habitat restoration projects. Ongoing threats that are not currently addressed by existing conservation plans include potential habitat loss on private lands, but there are relatively few known mardon skipper sites on private lands. Climate change may affect the mardon skipper and its habitat. Because the mardon skipper is distributed across a range of elevations and habitat types, and has documented use of multiple host-plant species, it may not be as vulnerable to climate change as some other more narrowly distributed specialist species.

Based on our review of the best available scientific and commercial information pertaining to the five factors, we find that the threats are not so severe or broad in scope as to indicate that the mardon skipper is in danger of extinction (endangered), or likely to become endangered within the foreseeable future (threatened), throughout all of its range. Therefore, we find that the mardon skipper does not meet the definition of an endangered or threatened species throughout its range.

The mardon skipper is listed as endangered by the State of Washington. Washington's listing of the mardon skipper was based on a status assessment of the species conducted in 1999 (Potter 1999), and relied on much of the same information that the Service considered in placing the mardon skipper on the candidate list that same year. A substantial amount of new information has become available since that time, however, which we have evaluated in making the present finding. Although the State of Washington has updated information on new population data and conservation efforts for the mardon skipper in their annual reports, they have not reconsidered the listed status of the species based on this information. Our analysis of the best available information considers the many positive conservation measures that have been implemented by both Federal and State agencies throughout the range of the mardon skipper, including actions by the State of Washington, to recover the species and ameliorate the threats that initially led to its State listing and Federal candidacy 13 years ago. In addition, we considered the numerous additional populations of the species (and subspecies) that have been documented since the mardon skipper first became a Federal candidate and was listed by the State. Our current evaluation of the best available information according to the Federal Endangered Species Act, as detailed in this finding, does not lead us to conclude that the mardon skipper meets the definition of an endangered species or threatened species throughout all or a significant portion of its range.

The Subspecies Polites mardon mardon *and* Polites mardon klamathensis

Polites mardon mardon

Polites mardon mardon faces the same threats as discussed in the rangewide evaluation previously, and we consider all conclusions reached regarding the degree of threat for the species as a whole to apply equally to the subspecies *P. m. mardon.* As a result, we find that this subspecies does not meet the definition of an endangered or threatened species throughout its range.

Polites mardon klamathensis

Polites mardon klamathensis faces the same threats as discussed in the rangewide evaluation previously; however, where relevant we have assessed threats specific or unique to the subspecies *Polites mardon klamathensis* separately throughout the rangewide evaluation. In general, we consider all conclusions reached regarding the degree of threat for the species as a whole to apply equally to the subspecies *P. m klamathensis.* As a result, we find that this subspecies does not meet the definition of an endangered or threatened species throughout its range.

Significant Portion of the Range

Having determined that the species *Polites mardon* and the subspecies *Polites mardon. mardon* and *Polites mardon klamathensis* do not meet the definition of a threatened or endangered species, we next consider whether there are any significant portions of the range where the mardon skipper is in danger of extinction or is likely to become in danger of extinction in the foreseeable future.

In determining whether a species is a threatened or endangered species in a significant portion of its range, we first identify any portions of the range of the species that warrant further consideration. The range of a species can theoretically be divided into portions an infinite number of ways. However, there is no purpose to analyzing portions of the range that are not reasonably likely to be both (1) significant and (2) meeting the definition of a threatened or endangered species. To identify only those portions that warrant further consideration, we

determine whether there is substantial information indicating that: (1) The portions may be significant, and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats applies only to portions of the species' range that are not significant, such portions will not warrant further consideration.

If we identify portions that warrant further consideration, we then determine whether the species is threatened or endangered in these portions of its range. Depending on the biology of the species, its range, and the threats it faces, the Service may address either the significance question or the status question first. Thus, if the Service considers significance first and determines that a portion of the range is not significant, the Service need not determine whether the species is threatened or endangered there. Likewise, if the Service considers status first and determines that the species is not threatened or endangered in a portion of its range, the Service need not determine if that portion is significant.

Applying the process described above for determining whether a species is threatened or endangered in a significant portion of its range, we considered the status question first to determine if any threats or potential threats acting individually or collectively threaten or endanger the species in some portion of its range. In analyzing the status of the mardon skipper across its range, the only area we identified where threats may be concentrated is the Puget prairies. We therefore considered whether the threats to the Puget prairie populations of *Polites mardon* or *Polites mardon mardon* are such that the species may be in danger of extinction there, now or within the foreseeable future, such that the Puget prairie populations may warrant further consideration as a potential significant portion of the range.

