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Contents

Federal Register

Vol. 75, No. 8

Wednesday, January 13, 2010

Agricultural Marketing Service
PROPOSED RULES
Tart Cherries Grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin, 1724–1731

Agriculture Department
See Agricultural Marketing Service
See Animal and Plant Health Inspection Service
See Forest Service

Animal and Plant Health Inspection Service
RULES
Change in Disease Status of the Republic of Korea With Regard to Foot-and-Mouth Disease and Rinderpest, 1697
NOTICES
Petition for Determination on Nonregulated Status for Genetically Engineered, Insect-Resistant Corn:
Syngenta Biotechnology, Inc., 1749–1751

Centers for Disease Control and Prevention
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1790
Meetings:
Study Team for the Los Alamos Historical Document Retrieval and Assessment Project, 1793–1794

Centers for Medicare & Medicaid Services
PROPOSED RULES
Medicare and Medicaid Programs:
Electronic Health Record Incentive Program, 1844–2011

Civil Rights Commission
NOTICES
Hearing on the Department of Justice's Actions:
New Black Panther Party Litigation and its Enforcement of Section 11(b) of the Voting Rights Act, 1751

Coast Guard
RULES
Drawbridge Operation Regulations:
Curtis Creek, Baltimore, MD, 1705–1706
Intracoastal Waterway (ICW), Inside Thorofare, Ventnor City, NJ, 1705
Upper Mississippi River, Dubuque, IA, 1706
Federal Civil Penalties Inflation Adjustment Act – 2009 Implementation, 1704–1705
Regulated Navigation Areas:
U.S. Navy Submarines, Hood Canal, WA, 1706–1709
Security Zones:
Escorted U.S. Navy Submarines in Sector Seattle Captain of the Port Zone, 1709–1712
PROPOSED RULES
Drawbridge Operation Regulations:
New Haven Harbor, Quinnipiac and Mill Rivers, CT, 1738–1741
NOTICES
Terminate Long Range Aids to Navigation (Loran–C) Signal; Correction, 1799–1800

Commerce Department
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration
See National Telecommunications and Information Administration

Comptroller of the Currency
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1840–1841

Defense Department
NOTICES
Meetings:
Board of Regents of the Uniformed Services University of the Health Sciences, 1756
National Defense University Board of Visitors (BOV), 1756

Drug Enforcement Administration
NOTICES
Importer of Controlled Substances; Application, 1812–1813
Manufacturer of Controlled Substances; Registration, 1813–1814

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1756–1757
Applications for New Awards (FY 2010):
Small Business Innovation Research Program (Phase I), 1757–1761

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Approval and Promulgation of Air Quality Implementation Plans:
Mississippi; Update to Materials Incorporated by Reference, 1712–1715
Revisions to the California State Implementation Plan:
San Joaquin Valley Unified Air Pollution Control District, 1715–1723
NOTICES
Approach to Using Toxicogenomic Data in U.S. EPA Human Health Risk Assessments:
Dibutyl Phthalate Case Study, 1770
Proposed Consent Decree, Clean Air Act Citizen Suit, 1770–1772
Receipt of Applications:
Pesticide Experimental Use Permits, 1772–1773
Receipt of Pesticide Petition:
Residues of Polymeric Polyhydroxy Acid in or on All Food Commodities, 1773–1775
Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations, 1775–1780

Executive Office of the President
See Presidential Documents

Farm Credit System Insurance Corporation
NOTICES
Meetings:
Farm Credit System Insurance Corporation Board, 1780

Federal Aviation Administration
RULES
Airworthiness Directives:
Dassault–Aviation Model Falcon 7X Airplanes, 1697–1699
PROPOSED RULES
Airworthiness Directives:
Sicma Aero Seat 9140 Series Passenger Seat, etc., 1731–1734
NOTICES
Membership Availability in the National Parks Overflights Advisory Group Aviation, 1834–1835
Surplus Property Release at Moore County Airport, Pinehurst/Southern Pines, North Carolina:
Request for Comments, 1839

Federal Communications Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1781–1784

Federal Deposit Insurance Corporation
NOTICES
Meetings:
FDIC Advisory Committee on Community Banking, 1784

Federal Election Commission
NOTICES
Meetings; Sunshine Act, 1784

Federal Energy Regulatory Commission
NOTICES
Combined Notice of Filings, 1761–1770

Federal Motor Carrier Safety Administration
NOTICES
Qualification of Drivers; Exemption Applications:
Vision, 1835–1839

Federal Reserve System
NOTICES
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 1784–1785

Federal Trade Commission
PROPOSED RULES
Children's Online Privacy Protection Rule–Safe Harbor Proposed Self-Regulatory Guidelines:
i–SAFE, Inc. Application for Safe Harbor, 1734–1735
NOTICES
Analysis of the Agreement Containing Consent Orders to Aid Public Comment:
Agrium Inc. and CF Industries Holding, Inc., 1785–1788

Fish and Wildlife Service
PROPOSED RULES
Endangered and Threatened Wildlife and Plants:
Determination That Designation of Critical Habitat is Prudent for the Jaguar, 1741–1744
Partial 90-Day Finding on a Petition to List 475 Species in the Southwestern United States as Threatened or Endangered With Critical Habitat; Correction, 1744–1745
NOTICES
Environmental Impact Statements; Availability, etc.:
Lower Florida Keys Refuges, Monroe County, FL, 1803–1806
Receipt of Endangered and Threatened Species Permit Applications, 1810–1811

Food and Drug Administration
NOTICES
Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors:
IRB Continuing Review After Clinical Investigation Approval; Availability, 1790–1791

Forest Service
NOTICES
Environmental Impact Statements; Availability, etc.:
Helena National Forest, MT, Stonewall Vegetation Project, 1748
Meetings:
Eastern Washington Cascades Provincial Advisory Committee and the Yakima Provincial Advisory Committee, 1749
Federal Lands Recreation Enhancement Act, (Title VIII, Pub. L. 108–447), 1749

General Services Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1788–1789

Health and Human Services Department
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See Health Resources and Services Administration
See National Institutes of Health
RULES
Health Information Technology:
Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014–2047

Health Resources and Services Administration
NOTICES
Maternal and Child Health Bureau, 1792

Homeland Security Department
See Coast Guard
See U.S. Customs and Border Protection

Industry and Security Bureau
RULES
Addition of Certain Persons on the Entity List:
Addition of Persons Acting Contrary to National Security or Foreign Policy Interests of the United States and Entry Modified for Clarification, 1699–1704

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

Internal Revenue Service
RULES
Modification to Consolidated Return Regulation:
Permitting an Election to Treat a Liquidation of a Target, Followed by a Recontribution to a New Target, as a Cross-Chain Reorganization, 1704

PROPOSED RULES
Section 3504 Agent Employment Tax Liability, 1735–1738

International Trade Administration
NOTICES
Extension of Time Limits for Preliminary Results of Antidumping Duty Administrative Review:
Light-Walled Rectangular Pipe and Tube from Turkey, 1751–1752
Postponement of Final Determination:
Prestressed Concrete Steel Wire Strand from the People's Republic of China, 1755

Justice Department
See Drug Enforcement Administration
See Justice Programs Office
See National Institute of Corrections

Justice Programs Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1811–1812

Land Management Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1800
Alaska Native Claims Selection, 1801
Environmental Impact Statements; Availability, etc.:
Proposed First Solar Desert Sunlight Solar Farm Project, Riverside County, California, 1801–1802
Restoration Design Energy Project and Possible Land Use Plan Amendment, 1807–1809

Maritime Administration
NOTICES
Assistance to Small Shipyards Grant Program, 1832–1834

National Institute of Corrections
NOTICES
Solicitation for a Cooperative Agreement – Curriculum Development:
Training for Correctional Industries Directors, 1814–1816

National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1789
Meetings:
Center for Scientific Review Special Emphasis Panel; Genetic and Genomic Analyses of Xenopus, 1796–1797
Center for Scientific Review Special Emphasis Panel; Hematopoietic Cellular Mechanisms, 1795–1796
Center for Scientific Review Special Emphasis Panel; Member Conflict, Tumor Immunology and Immunotherapy, 1792–1793
Center for Scientific Review Special Emphasis Panel; NHLBI Systems Biology, 1793
National Center for Complementary and Alternative Medicine Special Emphasis Panel, etc., 1796
National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, etc., 1792
National Institute of Nursing Research, 1794
National Institute of Nursing Research Initial Review Group, 1794
National Institute of Nursing Research Special Emphasis Panel, etc., 1794–1795
Prospective Grants of Exclusive Licenses:
Development of V–ATPase Inhibitor Compounds for Treatment of Human Cancers, etc., 1798–1799

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Exclusive Economic Zone Off Alaska:
Chiniak Gully Research Area for Vessels Using Trawl Gear, 1723
PROPOSED RULES
Fisheries Off West Coast States:
Coastal Pelagic Species Fisheries; Annual Specifications, 1745–1747
NOTICES
Meetings:
Fisheries of the Atlantic; Southeast Data, Assessment, and Review (SEDAR); Atlantic croaker and Atlantic menhaden, 1753–1754
Gulf of Mexico Fishery Management Council, 1754–1755
New England Fishery Management Council, 1752–1753
North Pacific Fishery Management Council, 1752

National Park Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1800–1801
Environmental Impact Statements; Availability, etc.:
General Management Plan, Gila Cliff Dwellings National Monument, NM, 1802–1803
New River Gorge National River, WV, 1806–1807
Meetings:
Big Cypress National Preserve Off-Road Vehicle (ORV) Advisory Committee, 1809
National Register of Historic Places:
Notification of Pending Nominations and Related Actions, 1809–1810

National Science Foundation
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1816–1819

National Telecommunications and Information Administration

NOTICES
Public Telecommunications Facilities Program:
Availability of Funds, 1755–1756

Nuclear Regulatory Commission
NOTICES
Application for License:
GE–Hitachi Global Laser Enrichment LLC (GLE Commercial Facility), 1819–1830
Final Regulatory Guide; Issuance, Availability, 1830
Meetings:
Advisory Committee on Reactor Safeguards (Planning and Procedures Subcommittee), 1830–1831
Advisory Committee on Reactor Safeguards (Subcommittee on AP 1000), 1831
Request for Resumes:
Advisory Committee on Reactor Safeguards, 1831–1832

Presidential Documents
PROCLAMATIONS
Special Observances:
National Influenza Vaccination Week (Proc. 8472), 2049–2052

Securities and Exchange Commission
NOTICES
Meetings; Sunshine Act, 1832

Transportation Department
See Federal Aviation Administration
See Federal Motor Carrier Safety Administration
See Maritime Administration

Treasury Department
See Comptroller of the Currency
See Internal Revenue Service
NOTICES
Meetings:
Debt Management Advisory Committee, 1839–1840

U.S. Customs and Border Protection
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 1799

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 1844–2011

Part III
Health and Human Services Department, 2014–2047

Part IV
Presidential Documents, 2049–2052

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.

3 CFR
Proclamations:
8472.....2051

7 CFR
Proposed Rules:
930.....1724

9 CFR
94.....1697

14 CFR
39.....1697
Proposed Rules:
39.....1731

15 CFR
744.....1699

16 CFR
Proposed Rules:
312.....1734

26 CFR
1.....1704
Proposed Rules:
31.....1735

33 CFR
27.....1704
117 (3 documents) 1705, 1706
165 (2 documents) 1706, 1709
Proposed Rules:
117.....1738

40 CFR
52 (3 documents) ...1712, 1715, 1716

42 CFR
Proposed Rules:
412.....1844
413.....1844
422.....1844
495.....1844

45 CFR
170.....2014

50 CFR
679.....1723
Proposed Rules:
17 (2 documents) 1741, 1744
660.....1745

Rules and Regulations

Federal Register
Vol. 75, No. 8
Wednesday, January 13, 2010

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

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS–2008–0147]

Change in Disease Status of the Republic of Korea With Regard to Foot-and-Mouth Disease and Rinderpest

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; delay of effective date.

SUMMARY: On December 28, 2009, we published a final rule in the **Federal Register** to add the Republic of Korea to the list of regions that are considered free of rinderpest and foot-and-mouth disease (FMD) and the list of regions that are subject to certain import restrictions on meat and meat products because of their proximity to or trading relationships with rinderpest- or FMD-affected countries. The final rule was scheduled to become effective on January 12, 2010. However, due to an outbreak of FMD reported by the Republic of Korea on January 6, 2010, we are delaying indefinitely the effective date of the final rule. This delay will allow the Animal and Plant Health Inspection Service to consider the issues raised by this development and decide what subsequent actions to take.

DATES: The effective date for the final rule amending 9 CFR part 94 published at 74 FR 68478–68480 on December 28, 2009, is delayed indefinitely.

FOR FURTHER INFORMATION CONTACT: Dr. Julia Punderson, Senior Staff Veterinarian, Regionalization Evaluation Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

In a final rule[1] published in the **Federal Register** on December 28, 2009 (74 FR 68478–68480, Docket No. APHIS–2008–0147), we amended the regulations in 9 CFR part 94 concerning the importation of animals and animal products by adding the Republic of Korea (South Korea) to the list in § 94.1 of regions declared free of FMD and rinderpest. We also added the Republic of Korea to the list in § 94.11 of regions that are declared to be free of these diseases, but that are subject to certain restrictions because of their proximity to or trading relationships with rinderpest- or FMD-affected regions.

The final rule was scheduled to become effective on January 12, 2010. However, on January 6, 2010, the Republic of Korea confirmed through laboratory diagnosis that an FMD outbreak occurred on a dairy farm in Kyonggi Province. As a consequence, we no longer consider the Republic of Korea to be free of FMD. Therefore, we are delaying the effective date of the final rule indefinitely. This delay will allow the Animal and Plant Health Inspection Service to consider the issues raised by this development and decide what subsequent actions to take.

■ Accordingly, the final rule amending 9 CFR part 94 published at 74 FR 68478–68480 on December 28, 2009, is delayed indefinitely.

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 8th day of January 2010.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010–478 Filed 1–8–10: 4:15 pm]

BILLING CODE 3410–34–S

[1] To view the final rule and related documents, go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2008–0147*).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–1252; Directorate Identifier 2009–NM–248–AD; Amendment 39–16173; AD 2010–02–02]

RIN 2120–AA64

Airworthiness Directives; Dassault-Aviation Model Falcon 7X Airplanes

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

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

> Several occurrences of untimely radio-altimeter lock-up have been reported, where the failed radio-altimeter indicated a negative distance to the ground despite the aircraft was flying at medium or high altitude.
>
> A locked radio-altimeter #1 leads to untimely inhibition of warnings that could be displayed along with certain abnormal conditions while the avionic system switches into landing mode during altitude cruise.
>
> * * * * *
>
> [Untimely radio-altimeter lock-up] may cause the crew to be unaware of possible system failures that could require urgent crew's actions.
>
> * * * * *

This AD requires actions that are intended to address the unsafe condition described in the MCAI.

DATES: This AD becomes effective January 28, 2010.

We must receive comments on this AD by March 1, 2010.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

• *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2009–0208, dated October 13, 2009 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> Several occurrences of untimely radio-altimeter lock-up have been reported, where the failed radio-altimeter indicated a negative distance to the ground despite the aircraft was flying at medium or high altitude.
>
> A locked radio-altimeter #1 leads to untimely inhibition of warnings that could be displayed along with certain abnormal conditions while the avionic system switches into landing mode during altitude cruise.
>
> Investigation in order to determine the root cause of radio-altimeter lock-up is in progress. In the meantime, Dassault Aviation has developed an operational procedure that in case of radio-altimeter #1 lock-up allows the crew, by depowering radio-altimeter #1, to restore in flight the system warning performance.
>
> Failure to comply with this interim flight procedure may cause the crew to be unaware of possible system failures that could require urgent crew's actions.
>
> This AD mandates application of a new abnormal Airplane Flight Manual (AFM) procedure when radio-altimeter #1 lock-up occurs and prohibits dispatch of the aeroplane with any radio-altimeter inoperative.

You may obtain further information by examining the MCAI in the AD docket.

FAA's Determination and Requirements of This AD

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

Differences Between the AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the AD.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because lock-up of the radio-altimeter could interfere with critical flight system annunciations and functions, which could cause the flightcrew to be unaware of possible system failures that could require urgent flightcrew actions. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2009–1252; Directorate Identifier 2009–NM–248–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this AD:

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

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

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2010–02–02 Dassault-Aviation: Amendment 39–16173. Docket No. FAA–2009–1252; Directorate Identifier 2009–NM–248–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective January 28, 2010.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Dassault-Aviation Model Falcon 7X airplanes, certificated in any category, all serial numbers.

Subject

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

Reason

(e) The mandatory continued airworthiness information (MCAI) states:

Several occurrences of untimely radio-altimeter lock-up have been reported, where the failed radio-altimeter indicated a negative distance to the ground despite the aircraft was flying at medium or high altitude.

A locked radio-altimeter #1 leads to untimely inhibition of warnings that could be displayed along with certain abnormal conditions while the avionic system switches into landing mode during altitude cruise.

Investigation in order to determine the root cause of radio-altimeter lock-up is in progress. In the meantime, Dassault Aviation has developed an operational procedure that in case of radio-altimeter #1 lock-up allows the crew, by depowering radio-altimeter #1, to restore in flight the system warning performance.

Failure to comply with this interim flight procedure may cause the crew to be unaware of possible system failures that could require urgent crew's actions.

This AD mandates application of a new abnormal Airplane Flight Manual (AFM) procedure when radio-altimeter #1 lock-up occurs and prohibits dispatch of the aeroplane with any radio-altimeter inoperative.

Compliance

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

Actions

(g) Within 14 days after the effective date of this AD: Revise the Limitations Section of the Dassault Falcon 7X Airplane Flight Manual (AFM) to include the following statement. This may be done by inserting a copy of this AD in the AFM.

"If radio-altimeter #1 lock-up conditions occur in flight, power off radio-altimeter #1, in accordance with the instructions of Falcon 7X AFM procedure 3–140–65.

Dispatch of the airplane with any radio-altimeter inoperative is prohibited."

Note 1: When a statement identical to that in paragraph (g) of this AD has been included in the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(h) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

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

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(i) Refer to MCAI EASA Airworthiness Directive 2009–0208, dated October 13, 2009, for related information.

Material Incorporated by Reference

(j) None.

Issued in Renton, Washington, on December 28, 2009.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010–103 Filed 1–12–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 0911171410–91427–01]

RIN 0694–AE78

Addition of Certain Persons on the Entity List: Addition of Persons Acting Contrary to the National Security or Foreign Policy Interests of the United States and Entry Modified for Clarification

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule amends the Export Administration Regulations (EAR) by adding additional persons to the Entity List (Supplement No. 4 to Part 744) on the basis of Section 744.11 of the EAR. These persons that are added to the Entity List have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. This rule also amends one entry by adding an additional address for this person listed on the Entity List.

The Entity List provides notice to the public that certain exports, reexports, and transfers (in-country) to parties identified on the Entity List require a license from the Bureau of Industry and Security (BIS) and that availability of license exceptions in such transactions is limited.

DATES: *Effective Date:* This rule is effective January 13, 2010. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

ADDRESSES: You may submit comments, identified by RIN 0694–AE78, by any of the following methods:

E-mail: publiccomments@bis.doc.gov Include "RIN 0694–AE78" in the subject line of the message.

Fax: (202) 482–3355. Please alert the Regulatory Policy Division, by calling (202) 482–2440, if you are faxing comments.

Mail or Hand Delivery/Courier: Timothy Mooney, U.S. Department of

Commerce, Bureau of Industry and Security, Regulatory Policy Division, 14th St. & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230, *Attn:* RIN 0694–AE78. Send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by e-mail to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th St. & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230. Comments on this collection of information should be submitted separately from comments on the final rule (i.e. RIN 0694–AE78)—all comments on the latter should be submitted by one of the three methods outlined above.

FOR FURTHER INFORMATION CONTACT: Elizabeth Scott Sangine, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, *Phone:* (202) 482–3343, *Fax:* (202) 482–3911, *E-mail: bscott@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Entity List provides notice to the public that certain exports, reexports, and transfers (in-country) to parties identified on the Entity List require a license from the Bureau of Industry and Security (BIS) and that availability of license exceptions in such transactions is limited. Persons are placed on the Entity List on the basis of certain sections of part 744 (Control Policy: End-User and End-Use Based) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from or changes to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and all decisions to remove or modify an entry by unanimous vote.

ERC Entity List Decisions

The ERC made a determination to add fifteen persons under sixteen entries to the Entity List on the basis of § 744.11 (License Requirements that Apply to Entities Acting Contrary to the National Security or Foreign Policy Interests of the United States) of the EAR. The sixteenth entry is to account for one person who has addresses in both China and Hong Kong. The sixteen entries added to the Entity List consist of one person in Armenia, two persons in China, seven persons in Hong Kong, four persons in Malaysia and two persons in Singapore.

The ERC reviewed § 744.11(b) (Criteria for revising the Entity List) in making the determination to add these persons to the Entity List. Under that paragraph, entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entity has been involved, is involved, or poses a significant risk of being or becoming involved in activities that are contrary to the national security or foreign policy interests of the United States and those acting on behalf of such entities may be added to the Entity List pursuant to § 744.11.

Paragraph (b) of § 744.11 includes an illustrative list of activities that could be contrary to the national security or foreign policy interests of the United States. This illustrative list of activities of concern is described under paragraphs (b)(1)–(b)(5). The persons being added to the Entity List under this rule have been determined by the ERC to be involved in activities that could be contrary to the national security or foreign policy interests of the United States.

Additions to the Entity List

This rule implements the decision of the ERC to add fifteen persons under sixteen entries to the Entity List on the basis of § 744.11 of the EAR. For all of the fifteen persons added to the Entity List, the ERC specifies a license requirement for all items subject to the EAR and establishes a license application review policy of a presumption of denial. The license requirement applies to any transaction in which items are to be exported, reexported or transferred (in-country) to such persons or in which such persons act as purchaser, intermediate consignee, ultimate consignee, or end-user. In addition, no license exceptions are available for shipments to those persons being added to the Entity List.

Specifically, this rule adds the following fifteen persons under sixteen entries to the Entity List:

Armenia

(1) *Bold Bridge International, LLC,* Room 463, H. Hakobyan 3, Yerevan, Armenia.

China

(1) *Chitron Electronics Company Ltd, a.k.a., Chi-Chuang Electronics Company Ltd (Chitron-Shenzhen),* 2127 Sungang Rd, Huatong Bldg, 19/F, Louhu Dist, Shenzhen, China 518001; and 169 Fucheng Rd, Fenggu Bldg., 7/F, Mianyang, China 621000; and Zhi Chun Rd, No 2 Bldg of Hoajing jiayuan, Suite #804, Haidian Dist, Beijing, China 100086; and 40 North Chang'an Rd, Xi'an Electronics Plaza Suite #516, Xi'an, China 710061; and 9 Huapu Rd, Chengbei Electronics & Apparatus Mall, 1/F Suite #39, Chengdu, China 610081; and 2 North Linping Rd Bldg 1. Suite #1706, Hongkou Dist, Shanghai, China 200086 (See alternate address under Hong Kong); and

(2) *Wong Yung Fai, a.k.a., Tonny Wong,* Unit 12B, Block 11, East Pacific Garden, Xiang Lin Road, Futian District, Shenzhen, China.