Although the rangewide mardon skipper population is relatively secure under current conditions, the Puget prairies represent the only portion of the species' historical and current distribution where there are confirmed extirpations of historical populations, and we can reasonably infer that the species' range has contracted due to the historical loss of Puget prairie habitat over the past century. We therefore considered the likely future condition of the Puget prairie populations under the presently observed rates of population change. Historically, mardon skippers were known to be present at eight Puget prairie sites, and are currently restricted to three known populations. The trends of the remaining populations are unknown due to limited and inconsistent monitoring data, but appear to have been relatively stable over the past decade, with 2 populations estimated to consist of hundreds of mardon skippers, and 1 population with likely over 1,000 skippers (Schultz *et al.* 2011, p. 370). Puget prairie sites with extant populations of mardon skippers are protected from further development through either State or Federal ownership. Mardon skipper habitat at these sites is: (1) Actively being managed to restore and maintain mardon skippers and other prairie species; or (2) at Joint Base Lewis-McChord being maintained by regular wildfires, and large areas of habitat are protected from development, off-road vehicle use, and military training due to the presence of unexploded ordnance. In addition, Joint Base Lewis-McChord is cooperating in an interagency effort to restore and maintain prairie habitats for the mardon skipper and other prairie species, discussed below.

Remaining prairie habitats in the south Puget Sound region are relatively small, isolated patches with little potential connectivity between patches (Schultz *et al.* 2011, p. 371). Because of this, historical prairie sites where mardon skippers have been extirpated are unlikely to be recolonized due to isolation from extant populations (Schultz *et al.* 2011, p. 371). There are a number of small prairie sites in the region that are currently in protected status and are actively being managed to maintain butterfly habitats that may serve as potential future reintroduction sites for mardon skippers (Anderson 2008, p. 2; Henry 2010, pp. 3–4). Beginning in 2007, the Joint Base Lewis-McChord Army Compatible Use Buffer (ACUB) initiative has supported the convening of a cooperative, interdisciplinary and interagency Butterfly Habitat Enhancement Team to develop and implement habitat improvements for mardon skipper and other rare butterflies on formerly occupied sites off the military reservation (Anderson 2008, p. 1). This interagency team is a source of funding for mardon skipper habitat management, population assessments, and mardon skipper life-history research at Puget prairie sites. These projects continue to maintain habitat and mardon skipper populations at the Scatter Creek Wildlife Area. The ongoing management to maintain mardon skipper populations and habitat at Puget prairie sites afford the species a high level of protection against further losses of habitat or populations. Because these conservation efforts have been implemented, are effective, and are expected to continue, we consider the Puget prairie population of the mardon skipper as not likely to become in danger of extinction within the foreseeable future.

As the best available information indicates that the Puget prairie population of mardon skipper at either the species or subspecies level is not likely to become in danger of extinction within the foreseeable future, we conclude that Puget prairie does not warrant further consideration as a potential significant portion of the range at this point in time. We did not identify any other potential significant portions of the range of the mardon skipper (*Polites mardon, Polites mardon mardon,* or *Polites mardon klamathensis*) that may meet the definition of a threatened or endangered species.

In *Defenders of Wildlife* v. *Norton,* 258 F.3d 1136, 1145 (9th Cir. 2001), the court ruled that a species may be an endangered species in a significant portion of its range ''if there are major geographical areas in which it is no longer viable but once was.'' Where the area in which the species is expected to survive is ''much smaller than its historical range,'' the determination of whether the species warrants listing turns on whether the lost portion of the range would be significant. As discussed above, the Puget Prairie population of the mardon skipper is the only portion of the species' range that is known to have contracted from the historical distribution. We conclude that current and future conservation efforts are expected to maintain mardon skippers and restore the species to additional Puget prairie habitats. Therefore, we have determined that neither the full species mardon skipper, nor the subspecies *Polites mardon mardon* or *Polites mardon klamathensis,* is an endangered or threatened species in a significant portion of its range.

We do not find that the mardon skipper, or the subspecies *Polites mardon mardon* or *Polites mardon klamathensis,* are in danger of extinction now, nor are they likely to become in danger of extinction within the foreseeable future throughout all or a significant portion of their range. Therefore, listing the mardon skipper *Polites mardon,* the subspecies *P. m.*

mardon, or the subspecies *Polites mardon klamathensis,* as a threatened or endangered species under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, the mardon skipper to our Washington Fish and Wildlife Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor the mardon skipper and encourage its conservation. If an emergency situation develops for the mardon skipper or any other species, we will act to provide immediate protection.