Hong Kong

(1) *Centre Bright Electronics Company Limited,* Unit 7A, Nathan Commercial Building 430–436 Nathan Road, Kowloon, Hong Kong; and Room D, Block 1, 6/F International Industrial Centre, 2–8 Kwei Tei Street, Shatin New Territories, Hong Kong;

(2) *Chitron Electronics Company Ltd, a.k.a., Chi-Chuang Electronics Company Ltd (Chitron-Shenzhen),* 6 Shing Yip St. Prosperity Plaza 26/F, Suite #06, Kwun Tong, Kowloon, Hong Kong (*See* alternate address under China);

(3) *Exodus Microelectronics Company Limited,* Unit 9B, Nathan Commercial Building, 430–436 Nathan Road, Kowloon, Hong Kong; *and* Unit 6B, Block 1, International Centre 2–8 Kwei Tei Street, Shatin, New Territories, Hong Kong; *and* Unit 6B, Block 1, International Industrial Centre, 2–8 Kwei Tei Street, Shatin, Hong Kong;

(4) *Hong Chun Tai,* Unit 27B, Block 8, Monte Vista, 9 Sha On Street, Ma On Shan New Territories, Hong Kong; *and* Unit 7A, Nathan Commercial Building, 430–436 Nathan Road Kowloon, Hong Kong; *and* Room D, Block 1, 6/F International Industrial Centre, 2–8 Kwei Tei Street, Shatin, New Territories, Hong Kong; *and* Unit 9B, Nathan Commercial Building, 430–436 Nathan Road Kowloon, Hong Kong;

(5) *Victory Wave Holdings Limited,* Unit 2401 A, Park-In Commercial Centre, 56 Dundas Street, Hong Kong; *and* Unit 2401A, 24/F Park-In Commercial Centre, 56 Dundas Street, Mongkok, Kowloon, Hong Kong;

(6) *Wong Wai Chung, a.k.a., David Wong,* Unit 27B, Block 8, Monte Vista, 9 Sha On Street, Ma On Shan, New Territories, Hong Kong; *and* Unit 7A, Nathan Commercial Building 430–436 Nathan Road, Kowloon, Hong Kong; *and* Room D, Block 1, 6/F International Industrial Centre, 2–8 Kwei Tei Street,

Shatin, New Territories, Hong Kong; and

(7) *Wong Yung Fai, a.k.a., Tonny Wong,* Unit 27B, Block 8, Monte Vista, 9 Sha On Street, Ma On Shan, New Territories, Hong Kong; and Unit 1006, 10/F Carnarvon Plaza, 20 Carnarvon Road, TST, Kowloon, Hong Kong; and Unit 7A, Nathan Commercial Building, 430–436 Nathan Road, Kowloon, Hong Kong; and Room D, Block 1, 6/F International Industrial Centre, 2–8 Kwei Tei Street, Shatin, New Territories, Hong Kong; and Unit 9B, Nathan Commercial Building 430–436 Nathan Road, Kowloon, Hong Kong; and Unit 2401A, 24/F Park-In Commercial Centre 56 Dundas Street, Mongkok, Kowloon, Hong Kong.

Malaysia

(1) *Alex Ramzi,* Suite 33–01, Menara Keck Seng, 203 Jalan Bukit Bintang, Kuala Lumpur, Malaysia 55100;

(2) *Amir Ghasemi,* Suite 33–01, Menara Keck Seng, 203 Jalan Bukit Bintang, Kuala Lumpur, Malaysia 55100;

(3) *Evertop Services Sdn Bhd,* Suite 33–01, Menara Keck Seng, 203 Jalan Bukit Bintang, Kuala Lumpur, Malaysia 55100; and

(4) *Majid Kakavand,* Suite 33–01, Menara Keck Seng, 203 Jalan Bukit Bintang, Kuala Lumpur, Malaysia 55100.

Singapore

(1) *Microsun Electronics Pte., Ltd,* Sim Lim Tower, 10 Jalan Besar, Singapore 208787; and

(2) *Opto Electronics Pte. Ltd,* Suite 11–08, Sim Lim Tower, 10 Jalan Besar, Singapore 208787.

A BIS license is required for the export, reexport or transfer (in-country) of any item subject to the EAR to any of the persons listed above, including any transaction in which any of the listed persons will act as purchaser, intermediate consignee, ultimate consignee, or end-user of the items. This listing of these persons also prohibits the use of License Exceptions (*see* part 740 of the EAR) for exports, reexports and transfers (in-country) of items subject to the EAR involving such persons.

Amendment to the Entity List

This rule also amends one Iranian entry currently on the Entity List by adding an additional address for the person listed, as follows:

Iran

(1) *Arash Dadgar,* No. 10, 64th St., Yousafabad, Tehran, Iran, 14638, and Unit 11, No. 35 South Iranshahr St, Tehran, Iran.

Savings Clause

Shipments of items removed from eligibility for a License Exception or export or reexport without a license (NLR) as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting or reexporting carrier, or en route aboard a carrier to a port of export or reexport, on January 13, 2010, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export or reexport without a license (NLR) so long as they are exported or reexported before February 12, 2010. Any such items not actually exported or reexported before midnight, on February 12, 2010, require a license in accordance with this rule.

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as extended by the Notice of August 13, 2009, 74 FR 41325 (August 14, 2009), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act.

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by the OMB under control numbers 0694–0088, "Multi-Purpose Application," which carries a burden hour estimate of 58 minutes to prepare and submit form BIS–748. Miscellaneous and recordkeeping activities account for 12 minutes per submission. Total burden hours associated with the Paperwork Reduction Act and Office and Management and Budget control number 0694–0088 are expected to increase slightly as a result of this rule.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States. (*See* 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et. seq.,* are not applicable.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

■ Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of August 13, 2009, 74 FR 41325 (August 14, 2009); Notice of November 6, 2009, 74 FR 58187 (November 10, 2009).

■ 2. Supplement No. 4 to part 744 is amended:

(a) By adding, in alphabetical order, the country of Armenia and one Armenian entity;

(b) By adding under China, People's Republic of, in alphabetical order, two Chinese entities;

(c) By adding under Hong Kong, in alphabetical order, seven Hong Kong entities;

(d) By adding under Malaysia, in alphabetical order, four Malaysian entities;

(e) By adding under Singapore, in alphabetical order, two Singaporean entities; and

(f) By revising under Iran, in alphabetical order, one Iranian entity "Arash Dadgar, No. 10, 64th St., Yousafabad, Tehran, Iran, 14638".

The additions and revision read as follows:

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST

Country	Entity	License requirement	License review policy	**Federal Register** citation
*	*	*	*	*
Armenia	Bold Bridge International, LLC, Room 463, H. Hakobyan 3, Yerevan, Armenia.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	*	*	*	*
China, People's Republic of.	Chitron Electronics Company Ltd, a.k.a., Chi-Chuang Electronics Company Ltd. (Chitron Shenzhen), 2127 Sungang Rd, Huatong Bldg, 19/F Louhu Dist, Shenzhen, China 518001; and 169 Fucheng Rd, Fenggu Bldg, 7/F, Mianyang, China 621000; and Zhi Chun Rd, No 2 Bldg of Hoajing jiayuan, Suite #804, Haidian Dist, Beijing, China 100086; and 40 North Chang'an Rd, Xi'an Electronics Plaza Suite #516, Xi'an, China 710061; and 9 Huapu Rd, Chengbei Electronics & Apparatus Mall, 1/F Suite #39, Chengdu, China 610081; and 2 North Linping Rd, Bldg 1, Suite #1706, Hongkou Dist, Shanghai, China 200086 (See alternate address under Hong Kong).	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	*	*	*	*
	Wong Yung Fai, a.k.a., Tonny Wong, Unit 12B, Block 11, East Pacific Garden, Xiang Lin Road, Futian District, Shenzhen, China.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	*	*	*	*
Hong Kong	Centre Bright Electronics Company Limited, Unit 7A, Nathan Commercial Building 430–436 Nathan Road, Kowloon, Hong Kong; and Room D, Block 1, 6/F International Industrial Centre, 2–8 Kwei Tei Street, Shatin New Territories, Hong Kong.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
	Chitron Electronics Company Ltd, a.k.a., Chi-Chuang Electronics Company Ltd (Chitron-Shenzhen), 6 Shing Yip St. Prosperity Plaza 26/F, Suite #06, Kwun Tong, Kowloon, Hong Kong (See alternate address under China).	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	*	*	*	*
	Exodus Microelectronics Company Limited, Unit 9B, Nathan Commercial Building 430–436 Nathan Road, Kowloon, Hong Kong; and Exodus Microelectronics Company Limited, Unit 6B, Block 1, International Centre 2–8 Kwei Tei Street, Shatin, New Territories, Hong Kong; and Exodus Microelectronics Company Limited, Unit 6B, Block 1, International Industrial Centre, 2–8 Kwei Tei Street, Shatin, Hong Kong.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	Federal Register citation
*	* *	* *	*	*
	Hong Chun Tai, Unit 27B, Block 8, Monte Vista, 9 Sha On Street, Ma On Shan New Territories, Hong Kong; and Unit 7A, Nathan Commercial Building, 430–436 Nathan Road Kowloon, Hong Kong; and Room D, Block 1, 6/F International Industrial Centre, 2–8 Kwei Tei Street, Shatin, New Territories, Hong Kong; and Unit 9B, Nathan Commercial Building, 430–436 Nathan Road Kowloon, Hong Kong.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	* *	* *	*	*
	Victory Wave Holdings Limited, Unit 2401 A, Park-In Commercial Centre, 56 Dundas Street, Hong Kong; and Unit 2401A, 24/F Park-In Commercial Centre, 56 Dundas Street, Mongkok, Kowloon, Hong Kong.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	* *	* *	*	*
	Wong Wai Chung, a.k.a., David Wong, Unit 27B, Block 8, Monte Vista, 9 Sha On Street, Ma On Shan, New Territories, Hong Kong; and Unit 7A, Nathan Commercial Building 430–436 Nathan Road, Kowloon, Hong Kong; and Room D, Block 1, 6/F International Industrial Centre, 2–8 Kwei Tei Street, Shatin, New Territories, Hong Kong.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
	Wong Yung Fai, a.k.a., Tonny Wong, Unit 27B, Block 8, Monte Vista, 9 Sha On Street, Ma On Shan, New Territories, Hong Kong; and Unit 1006, 10/F Carnarvon Plaza, 20 Carnarvon Road, TST, Kowloon, Hong Kong; and Unit 7A, Nathan Commercial Building, 430–436 Nathan Road, Kowloon, Hong Kong; and Room D, Block 1, 6/F International Industrial Centre, 2–8 Kwei Tei Street, Shatin, New Territories, Hong Kong; and Unit 9B, Nathan Commercial Building 430–436 Nathan Road, Kowloon, Hong Kong; and Unit 2401A, 24/F Park-In Commercial Centre, 56 Dundas Street, Mongkok, Kowloon, Hong Kong.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	* *	* *	*	*
Iran	Arash Dadgar, No. 10, 64th St., Yousafabad, Tehran, Iran, 14638, and Unit 11, No. 35 South Iranshahr St., Tehran, Iran.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	73 FR 54506, 9/22/08 75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	* *	* *	*	*
Malaysia	Alex Ramzi, Suite 33–01, Menara Keck Seng, 203 Jalan Bukit Bintang, Kuala Lumpur, Malaysia 55100.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
	Amir Ghasemi, Suite 33–01, Menara Keck Seng, 203 Jalan Bukit Bintang, Kuala Lumpur, Malaysia 55100.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	* *	* *	*	*
	Evertop Services Sdn Bhd, Suite 33–01, Menara Keck Seng, 203 Jalan Bukit Bintang, Kuala Lumpur, Malaysia 55100.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	Federal Register citation
*	* *	* *	*	*
	Majid Kakavand, Suite 33–01, Menara Keck Seng, 203 Jalan Bukit Bintang, Kuala Lumpur, Malaysia 55100.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	* *	* *	*	*
Singapore	Microsun Electronics Pte. Ltd, Sim Lim Tower, 10 Jalan Besar, Singapore 208787.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	* *	* *	*	*
	Opto Electronics Pte. Ltd, Suite 11–08, Sim Lim Tower, 10 Jalan Besar, Singapore 208787.	For all items subject to the EAR. (*See* § 744.11 of the EAR).	Presumption of denial.	75 FR [INSERT FR PAGE NUMBER] January 13, 2010.
*	* *	* *	*	*

Dated: January 7, 2010.

Matthew S. Borman,

Deputy Assistant Secretary, for Export Administration.

[FR Doc. 2010–455 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–35–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9458]

RIN 1545–BI72

Modification to Consolidated Return Regulation Permitting an Election To Treat a Liquidation of a Target, Followed by a Recontribution to a New Target, as a Cross-Chain Reorganization

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to temporary regulations (TD 9458), which were published in the **Federal Register** on Friday, September 4, 2009, relating to modification to consolidated return regulation permitting an election to treat a liquidation of a target, followed by a recontribution to a new reorganization.

DATES: The correction is effective January 13, 2010, and is applicable beginning September 4, 2009.

FOR FURTHER INFORMATION CONTACT: Guy Traynor at (202) 622–3693 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulation that is the subject to this correction is under section 1502 of the Internal Revenue Code.

Need for Correction

As published September 4, 2009 (74 FR 45757), temporary regulations (TD 9458), contains an error which may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment.

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority for part 1 continues to read in part as follows:

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

■ **Par. 2.** Paragraph (f)(5)(ii)(G) is added following paragraph (f)(5)(ii)(F)(3), to read as follows:

§ 1.1502–13T Intercompany transactions (temporary).

* * * * *

(f) * * *

(5) * * *

(ii) * * *

(G) *Expiration date.* Paragraphs (f)(5)(ii)(B), (B)(1), (B)(2) and (F)(1), (2), and (3) of this section will expire on September 3, 2012.

* * * * *

Guy R. Traynor,

Federal Register Liaison, Publications & Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure & Administration).

[FR Doc. 2010–416 Filed 1–12–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 27

[Docket No. USCG–2009–0891]

RIN 1625–AB40

Federal Civil Penalties Inflation Adjustment Act—2009 Implementation

AGENCY: Coast Guard, DHS.

ACTION: Final rule; correction.

SUMMARY: The Coast Guard is correcting a final rule that appeared in the **Federal Register** of December 23, 2009 (74 FR 68150). The document concerned the adjustment of fines and other civil monetary penalties.

DATES: Effective January 13, 2010.

FOR FURTHER INFORMATION CONTACT: Ms. Heather Young, CG–5232, Coast Guard; telephone 202–372–1022.

SUPPLEMENTARY INFORMATION: In FR Doc. E9–30493 appearing on page 68150 in the second column under **DATES,** correct "This final rule is effective 30 days after December 23, 2009" to read "This final rule is effective January 22, 2010".

Dated: January 6, 2010.

Mark W. Skolnicki,

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

[FR Doc. 2010–432 Filed 1–12–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–1093]

Drawbridge Operation Regulation; Intracoastal Waterway (ICW), Inside Thorofare, Ventnor City, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulations governing the operation of the Dorset Avenue Bridge, at ICW mile 71.2, across Inside Thorofare, at Ventnor City. This bridge is a double-leaf bascule drawbridge. The deviation restricts the operation of the draw span to facilitate structural rehabilitation to one of the bascule leafs.

DATES: This deviation is effective from 7 a.m. on January 20, 2010 until 11 p.m. on April 17, 2010.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2009–1093 and are available online by going to *http://www.regulations.gov*, inserting USCG–2009–1093 in the "Keyword" box and then clicking "Search". They are also available for inspection or 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mrs. Sandra Elliott, Bridge Management Specialist, Fifth District; Coast Guard; telephone 757–398–6557, e-mail *Sandra.S.Elliott@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Dorset Avenue Bridge has a vertical clearance in the closed position of 9 feet at mean high water and 12 feet at mean low water.

A.P. Construction, Inc., on behalf of Atlantic County who owns and operates this double-leaf bascule drawbridge, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.733(g), to facilitate deck repairs.

Under this temporary deviation, the drawbridge will provide a partial opening of the lift spans for vessels. The deck repairs require immobilizing half of the draw span to single-leaf operation beginning at 7 a.m. on Wednesday, January 20, 2010, until and including 11 p.m. on Saturday, April 17, 2010.

Consequently, passage under the bridge will be limited to a 25-foot width for the duration of the project.

The single-bascule leaf not under repair will continue to open for vessels. Prior to an opening of this single-bascule leaf, a work barge occupying the channel underneath this span will also be moved. Finally, the drawbridge will open in the event of an emergency.

Bridge opening data, supplied by Atlantic County and reviewed by the U.S. Coast Guard, revealed a small amount of vessel openings of the draw span from January 2009 to April 2009. Specifically, the bridge opened for vessels 4, 11, 11, and 19 times during the months of January to April 2009, respectively. Vessels that can pass under the bridge without a full bridge opening may continue to do so at all times. Mariners requiring the full opening of the lift spans will be directed to use the Atlantic Ocean as the alternate route.

The Coast Guard will inform the users of the waterway through our Local and Broadcast Notices to Mariners of the closure periods for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: December 18, 2009.

Waverly W. Gregory, Jr.,

Chief, Bridge Administration Branch, By direction of the Commander, Fifth Coast Guard District.

[FR Doc. 2010–434 Filed 1–12–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2009–1107]

RIN 1625–AA09

Drawbridge Operation Regulations; Curtis Creek, Baltimore, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulations governing the operation of the I695 Bridge across Curtis Creek, mile 0.9, at Baltimore, MD. The deviation is necessary to facilitate mechanical repairs to the bridge. This temporary deviation allows the drawbridge to remain in the closed position during the deviation period.

DATES: This deviation is effective from 8 a.m. on January 9, 2010, to 8 p.m. on March 28, 2010.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2009–1107 and are available online by going to *http://www.regulations.gov,* inserting USCG–2009–1107 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Bill H. Brazier, Bridge Management Specialist, Fifth Coast Guard District; telephone 757–398–6422, e-mail *Bill.H.Brazier@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Maryland Transportation Authority, who owns and operates this double-leaf bascule drawbridge, has requested a temporary deviation from the current operating regulations set forth in 33 CFR 117.557 to facilitate mechanical repairs.

The I695 Bridge, a double-leaf bascule drawbridge, has a vertical clearance in the closed position to vessels of 58 feet, above mean high water. The draw of the bridge shall open on signal if at least a

one-hour notice is given to the Maryland Transportation Authority in Baltimore, as required by 33 CFR 117.557.

Under this temporary deviation, the drawbridge will be maintained in the closed position to vessels to facilitate repairs to trunnion bearings on two separate closure periods. The first period will begin at 8 a.m. on January 9, 2010, until and including 8 p.m. on February 6, 2010; and the second period will start again at 8 a.m. on March 1, 2010, until and including 8 p.m. on March 28, 2010. Vessels may pass underneath the bridge while the bridge is in the closed position. There are no alternate routes for vessels transiting this section of Curtis Creek and the bridge will not be able to open in the event of an emergency.

Coast Guard vessels bound for the Coast Guard Yard at Curtis Bay, as well as a significant amount of commercial vessel traffic, must pass beneath the I695 Bridge. The Coast Guard has carefully coordinated the restrictions with the Yard and the commercial users of the waterway. Additionally, the Coast Guard will inform unexpected users of the waterway through our Local and Broadcast Notices to Mariners of the closure periods for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: December 24, 2009.

Waverly W. Gregory, Jr.,

Chief, Bridge Administration Branch, Fifth Coast Guard District.

[FR Doc. 2010–437 Filed 1–12–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket Number USCG–2009–1097]

Drawbridge Operation Regulations; Upper Mississippi River, Dubuque, IA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation governing the operations of the Dubuque Railroad Drawbridge, across the Upper Mississippi River, Mile 579.9, Dubuque, Iowa. The deviation is necessary to allow time for performing needed maintenance and repairs to the bridge. This deviation allows the bridge to open on signal if at least 24 hours advance notice is given from 12:01 a.m. January 15, 2010 until 9 a.m., March 15, 2010.

DATES: This deviation is effective from 12:01 a.m. January 15, 2010 until 9 a.m., March 15, 2010.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2009–1097 and are available online by going to *http://www.regulations.gov,* inserting USCG–2009–1097 in the "Keyword" and then clicking "Search". They are also available for inspection or 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Roger K. Wiebusch, Bridge Administrator, Coast Guard; telephone (314) 269–2378, e-mail *Roger.K.Wiebusch@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Canadian National Railway Company requested a temporary deviation for the Dubuque Railroad Drawbridge, across the Upper Mississippi, mile 579.9, at Dubuque, Iowa to open on signal if at least 24 hours advance notice is given in order to facilitate needed bridge maintenance and repairs. The Dubuque Railroad Drawbridge currently operates in accordance with 33 CFR 117.5, which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart. In order to facilitate the needed bridge work, the drawbridge must be kept in the closed-to-navigation position. This deviation allows the bridge to open on signal if at least 24 hours advance notice is given from 12:01 a.m. January 15, 2010 until 9 a.m., March 15, 2010.

There are no alternate routes for vessels transiting this section of the Upper Mississippi River.

The Dubuque Railroad Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 19.9 feet above normal pool. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. These interests will not be significantly impacted due to the reduced navigation in winter months. This temporary deviation has been coordinated with waterway users. No objections were received.

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

Dated: 22 December 2009.

Roger K. Wiebusch,

Bridge Administrator.

[FR Doc. 2010–436 Filed 1–12–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–1058]

RIN 1625–AA11

Regulated Navigation Area; U.S. Navy Submarines, Hood Canal, WA

AGENCY: Coast Guard, DHS.

ACTION: Interim rule with request for comments.

SUMMARY: The Coast Guard is establishing a regulated navigation area (RNA) covering the Hood Canal in Washington that will be in effect whenever any U.S. Navy submarine is operating in the Hood Canal and being escorted by the Coast Guard. The RNA is necessary to help ensure the safety and security of the submarines, their Coast Guard security escorts, and the maritime public in general. The RNA will do so by requiring all persons and vessels located within the RNA to follow all lawful orders and/or directions given to them by Coast Guard security escort personnel.

DATES: This rule is effective January 13, 2010. Comments and related material must reach the Coast Guard on or before April 13, 2010. Requests for public meetings must be received by the Coast Guard on or before February 12, 2010.

ADDRESSES: You may submit comments identified by docket number USCG–2009–1058 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of

Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *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.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this interim rule, call or e-mail LT Matthew N. Jones, Staff Attorney, Thirteenth Coast Guard District; telephone 206–220–7155, e-mail *Matthew.N.Jones@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.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2009–1058), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via *http://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 Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rule" and insert "USCG–2009–1058" in the "Keyword" box. Click "Search" then click on the balloon shape in the "Actions" column. If you submit 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 may change this rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble 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–2009–1058" and click "Search." Click the "Open Docket Folder" in the "Actions" column. 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of 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 a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before February 12, 2010 using one of the four methods specified under **ADDRESSES.** Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register.**

Regulatory Information

The Coast Guard is issuing this interim 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 the narrow confines of the Hood Canal make it particularly difficult for the Coast Guard to escort U.S. Navy submarines through the canal without risk to the submarines, their Coast Guard escorts, or the general maritime public, immediate action is required to protect safety within the canal, and any delay would be contrary to the public interest.

For the same reason, 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.**

Background and Purpose

U.S. Navy submarines frequently operate in the Hood Canal. Due to the numerous safety and security concerns involved with submarine operations near shore in very restricted waters, the Coast Guard provides security escorts of submarines when operating in that area. Security escorts of this type require the Coast Guard personnel on-scene to make quick judgments about the intent of vessels operating in close proximity to the submarines and decide, occasionally with little information about the vessels or persons on board, whether or not they pose a threat to the submarine. The narrow confines of the Hood Canal make this a particularly difficult task as it forces the submarines and their Coast Guard security escorts to frequently come into close quarters contact with the maritime public.

The RNA established by this rule will allow Coast Guard security escort personnel to order and/or direct persons and vessels operating within the RNA to stop, move, change orientation, *etc.* The ability to do so will help avoid unnecessary and potentially dangerous close quarters contact between Coast Guard security escorts and the maritime public within the Hood Canal. In addition, it will give Coast Guard security escorts an additional tool for determining the intent of vessels that,

for whatever reason, are operating too close to an escorted submarine. Both of these effects will help ensure the safety and security of the submarines, their Coast Guard security escorts, and the maritime public in general.

Discussion of Rule

This rule establishes an RNA covering the Hood Canal in Washington that will be in effect whenever any U.S. Navy submarine is operating in the Hood Canal and being escorted by the Coast Guard. All persons and vessels located within the RNA are required to follow all lawful orders and/or directions given to them by Coast Guard security escort personnel.

Regulatory Analyses

We developed this interim 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.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

The Coast Guard has made this determination based on the fact that (1) the RNA is only in effect for the short periods of time when submarines are operating in Hood Canal and being escorted by the Coast Guard and (2) vessels may freely operate within the RNA to the extent permitted by other law or regulation unless given a lawful order and/or direction by Coast Guard security escort personnel.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit the RNA when it is in effect. The RNA will not, however, have a significant economic impact on a substantial number of small entities because (1) the RNA is only in effect for the short periods of time when submarines are operating in Hood Canal and being escorted by the Coast Guard and (2) vessels may freely operate within the RNA to the extent permitted by other law or regulation unless given a lawful order and/or direction by Coast Guard security escort personnel.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see* **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

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 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.

Taking of Private Property

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

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.

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.

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.