We will continue to monitor the condition of the mardon skipper throughout its range. In the event that conditions or threats change and the species becomes imperiled, we could again consider whether it is appropriate to list the species as endangered or threatened under the Act. We will continue to provide technical assistance to Federal, State, and other entities and encourage them to address the conservation needs of the mardon skipper. We will continue to work with these agencies and entities to collect additional biological information, monitor the status of the mardon skipper, and monitor the progress of its conservation efforts.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Washington Fish and Wildlife Office (see **ADDRESSES** section).

Author(s)

The primary authors of this notice are staff members of the Washington Fish and Wildlife Office.

Authority

The authority for this section is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: August 20, 2012.

Benjamin N. Tuggle,

Acting Director, Fish and Wildlife Service.

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Tuesday, September 4, 2012

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FEDERAL REGISTER PAGES AND DATE, SEPTEMBER

53769–54352 4

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H.R. 1402/P.L. 112–170

To authorize the Architect of the Capitol to establish battery recharging stations for privately owned vehicles in parking areas under the jurisdiction of the House of Representatives at no net cost to the Federal Government. (Aug. 16, 2012; 126 Stat. 1303)

H.R. 3670/P.L. 112–171

To require the Transportation Security Administration to comply with the Uniformed Services Employment and Reemployment Rights Act. (Aug. 16, 2012; 126 Stat. 1306)

H.R. 4240/P.L. 112–172

Ambassador James R. Lilley and Congressman Stephen J. Solarz North Korea Human Rights Reauthorization Act of 2012 (Aug. 16, 2012; 126 Stat. 1307)

S. 3510/P.L. 112–173

To prevent harm to the national security or endangering the military officers and civilian employees to whom internet publication of certain information applies, and for other purposes. (Aug. 16, 2012; 126 Stat. 1310)

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A new table will be published in the first issue of each month.

Date of FR publication	15 days after publication	21 days after publication	30 days after publication	35 days after publication	45 days after publication	60 days after publication	90 days after publication
September 4	Sep 19	Sep 25	Oct 4	Oct 9	Oct 19	Nov 5	Dec 3
September 5	Sep 20	Sep 26	Oct 5	Oct 10	Oct 22	Nov 5	Dec 4
September 6	Sep 21	Sep 27	Oct 9	Oct 11	Oct 22	Nov 5	Dec 5
September 7	Sep 24	Sep 28	Oct 9	Oct 12	Oct 22	Nov 6	Dec 6
September 10	Sep 25	Oct 1	Oct 10	Oct 15	Oct 25	Nov 9	Dec 10
September 11	Sep 26	Oct 2	Oct 11	Oct 16	Oct 26	Nov 13	Dec 10
September 12	Sep 27	Oct 3	Oct 12	Oct 17	Oct 29	Nov 13	Dec 11
September 13	Sep 28	Oct 4	Oct 15	Oct 18	Oct 29	Nov 13	Dec 12
September 14	Oct 1	Oct 5	Oct 15	Oct 19	Oct 29	Nov 13	Dec 13
September 17	Oct 2	Oct 9	Oct 17	Oct 22	Nov 1	Nov 16	Dec 17
September 18	Oct 3	Oct 9	Oct 18	Oct 23	Nov 2	Nov 19	Dec 17
September 19	Oct 4	Oct 10	Oct 19	Oct 24	Nov 5	Nov 19	Dec 18
September 20	Oct 5	Oct 11	Oct 22	Oct 25	Nov 5	Nov 19	Dec 19
September 21	Oct 9	Oct 12	Oct 22	Oct 26	Nov 5	Nov 20	Dec 20
September 24	Oct 9	Oct 15	Oct 24	Oct 29	Nov 8	Nov 23	Dec 24
September 25	Oct 10	Oct 16	Oct 25	Oct 30	Nov 9	Nov 26	Dec 24
September 26	Oct 11	Oct 17	Oct 26	Oct 31	Nov 13	Nov 26	Dec 26
September 27	Oct 12	Oct 18	Oct 29	Nov 1	Nov 13	Nov 26	Dec 26
September 28	Oct 15	Oct 19	Oct 29	Nov 2	Nov 13	Nov 27	Dec 27