Energy Effects

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

require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

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 concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves the establishment of a regulated navigation area. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, 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 AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 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 § 165.1328 to read as follows:

§ 165.1328 Regulated Navigation Area; U.S. Navy Submarines, Hood Canal, Washington.

(a) *Location.* The following area is a regulated navigation area (RNA): All waters of the Hood Canal in Washington whenever any U.S. Navy submarine is operating in the Hood Canal and being escorted by the Coast Guard.

(b) *Regulations.* All persons and vessels located within the RNA created by paragraph (a) shall follow all lawful orders and/or directions given to them by Coast Guard security escort personnel. 33 CFR Section 165, Subpart B, contains additional provisions applicable to the RNA created in paragraph (a).

(c) *Notification.* The Coast Guard security escort will attempt, when necessary and practicable, to notify any persons or vessels in the RNA created in paragraph (a) of its existence via VHF Channel 16 and/or any other means reasonably available.

Dated: December 16, 2009.

G.T. Blore,

Rear Admiral, U.S. Coast Guard, Commander, Thirteenth Coast Guard District.

[FR Doc. 2010–433 Filed 1–12–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–1057]

RIN 1625–AA87

Security Zone; Escorted U.S. Navy Submarines in Sector Seattle Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Interim rule with request for comments.

SUMMARY: The Coast Guard is establishing a moving security zone around any U.S. Navy submarine that is operating in the Sector Seattle Captain of the Port Zone, which includes the Puget Sound and coastal waters of the State of Washington, and is being escorted by the Coast Guard. The security zone is necessary to help ensure the security of the submarines, their Coast Guard security escorts, and the maritime public in general. The security zone will do so by prohibiting all persons and vessels from coming within 1,000 yards of an escorted submarine unless authorized by the Coast Guard patrol commander.

DATES: This rule is effective January 13, 2010. Comments and related material must reach the Coast Guard on or before April 13, 2010. Requests for public meetings must be received by the Coast Guard on or before February 12, 2010.

ADDRESSES: You may submit comments identified by docket number USCG–2009–1057 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *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.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this interim rule, call or e-mail LT Matthew N. Jones, Staff Attorney, Thirteenth Coast Guard District; telephone 206–220–7155, e-mail *Matthew.N.Jones@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.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2009–1057), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via *http://*

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 Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rule" and insert "USCG–2009–1057" in the "Keyword" box. Click "Search," then click on the balloon shape in the "Actions" column. If you submit 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 may change this rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble 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–2009–1057" and click "Search." Click the "Open Docket Folder" in the "Actions" column. 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of 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 a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before February 12, 2010 using one of the four methods specified under **ADDRESSES.** Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register.**

Regulatory Information

The Coast Guard is issuing this interim 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 publishing an NPRM would be contrary to the public interest since U.S. Navy submarine operations in the Sector Seattle Captain of the Port Zone are ongoing, making the security zone created by this rule immediately necessary to help ensure the security of the submarines, their Coast Guard security escorts, and the maritime public in general.

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** because waiting 30 days would be contrary to the public interest since U.S. Navy submarine operations in the Sector Seattle Captain of the Port Zone are ongoing, making the security zone created by this rule immediately necessary to help ensure the security of the submarines, their Coast Guard security escorts, and the maritime public in general.

Background and Purpose

U.S. Navy submarines frequently operate in the Sector Seattle Captain of the Port Zone as defined in 33 CFR 3.65–10, which includes the Puget Sound and coastal waters of the State of Washington. Due to the numerous security concerns involved with submarine operations near shore, the Coast Guard frequently provides security escorts of submarines when operating in those areas. Security escorts of this type require the Coast Guard personnel on-scene to make quick judgments about the intent of vessels operating in close proximity to the submarines and decide, occasionally with little information about the vessels or persons on board, whether or not they pose a threat to the submarine.

The security zone established by this rule will keep persons and vessels a sufficient distance away from submarines operating in and around the Puget Sound and coastal waters of Washington so as to (1) avoid unnecessary and potentially dangerous contact with or distraction of Coast Guard security escorts and (2) give Coast Guard security escorts additional time and space to determine the intent of vessels that, for whatever reason, are operating too close to a submarine. Both of these effects will help ensure the security of the submarines, their Coast Guard security escorts, and the maritime public in general.

Discussion of Rule

This rule establishes a moving security zone encompassing all waters within 1,000 yards of any U.S. Navy submarine that is operating in the Sector Seattle Captain of the Port Zone as defined in 33 CFR 3.65–10, which includes the Puget Sound and coastal waters of the State of Washington, and is being escorted by the Coast Guard. All persons and vessels are prohibited from entering the security zone unless authorized by the Coast Guard patrol commander. While naval vessel protection zones, under 33 CFR 165.2030, around these escorted U.S. Navy submarines are still in effect, persons would need to seek permission from the Coast Guard patrol commander to enter within 1,000 yards of these escorted submarines while they are in the Sector Seattle Captain of the Port Zone.

Regulatory Analyses

We developed this interim 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.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

The Coast Guard has made this determination based on the fact that (1) the security zone is only in effect for the

short periods of time when submarines are operating in and around the Puget Sound and other coastal waters of Washington and being escorted by the Coast Guard, (2) the security zone moves with the submarines, (3) vessels will be able to transit around the security zone at most locations in the Puget Sound and other coastal waters of Washington, and (4) vessels may, if necessary, be authorized to enter the security zone with the permission of the Coast Guard patrol commander.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit an area covered by the security zone. The security zone will not, however, have a significant economic impact on a substantial number of small entities because (1) the security zone is only in effect for the short periods of time when submarines are operating in and around the Puget Sound and other coastal waters of Washington and being escorted by the Coast Guard, (2) the security zone moves with the submarines, (3) vessels will be able to transit around the security zone at most locations in the Puget Sound and other coastal waters of Washington, and (4) vessels may, if necessary, be authorized to enter the security zone with the permission of the Coast Guard patrol commander.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

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 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.

Taking of Private Property

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

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.

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.

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.

Energy Effects

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

Technical Standards

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

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

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 concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves the establishment of a security zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, 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 AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 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 § 165.1327 to read as follows:

§ 165.1327 Security Zone; Escorted U.S. Navy Submarines in Sector Seattle Captain of the Port Zone.

(a) *Location.* The following area is a security zone: All waters within 1,000 yards of any U.S. Navy submarine that is operating in the Sector Seattle Captain of the Port Zone, as defined in 33 CFR 3.65–10, and that is being escorted by the Coast Guard.

(b) *Regulations.* In accordance with the general regulations in 33 CFR part 165, subpart D, no person or vessel may enter or remain in the security zone created by paragraph (a) of this section unless authorized by the Coast Guard patrol commander. 33 CFR part 165, subpart D, contains additional provisions applicable to the security zone created in paragraph (a) of this section.

(c) *Notification.* The Coast Guard security escort will attempt, when necessary and practicable, to notify any persons or vessels inside or in the vicinity of the security zone created in paragraph (a) of this section of its existence via VHF Channel 16 and/or any other means reasonably available.

Dated: December 16, 2009.

G.T. Blore,

Rear Admiral, U.S. Coast Guard, Commander, Thirteenth Coast Guard District.

[FR Doc. 2010–438 Filed 1–12–10; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MS–200923; FRL–9088–6]

Approval and Promulgation of Air Quality Implementation Plans; Mississippi; Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; administrative change.

SUMMARY: EPA is publishing this action to provide the public with notice of the update to the Mississippi State Implementation Plan (SIP) compilation. In particular, materials submitted by Mississippi that are incorporated by reference (IBR) into the Mississippi SIP are being updated to reflect EPA-approved revisions to Mississippi's SIP that have occurred since the last update. In this action, EPA is also notifying the public of the correction of certain typographical errors.

DATES: This action is effective January 13, 2010.

ADDRESSES: SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection at the following locations: Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, GA 30303; the Air and Radiation Docket and Information Center, EPA Headquarters Library, Infoterra Room (Room Number 3334), EPA West Building, 1301 Constitution Ave., NW., Washington, DC 20460, and the National Archives and Records Administration. If you wish to obtain materials from a docket in the EPA Headquarters Library, please call the Office of Air and Radiation (OAR) Docket/Telephone number: (202) 566–1742. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Ms. Twunjala Bradley at the above Region 4 address or at (404) 562–9352.

SUPPLEMENTARY INFORMATION: Each state has a SIP containing the control measures and strategies used to attain and maintain the national ambient air quality standards (NAAQS). The SIP is extensive, containing such elements as air pollution control regulations, emission inventories, monitoring networks, attainment demonstrations, and enforcement mechanisms.

Each state must formally adopt the control measures and strategies in the SIP after the public has had an opportunity to comment on them and then submit the SIP to EPA. Once these control measures and strategies are approved by EPA, after notice and comment, they are incorporated into the federally approved SIP and are identified in part 52 "Approval and Promulgation of Implementation Plans," Title 40 of the Code of Federal Regulations (40 CFR part 52). The full text of the state regulation approved by EPA is not reproduced in its entirety in 40 CFR part 52, but is "incorporated by reference." This means that EPA has approved a given state regulation with a specific effective date. The public is referred to the location of the full text version should they want to know which measures are contained in a given SIP. The information provided allows EPA and the public to monitor the extent to which a state implements a SIP to attain and maintain the NAAQS and to take enforcement action if necessary.

The SIP is a living document which the state can revise as necessary to address the unique air pollution problems in the state. Therefore, EPA from time to time must take action on SIP revisions containing new and/or revised regulations as being part of the SIP. On May 22, 1997, (62 FR 27968), EPA revised the procedures for incorporating by reference, into the CFR, materials submitted by states in their EPA-approved SIP revisions. These changes revised the format for the identification of the SIP in 40 CFR part 52, stream-lined the mechanisms for announcing EPA approval of revisions to a SIP, and stream-lined the mechanisms for EPA's updating of the IBR information contained for each SIP in 40 CFR part 52. The revised procedures also called for EPA to maintain "SIP Compilations" that contain the federally-approved regulations and source specific permits submitted by each state agency. These SIP Compilations are contained in 3-ring binders and are updated primarily on an annual basis. Under the revised procedures, EPA is to periodically publish an informational document in the rules section of the **Federal Register** when updates are made to a SIP Compilation for a particular state. EPA's 1997 revised procedures were formally applied to Mississippi on July 1, 1997 (62 FR 35441).

This action represents EPA's publication of the Mississippi SIP Compilation update, appearing in 40 CFR part 52. In addition, notice is provided of the following typographical corrections to Table (c) of paragraph 52.1270, as described below:

1. Correcting typographical errors listed in Table 1 of paragraph 52.127(c), as described below:

A. State Citation APC–S–1 Section 6 State Effective Date is revised to read "5/28/99."
B. State Citation APC–S–2 Sections I thru XVII EPA Approval Date and Citation is revised to read "7/10/06, 71 FR 38773" respectively.
C. State Citation APC–S–2 Section I State Effective Date is revised to read "8/27/05."
D. State Citation APC–S–2 Section XVI EPA Approval Date Citation is revised to read "71 FR 38773."
E. State Citation APC–S–2 is revised to read, "Section I."
F. State Citation APC–S–3 Section 2 is revised to read "2/4/72."

2. Revising the date format listed in paragraphs 52.1270(c). Revise the date format in the "State effective date," and "EPA approval date," columns for consistency. Dates are numerical month/day/year without additional zeros.

EPA has determined that today's action falls under the "good cause" exemption in the section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon finding "good cause," authorizes agencies to dispense with public participation and section 553(d)(3) which allows an agency to make an action effective immediately (thereby avoiding the 30-day delayed effective date otherwise provided for in the APA). Today's administrative action simply codifies provisions which are already in effect as a matter of law in Federal and approved state programs and corrects typographical errors appearing the **Federal Register.** Under section 553 of the APA, an agency may find good cause where procedures are "impractical, unnecessary, or contrary to the public interest." Public comment for this administrative action is "unnecessary" and "contrary to the public interest" since the codification (and typographical corrections) only reflect existing law. Immediate notice of this action in the **Federal Register** benefits the public by providing the public notice of the updated Mississippi SIP Compilation and notice of typographical corrections to the Mississippi "Identification of Plan" portion of the **Federal Register**.

Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this administrative action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. This action is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866. Because the Agency has made a "good cause" finding that this action is not subject to notice-and-comment requirements under the APA or any other statute as indicated in the Supplementary Information section above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This administrative action also 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, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it 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 (64 FR 43255, August 10, 1999). This administrative action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant. This administrative action does not involve technical standards; thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The administrative action also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). This administrative action does not impose an information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). EPA's compliance with these Statutes and Executive Orders for the underlying rules are discussed in previous actions taken on the State's rules.

B. Submission to Congress and the Comptroller General

The Congressional Review Act (CRA) (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. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. Today's administrative action simply codifies (and corrects) provisions which are already in effect as a matter of law in Federal and approved State programs. 5 U.S.C. 808(2). These announced actions were effective when EPA approved them through previous rulemaking actions. 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 this action in the **Federal Register**. This update to Mississippi's SIP Compilation and correction of typographical errors is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

EPA has also determined that the provisions of section 307(b)(1) of the Clean Air Act pertaining to petitions for judicial review are not applicable to this action. This action is simply an announcement of prior rulemakings that have previously undergone notice and comment rulemaking. Prior EPA rulemaking actions for each individual component of the Mississippi SIP compilation previously afforded interested parties the opportunity to file a petition for judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of such rulemaking action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 6, 2009.

Beverly H. Banister,

Acting Regional Administrator, Region 4.

■ 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 Z—Mississippi

■ 2. Section 52.1270 paragraphs (b) and (c) are revised to read as follows:

§ 52.1270 Identification of plan.

* * * * *

(b) Incorporation by reference.

(1) Material listed in paragraph (c) of this section with an EPA approval date prior to October 3, 2007, for Mississippi was approved for incorporation by reference by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval, and notice of any change in the material will be published in the **Federal Register**. Entries in paragraphs (c) and (d) of this section with EPA approval dates after October 3, 2007, for Mississippi will be incorporated by reference in the next update to the SIP compilation.

(2) EPA Region 4 certifies that the rules/regulations provided by EPA in the SIP compilation at the addresses in paragraph (b)(3) of this section are an exact duplicate of the officially promulgated State rules/regulations which have been approved as part of the State Implementation Plan as of the dates referenced in paragraph (b)(1).

(3) Copies of the materials incorporated by reference may be inspected at the Region 4 EPA Office at 61 Forsyth Street, SW., Atlanta, GA 30303, the Air and Radiation Docket and Information Center, EPA Headquarters Library, Infoterra Room (Room Number 3334), EPA West Building, 1301 Constitution Ave., NW., Washington, DC 20460, and the National Archives and Records Administration. If you wish to obtain materials from a docket in the EPA Headquarters Library, please call the Office of Air and Radiation (OAR) Docket/Telephone number: (202) 566–1742. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(c) EPA Approved Mississippi Regulations.

EPA-APPROVED MISSISSIPPI REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
APC–S–1 Air Emission Regulations for the Prevention, Abatement, and Control of Air Contaminants				
Section 1	General	1/9/94	2/12/96, 61 FR 5295.	
Section 2	Definitions	1/9/94	2/12/96, 61 FR 5295.	
Section 3	Specific Criteria for Sources of Particulate Matter.	5/28/99	12/20/02, 67 FR 77926.	
Section 4	Specific Criteria for Sources of Sulfur Compounds.	1/9/94	2/12/96, 61 FR 5295.	
Section 5	Specific Criteria for Sources of Chemical Emissions.	1/9/94	2/12/96, 61 FR 5295.	
Section 6	New Sources	5/28/99	12/20/02, 67 FR 77926	Subsection 2, "Other Limitations," and Subsection 3, "New Source Performance Standards," are not federally approved.
Section 7	Exceptions	2/4/72	5/31/72, 37 FR 10875.	
Section 9	Stack Height Considerations.	5/1/86	9/23/87, 52 FR 35704.	
Section 10	Provisions for Upsets, Startups, and Shutdowns.	1/9/94	2/12/96, 61 FR 5295.	
Section 11	Severability	1/9/94	2/12/96, 61 FR 5295.	
Section 14	Provision for the Clean Air Interstate Rule	12/17/06	10/3/07, 72 FR 56268.	
APC–S–2 Permit Regulations for the Construction and/or Operation of Air Emissions Equipment				
Section I	General Requirements	8/27/05	7/10/06, 71 FR 38773.	
Section II	General Standards Applicable to All Permits	8/27/05	7/10/06, 71 FR 38773.	
Section III	Application For Permit To Construct and State Permit To Operate New Stationary Source.	8/27/05	7/10/06, 71 FR 38773.	
Section IV	Public Participation and Public Availability of Information.	8/27/05	7/10/06, 71 FR 38773.	
Section V	Application Review	8/27/05	7/10/06, 71 FR 38773.	
Section VI	Compliance Testing	8/27/05	7/10/06, 71 FR 38773.	
Section VII	Emission Evaluation Report	8/27/05	7/10/06, 71 FR 38773.	
Section VIII	Procedures for Renewal of State Permit To Operate.	8/27/05	7/10/06, 71 FR 38773.	
Section IX	Reporting and Record Keeping	8/27/05	7/10/06, 71 FR 38773.	
Section X	Emission Reduction Schedule	8/27/05	7/10/06, 71 FR 38773.	
Section XI	General Permits	8/27/05	7/10/06, 71 FR 38773.	
Section XII	Multi-Media Permits	8/27/05	7/10/06, 71 FR 38773.	
Section XIII	Exclusions	8/27/05	7/10/06, 71 FR 38773.	
Section XIV	CAFO	8/27/05	7/10/06, 71 FR 38773.	
Section XV	Options	8/27/05	7/10/06, 71 FR 38773.	
Section XVI	Permit Transfer	8/27/05	7/10/06, 71 FR 38773.	
Section XVII	Severability	8/27/05	7/10/06, 71 FR 38773.	

EPA-APPROVED MISSISSIPPI REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
APC–S–3 Regulations for the Prevention of Air Pollution Emergency Episodes				
Section 1	General	2/4/72	5/31/72, 37 FR 10875.	
Section 2	Definitions	2/4/72	5/31/72, 37 FR 10875.	
Section 3	Episode Criteria	6/3/88	11/13/89, 54 FR 47211.	
Section 4	Emission Control Action Programs	2/4/72	5/31/72, 37 FR 10875.	
Section 5	Emergency Orders	6/3/88	11/13/89, 54 FR 47211.	
APC–S–5 Regulations for the Prevention of Significant Deterioration of Air Quality				
All		8/27/05	7/10/06, 71 FR 38773.	

* * * * *

[FR Doc. 2010–348 Filed 1–12–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2009–0474; FRL–9100–1]

Revisions to the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval of revisions to the San Joaquin Valley Unified Air Pollution Control District (SJVAPCD) portion of the California State Implementation Plan (SIP). These revisions were proposed in the **Federal Register** on August 14, 2009 and concern oxides of nitrogen (NO_X) and particulate matter (PM) emissions from boilers of various capacities. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: *Effective Date:* This rule is effective on February 12, 2010.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2009–0474 for this action. The index to the docket is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Idalia Perez, EPA Region IX, (415) 972–3248, *perez.idalia@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 August 14, 2009 (74 FR 41104), EPA proposed to approve the following rules into the California SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
SJVAPCD	4306	Boilers, Steam Generators and Process Heaters—Phase 3.	10/16/08	03/17/09
SJVAPCD	4307	Boilers, Steam Generators and Process Heaters—2.0 MMbtu/hr to 5.0 MMbtu/hr.	10/16/08	03/17/09

We proposed to approve these rules because we determined that they complied with the relevant CAA requirements. Our proposed action contains more information on the rules 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 no comments.

III. EPA Action

Since publication of the proposed action, we identified two minor issues regarding Rule 4307 that do not change our assessment that the submitted rule complies with the relevant CAA requirements. Nonetheless, revisions to these provisions should be made when the Rule is next revised.

We have identified the possibility that some units that are subject to Rule 4307 do not need exemptions from basic emission limits during start-up and shutdown periods as long as they are maintained and operated appropriately. For example, we believe that heater treaters which rely only on low-NO_X burners for compliance are capable of consistent compliance with the Rule's basic emission limits during these periods. As a result, Section 5.4 should be revised to remove the start-up and shutdown exemption period for such devices.

Currently Section 6.1.4 requires recordkeeping only if the start-up and shut-down event exceeds the limitations of the duration of such events in Section 5.4.1 or 5.4.2. EPA recommends that Section 6.1.4 of Rule 4307 be revised to require records that specify the duration of all start-up and shut-down periods (at least for units located at Title V facilities). EPA notes that the limited applicability of the current version of 6.1.4 may not be appropriate in other rules, particularly those where periodic or continuous monitoring is required.

No comments were submitted that change our assessment that the submitted rules comply with the relevant CAA requirements. Therefore, as authorized in section 110(k)(3) of the Act, EPA is fully approving these rules 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, 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, these rules do 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 March 15, 2010. 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, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Dated: November 23, 2009.

Laura Yoshii,

Acting 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)(363)(i)(A)(*3*) and (*4*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(363) * * *

(i) * * *

(A) * * *

(*3*) Rule 4306, "Boilers, Steam Generators and Process Heaters—Phase 3, " adopted on October 16, 2008.

(*4*) Rule 4307, "Boilers, Steam Generators and Process Heaters—2.0 MMbtu/hr to 5.0 MMbtu/hr," adopted on October 16, 2008.

* * * * *

[FR Doc. 2010–352 Filed 1–12–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2009–0024; FRL–9097–2]

Revisions to the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing a limited approval and limited disapproval of revisions to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) portion of the California State Implementation Plan (SIP). This action was proposed in the **Federal Register** on August 19, 2009, and concerns a local fee rule that applies to major sources of volatile organic compound and nitrogen oxide emissions in the San Joaquin Valley ozone nonattainment area. Under authority of the Clean Air Act as amended in 1990 (CAA or the Act), this action simultaneously approves a local rule that regulates these emission sources and directs California to correct rule deficiencies.

DATES: *Effective Date:* This rule is effective on February 12, 2010.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2009–0024 for this action. The index to the docket is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.*, copyrighted material), and some may not be publicly available in either location (*e.g.*, CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Mae Wang, EPA Region IX, (415) 947–4124, *wang.mae@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
A. Commenting Parties
B. Summary of Comments and EPA Responses
1. EPA Response to the Clean Air Act Advisory Committee Letter
2. Consideration of Rule 3170 as an Alternative Program
3. Exemption for Units That Begin Operation After the Attainment Year
4. Exemption for "Clean Emission Units"
5. Defining the Baseline Period as the Attainment Year and the Immediately Preceding Year
6. Allowing Averaging Over 2–5 Years To Establish Baseline Emissions
7. Stationary Versus Mobile Sources
8. Impacts of Rule 3170 on Small Businesses
9. Unintended Consequences of Rule 3170
10. Incorrect Statement of Baseline Emissions
11. Ambiguity on Fees for Both VOCs and NO_X
12. Definition of "Major Source"
13. Sunset Provision for Section 185 Fees
III. EPA Action
IV. Statutory and Executive Order Reviews

I. Proposed Action

On August 19, 2009 (74 FR 41826), EPA proposed a limited approval and limited disapproval of the following rule that was submitted for incorporation into the California SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
SJVUAPCD	3170	Federally Mandated Ozone Nonattainment Fee	05/16/02	08/06/02

We proposed a limited approval because we determined that this rule improves the SIP and is largely consistent with the relevant CAA requirements. We simultaneously proposed a limited disapproval because some rule provisions do not fully meet the statutory CAA section 185 requirement. These provisions include the following:

1. An exemption for units that begin operation after the attainment year.
2. An exemption for any "clean emission unit."
3. The definition of the baseline period as two consecutive years.
4. The allowance of averaging baseline emissions over a period of 2–5 years "if those years are determined by the APCO as more representative of normal source operation."
5. An inappropriate definition of the term "Major Source." Our proposed action contains more information on the basis for this rulemaking and on our evaluation of the submittal.

II. Public Comments and EPA Responses

A. Commenting Parties

EPA's proposed action provided a 30-day public comment period. During this period, we received the following 12 comment letters from 11 parties:

1. American Chemistry Council, letter from Lorraine Gershman, dated September 18, 2009.
2. American Petroleum Institute, letter from Ted Steichen, dated September 18, 2009.
3. Association of Irritated Residents, letter from Brent Newell, Center on Race, Poverty, and the Environment, dated September 18, 2009.
4. California Small Business Alliance, letter from William R. La Marr, dated August 11, 2009.
5. The Clean Energy Group, letter from Michael Bradley, dated September 18, 2009.
6. County Sanitation Districts of Los Angeles County, letter from Stephen R. Maguin and Gregory M. Adams, dated August 11, 2009.
7. County Sanitation Districts of Los Angeles County, letter from Stephen R. Maguin and Gregory M. Adams, dated September 18, 2009.
8. EarthJustice, letter from Paul Cort, dated September 18, 2009.
9. San Joaquin Valley Unified APCD, letter from Seyed Sadredin, dated September 17, 2009.
10. The Section 185 Working Group, letter from Jason C. Moore, Baker Botts, dated August 13, 2009.
11. Southern California Air Quality Alliance, letter from Curtis L. Coleman, Esq., dated August 12, 2009.
12. Western States Petroleum Association, letter from David R. Farabee, Pillsbury Winthrop Shaw Pittman LLP, dated September 18, 2009.

B. Summary of Comments and EPA Responses

The comments and our responses are summarized below. The comments have been grouped into general categories.

1. EPA Response to the Clean Air Act Advisory Committee Letter

On May 15, 2009, the Clean Air Act Advisory Committee (CAAAC) sent a letter to EPA Acting Assistant Administrator Elizabeth Craig regarding issues related to the implementation of CAA section 185. The CAAAC asked EPA to review and address whether it is "legally permissible under either section 185 or 172(e) of the Clean Air Act for a State to exercise discretion" to develop fee program SIPs employing one or more of a list of CAAAC-identified program options (*see http://www.epa.gov/air/caaac/185wg*).

Comments: Several commenters specifically requested that EPA respond to the CAAAC letter prior to taking final action on SJVUAPCD Rule 3170. Commenters also suggested that EPA provide final guidance regarding flexibility under either CAA section 185 or 172(e) before disapproving any elements of SJVUAPCD Rule 3170.

Response: EPA intends to respond more fully to the issues raised by the CAAAC letter. EPA, however, cannot delay action on SJVUAPCD Rule 3170 because we are under a legal obligation to sign a **Federal Register** notice for our final action on Rule 3170 by December 11, 2009. This obligation is imposed by a consent decree between EPA and the Center for Race, Poverty and the Environment (CRPE) to settle CRPE's litigation alleging that EPA had failed to act on Rule 3170 in a timely manner. The consent decree was entered on August 18, 2009, by the U.S. District Court for the Northern District of California, case number 08–cv–05650 CW.

We note that CAA section 172(e) does not directly apply to the transition from the 1-hour ozone standard to the 1997 8-hour ozone standard because that provision applies only where the revised standard is less stringent than the standard it replaces. However, because the CAA does not directly address anti-backsliding where there is a new more stringent standard, EPA determined to apply the principles of CAA section 172(e) for purposes of addressing anti-backsliding for the transition from the 1-hour standard to the 1997 8-hour standard. EPA also notes that the State has not requested that EPA review Rule 3170 pursuant to the principles in CAA section 172(e) and thus, for purposes of taking action on Rule 3170, it is not necessary for EPA to take a final position regarding

whether it could approve a substitute program for the program specified under CAA section 185.

2. Consideration of Rule 3170 as an Alternative Program

CAAAC's May 15, 2009, letter identifies as a program option an exemption from fees for "well-controlled" sources. In our proposed action on Rule 3170, we noted this exemption as a basis for not being able to fully approve the rule as meeting section 185 of the Act. We further noted that the State has not requested that EPA review the SIP to determine whether it would be equivalent to CAA section 185 under the principles of section 172(e) and has not made a demonstration that the program it has submitted would ensure controls that are "not less stringent" than those required under section 185. Thus, we stated that we were not addressing whether it is legally permissible for a State to adopt an alternative program at least as stringent as a section 185 fee program, or if so, whether such alternative program could contain a clean unit exemption.

Comments: One commenter encouraged EPA to work with SJVUAPCD to consider Rule 3170 as an alternative program under the provisions of CAA section 172(e). The commenter felt that this rule as written would encourage area-wide emission reductions and meet the goals of CAA section 185 without sacrificing stringency.

One commenter stated that even if the District had submitted Rule 3170 pursuant to 172(e), or attempts to make a 172(e) demonstration to justify the clean unit exemption or other deficiency, CAA section 172(e) does not apply in this situation and cannot justify Rule 3170's failure to comply with CAA section 185. The commenter stated that section 172(e) only applies where EPA has relaxed a national primary ambient air quality standard (NAAQS). As a result, CAA section 172(e) does not support the exemptions in Rule 3170.

Response: We agree with the comment that CAA section 172(e) does not directly apply where EPA has promulgated a more stringent NAAQS. However, as noted above, because the Act does not address the principles that apply when there is a transition to a more stringent NAAQS, EPA determined that it was reasonable to apply the principles in section 172(e). Thus, to the extent section 172(e) would authorize EPA to allow alternatives to statutory programs such as the fee program in CAA section 185, EPA's application of the principles in section 172(e) to the anti-backsliding requirements for the 1-hour standard would provide EPA with the discretion to authorize an alternative program. Also, as noted above, EPA has not yet stated whether it would approve such programs for purposes of the anti-backsliding requirements of the 1-hour ozone standard.

Because the State has not submitted the program as an alternative program consistent with the principles in CAA section 172(e), EPA is not required to take a position in this rulemaking on whether it would approve such alternatives or whether the submitted program is consistent with those principles. We will continue to work with the State to ensure that they adopt a program that is fully consistent with the requirements of the CAA.

3. Exemption for Units That Begin Operation After the Attainment Year

Section 4.2 of SJVUAPCD Rule 3170 exempts units that begin operation after the attainment year. In its proposed action, EPA stated that CAA section 185 does not provide for an exemption for emission units that begin operation after the attainment year, so this exemption does not fully comply with the CAA. Rather, it requires "each major source" to pay the fee (*see* CAA section 185(a)).

Comments: Several commenters disagreed with EPA's proposed action on this particular provision. They felt that this exemption is consistent with the CAA requirements and therefore should not be considered a deficiency. They also felt that imposing fees on these units would be an unfair burden, resulting in an unfair business environment. One commenter expressed that imposing fees on new units would only serve to hinder the ability of new, cleaner units to displace older, dirtier units. Another commenter expressed that while CAA section 185 does not provide an express exemption for new units, EPA has sufficient discretion to approve the new unit exemption in Rule 3170.

Two commenters agreed with EPA's proposed action on this particular provision. They felt that this exemption violates the requirements of CAA section 185 and is a rule deficiency that is a basis for disapproval of the rule. One commenter stated that the CAA section 185 language is plain and unambiguous, and clearly does not allow such an exemption. The other commenter added that there is no statutory authority for splitting a stationary source into separate emission units for the purpose of determining fees.

Response: CAA section 185 does not provide for an exemption for units beginning operation after the attainment year. Rather, it requires that "each major stationary source" must pay the fee and that the baseline emissions are those from the major source in the attainment year. The word "each" does not lend itself to an interpretation that would exclude new major sources or new units at existing major sources from the fee obligation. The equity concerns cannot override the statutory requirement.

4. Exemption for "Clean Emission Units"

Section 4.3 of SJVUAPCD Rule 3170 exempts any "clean emission unit" from the requirements of the rule. Section 3.6 defines a clean emission unit as a unit that is equipped with an emissions control technology that either has a minimum 95% control efficiency (85% for lean-burn internal combustion engines), or meets the requirements for achieved-in-practice Best Achievable Control Technology as accepted by the APCO during the 5 years immediately prior to the end of the attainment year. The District's staff report for Rule 3170 states that the exemption is intended to address "the difficulty of reducing emissions from units with recently installed BACT." In its proposed action, EPA expressed that although EPA understands the District's intention, the exemption does not comply with CAA section 185, for the same reason as noted above for new emission units.

Comments: Several commenters disagreed with EPA's proposed action on this particular provision. They felt that this exemption is consistent with the CAA requirements and therefore should not be considered a deficiency. Several commenters believe that Congress did not intend to impose fees on units that are already as clean as possible. The imposition of fees on these units may, in many cases, force a curtailment in operations to reduce emissions.

Two commenters agreed with EPA's proposed action on this particular provision. They felt that this exemption violates CAA section 185 requirements and is a rule deficiency that is a basis for disapproval of the rule. These commenters stated that the CAA section 185 language is plain and unambiguous, clearly does not allow such an exemption, that there is no suggestion in the CAA that the best controlled sources are entitled to any other "reward" or exemption, and that section 185 is not a program to penalize only the less-regulated sources. One commenter expressed that Congress understood that the level of control among sources might vary because CAA section 185(b)(2)

specifies that the baseline comes from the lower of actuals or allowables, and that the allowables baseline is to be based on the emissions allowed "under the permit" unless the source has no permit and is only subject to limits provided under the SIP. The commenter stated that it would defeat this express language to exempt sources from paying a fee based on some arbitrary notion of being "clean enough."

Response: As explained above, CAA section 185 mandates that the fee is paid by "each" major source based on the emissions from that source in the baseline year. There is nothing in the language of CAA section 185 that contemplates that certain sources or that certain emissions from a source are not subject to the fee.

5. Defining the Baseline Period as the Attainment Year and the Immediately Preceding Year

Section 3.2.1 of Rule 3170 defines the baseline period as two consecutive years consisting of the attainment year and the year immediately prior to the attainment year. In contrast, CAA section 185(b)(2) establishes the attainment year as the baseline period. While CAA section 185(b)(2) also provides discretion to calculate baseline emissions over a period of more than one calendar year, that option is limited to sources with emissions that are irregular, cyclical, or otherwise vary significantly from year to year. Thus, in its proposed action, EPA stated that section 3.2.1 of SJVUAPCD Rule 3170 is inconsistent with the CAA because it provides a different baseline than that required by the CAA (two years instead of one) regardless of whether the emissions are irregular, cyclical or vary significantly from year to year.

Comments: Six commenters disagreed with EPA's proposed action on this particular provision. They felt that this provision is consistent with the CAA requirements as interpreted in a March 21, 2008 memorandum from William Harnett, Director of the Air Quality Policy Division, to the Regional Air Division Directors, entitled, "Guidance on Establishing Emissions Baselines under Section 185 of the Clean Air Act (CAA) for Severe and Extreme Ozone Nonattainment Areas that Fail to Attain the 1-hour Ozone NAAQS by their Attainment Date," ("Section 185 Baseline Guidance") and therefore should not be considered a deficiency.[1] Commenters objected to EPA's view that the five-year lookback option in SJVUAPCD Rule 3170 be available only upon a site-specific consideration of representativeness or cyclicality. One commenter stated that NSR reform was enacted precisely to replace such a case-by-case review. The commenter also stated SJVUAPCD's approach was consistent with EPA's New Source Review approach for multi-year baselines. The commenter felt that a simple multi-year baseline would flexibly and efficiently satisfy the statutory language and intent.

Two commenters agreed with EPA's proposed action on this particular provision. They felt that this exemption violates the CAA section 185 requirements and is a rule deficiency that is a basis for disapproval of the rule. One commenter stated that CAA section 185 language is plain and unambiguous, and clearly does not allow the baseline to be calculated over two years for all sources. The second commenter stated that section 3.2.1 of Rule 3170 should be revised to clarify that the baseline for most sources will be the emissions in the attainment year of 2010, and provide clear criteria for allowing sources to use an alternative baseline period.

Response: The language of CAA section 185 provides EPA with discretion to issue guidance that would allow for the baseline period to be more than one calendar year. However, CAA section 185 allows EPA to do so only for sources whose emissions are irregular, cyclical, or otherwise vary significantly from year to year. EPA's Section 185 Baseline Guidance referred to this connection by stating that, "where source emissions are irregular, cyclical, or otherwise vary significantly, the CAA provides that the U.S. Environmental Protection Agency (EPA) may issue guidance providing an alternative method to calculate the baseline amount." EPA issued the Section 185 Baseline Guidance to provide guidance for an alternative method for calculating the emissions baseline in these situations. Hence, section 3.2.1 of Rule 3170 does not conform to CAA section 185 because it allows all sources to calculate their baseline over a two-year period, regardless of whether emissions are irregular, cyclical, or otherwise vary significantly.

6. Allowing Averaging Over 2–5 Years To Establish Baseline Emissions

Section 3.2.2 of Rule 3170 allows averaging over 2–5 years to establish baseline emissions. CAA section 185(b)(2) states that EPA may issue guidance authorizing such an alternative method of calculating baseline emissions. EPA's Section 185 Baseline Guidance addresses the issue of alternative methods for calculating baseline emissions. The use of these alternative methods is associated with sources whose emissions are irregular, cyclical, or otherwise vary significantly from year to year. The averaging period allowed in section 3.2.2 of Rule 3170 appears consistent with EPA's Section 185 Baseline Guidance. The language in section 3.2.2, however, allows such averaging "if those years are determined by the APCO as more representative of normal source operation." In its proposed action, EPA stated that it considers this language as less stringent than the criteria in the CAA, and therefore the rule should be amended to specify use of the expanded averaging period only if a source's emissions are irregular, cyclical, or otherwise vary significantly from year to year.

Comments: Several commenters disagreed with EPA's proposed action on this particular provision. They felt that this exemption is consistent with the CAA requirements and the Section 185 Baseline Guidance, and therefore should not be considered a deficiency. The SJVUAPCD stated that its intention in implementing this provision is that the criteria of being "more representative of normal source operation" would require a source to demonstrate to the satisfaction of the APCO that the emissions are irregular, cyclical, or otherwise vary significantly from year to year. One commenter disagreed with EPA's assessment that the phrase, "more representative of normal source operation" was less stringent that the CAA section 185 language.

Two commenters agreed with EPA's proposed action on this particular provision. They felt that this exemption violates the CAA section 185 requirements and is a rule deficiency that is a basis for disapproval of the rule. One commenter stated that the CAA section 185 language is plain and unambiguous, and clearly does not allow such an exemption.

Response: EPA disagrees that unlimited APCO discretion in determining normal source operation is consistent with CAA section 185. Rule 3170 does not specify any criteria for how the APCO would make a determination that a certain baseline is "more representative of normal source operation" than the baseline specified by CAA section 185 (*i.e.,* the attainment year). It is not clear that the APCO's

[1] EPA's Section 185 Baseline Guidance provides that an acceptable alternative baseline for sources whose emissions are irregular, cyclical, or otherwise vary significantly from year to year is the 10-year lookback period found in EPA's regulations for Prevention of Significant Deterioration of Air Quality (PSD) (40 CFR 52.21(b)(48)).

discretion would involve an assessment of whether a source's emissions are irregular, cyclical, or otherwise variable. Therefore, EPA continues to view the language in section 3.2.2 of Rule 3170 as a deficiency that needs to be corrected.

7. Stationary Versus Mobile Sources

Comment: Several commenters stated that most ozone nonattainment areas classified as severe or extreme are now dominated by mobile source emissions, and that stationary sources are not the major contributor of emissions. Commenters stated that CAA section 185 is functionally obsolete and will result in substantial adverse financial impacts to facility operators with little or no air quality benefit. One commenter stated that individual sources do not have the ability to assure attainment of the standard; consequently, the fee is an unconstitutional bill of attainder.

Response: The approach outlined in the CAA to reduce emissions in defined air basins acknowledges that no single source is responsible for an area's nonattainment, but that the total collective contribution of many individual sources affects an area's pollution problem. As such, the CAA extensively regulates both mobile sources and stationary sources. Whether or not CAA section 185 is functionally obsolete is an issue for Congress. As long as CAA section 185 remains the law, EPA's obligation is to ensure compliance with it. We disagree with the commenter that claims that since individual sources cannot ensure attainment of the ozone NAAQS, section 185 is an unconstitutional bill of attainder. Section 185 does not result in any party being declared guilty of a crime. Rather, it is a means of encouraging certain sources to reduce emissions of pollutants that contribute to unhealthy ambient ozone levels. The Courts have long held that the Commerce clause gives Congress the authority to regulate sources of air pollution. The fee provision of CAA section 185 acts as an incentive for major sources of air pollution to reduce emissions. Thus, it is a proper exercise of Congressional authority under the Commerce clause.

8. Impacts of Rule 3170 on Small Businesses

Comment: Commenters stated that hundreds of small businesses will be affected by CAA section 185 requirements, as well as hospitals, medical centers, schools and other essential public services. Commenters stated that applying CAA section 185 fees to small businesses that are in compliance with all applicable regulations will demonstrate that the fees are unreasonable, expensive, and do nothing to reduce and assure emission reductions. One commenter stated that the fees would be inconsistent with the Small Business Regulatory Flexibility Act and that the fees should not be applied to businesses meeting the definition of "small" under CAA section 507.

Response: Although CAA section 185 allows for exemptions for certain low-population areas (see section 185(e)), section 185 does not grant States or EPA discretion to exempt small businesses from the requirements of the program. The Regulatory Flexibility Act applies where EPA is promulgating regulations that may have a significant impact on a substantial number of small businesses. Here, it is the CAA, not EPA's action that imposes the fee on sources. Moreover, in this instance, EPA is not promulgating regulations, but rather reviewing a State plan. EPA does not have the authority to consider the impacts on small businesses that result from direct application of the statute or through applications of the State program. Moreover, even if EPA were promulgating a regulation that was determined to have a significant impact on a substantial number of small entities, we note that the RFA does not prohibit any specific regulatory result, as suggested by the commenters. Rather it only requires that the Agency take certain actions in order to fully consider the potential impacts of the regulation.

9. Unintended Consequences of Rule 3170

Comment: One commenter stated that renewable energy facilities may need to reduce throughput as a result of CAA section 185 requirements and this would be contrary to efforts to reduce greenhouse gases and increase the penetration of renewable energy.

Response: Sources have several ways to comply with the requirements of CAA section 185, and this could include reducing throughput to eliminate or reduce the fee amount. Regardless of the consequence of the manner in which a major source chooses to comply with the requirements, section 185 does not provide States or EPA with authority to exempt major stationary sources from complying with section 185.

10. Incorrect Statement of Baseline Emissions

Comment: One commenter stated that section 5.1 of Rule 3170 needs to be revised to accurately define the baseline emissions to be used in the calculation of the fee amount. In addition, the definition of baseline emissions fails to include the possibility that a source will not have a permit issued for the attainment year, in which case the allowable emissions are to be based on the emissions allowed under the applicable implementation plan (*see* CAA section 185(b)(2)). While such circumstances may be rare, the District should include language that mirrors the statute to avoid any potential conflict.

Response: While we think it is unlikely that any sources would not fall within the current definition, we agree with the commenter and recommend that the calculation in section 5.1 of Rule 3170 be revised to more closely conform to the language in CAA section 185. The definition of the variable "B" in the fee calculation should include the clarification that if no permit has been issued for the attainment year, then "B" should be the lower of the actual VOC or emissions during the baseline period, or the amount of VOC or NO_X emissions allowed under the applicable implementation plan during the baseline period.

11. Ambiguity on Fees for Both VOCs and NO_X

Comment: One commenter expressed that the fee calculation in section 5.0 of Rule 3170 is ambiguous regarding whether the fee is due for VOCs and NO_X, or just one or the other. Sources must pay a fee for both VOC emissions in excess of 80% of the VOC baseline emissions and NO_X emissions in excess of 80% of the NO_X baseline emissions. Section 5.0 of Rule 3170 should be revised to clarify this point.

Response: EPA agrees that the fee is required for both VOC and NO_X emissions. We believe that the District and sources understand the fee program applies to both VOC and NO_X emissions, and that the language in section 5.1 of SJVUAPCD Rule 3170 is sufficiently clear in that respect. For example, the District staff report for Rule 3170 contained a sample fee calculation which also made it clear that a separate fee would be assessed for VOC emissions and NO_X emissions. While we do not believe any revisions to the rule are necessary, we recommend that SJVUAPCD consider whether further clarification might be helpful.

12. Definition of "Major Source"

Section 3.4 of Rule 3170 defines the term "Major Source" by referring to the definition in SJVUAPCD Rule 2201 (New and Modified Stationary Source Review Rule). The current SIP-approved

version of Rule 2201 was adopted by the SJVUAPCD on December 19, 2002, and approved by EPA on May 17, 2004 (69 FR 27837). This version of Rule 2201 defines "Major Source" as a stationary source with VOC or NO_X emissions of over 50,000 pounds per year (25 tons per year). The CAA defines the major source threshold as 10 tons per year for ozone nonattainment areas classified as extreme. The SJVUAPCD amended Rule 2201 on December 18, 2008, and submitted it for inclusion in the SIP on March 17, 2009. This amended version includes the 10 tons per year threshold, but has not been approved into the SIP. Therefore, in its proposed action, EPA stated that Rule 3170's reliance on Rule 2201 to define major sources is not approvable at this time. If a version of Rule 2201 that contains the appropriate major source threshold is approved into the SIP prior to finalizing the proposed action, then section 3.4 would no longer be cited as a deficiency in Rule 3170.

Comments: Several commenters disagreed with EPA's proposed action on this particular provision. They felt that this discrepancy would be resolved prior to the assessment or collection of any section 185 fees when Rule 2201 is approved into the SIP. One commenter also expressed that the thresholds in Rule 2201 are currently binding under State law, and therefore the "Major Source" definition in Rule 3170 should not be considered a deficiency that would result in the disapproval of the rule.

Two commenters agreed with EPA's proposed action on this particular provision. One commenter felt that this definition is currently inconsistent with CAA requirements, noting that EPA has allowed Rule 2201 to remain out of date for 5 years. However, in the current situation, the commenter agreed that this definition is a rule deficiency that is a basis for disapproval of the rule. One commenter added that the definition of "Major Source" in Rule 2201 does not match the definition in CAA section 182(e). For example, Rule 2201's definition excludes fugitive emissions for certain sources, only includes potential emissions from units with valid permits, and credits limits in authorities to construct that may or may not reflect actual emissions. As a result, the commenter felt that EPA is incorrect in suggesting that this deficiency will be resolved once the revised version of Rule 2201 is approved into the SIP. The commenter felt that section 3.4 of Rule 3170 should be revised to mirror the definition of "major source" in CAA section 182(e), which includes all emissions of VOC or NO_X, and looks at the larger of actual or potential emissions.

Response: EPA disagrees with the statement that the December 18, 2008, version of Rule 2201 is currently binding under State law. That version of the rule specifically states that it does not go into effect until EPA issues final approval of the rule into the SIP. The "Major Source" definition in Rule 3170 continues to be a deficiency until it is revised to be consistent with the CAA. Further, we agree that since we have not yet fully reviewed and acted on Rule 2201, we cannot say for a certainty that approval of that rule would eliminate any deficiency with respect to the definition of major sources under Rule 3170. We will continue to work with the State to ensure that it develops a section 185 program that fully complies with the Act.

13. Sunset Provision for Section 185 Fees

Comment: One commenter highlighted the need for EPA to address the legality and process of establishing a sunset provision for section 185 fees, an issue identified in the CAAAC letter. Because the 1-hour ozone standard has been replaced with the 8-hour standard, EPA may not be able to make the findings necessary to redesignate an area as attainment for the 1-hour standard. This situation would require the imposition of fees indefinitely. The commenter feels that this issue must be resolved if EPA finalizes action on Rule 3170.

Response: EPA is aware of the issue raised by the commenter and intends to address in future guidance or rulemaking the issue of when section 185 fees would no longer apply.

III. EPA Action

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, as authorized in sections 110(k)(3) and 301(a) of the Act, EPA is finalizing a limited approval of the submitted rule. This action incorporates the submitted rule into the California SIP, including those provisions identified as deficient. As authorized under section 110(k)(3), EPA is simultaneously finalizing a limited disapproval of the rule. As a result, sanctions will be imposed unless EPA approves subsequent SIP revisions that correct the rule deficiencies within 18 months of the effective date of this action. These sanctions will be imposed under section 179 of the Act according to 40 CFR 52.31. In addition, EPA must promulgate a Federal implementation plan (FIP) under section 110(c) unless we approve subsequent SIP revisions that correct the rule deficiencies within 24 months. Note that the submitted rule has been adopted by the SJVUAPCD, and EPA's final limited disapproval does not prevent the local agency from enforcing it.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled "Regulatory Planning and Review."

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements 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 not-for-profit enterprises, and small governmental jurisdictions.

This rule will not have a significant impact on a substantial number of small entities because SIP approvals and limited approvals/limited disapprovals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because this limited approval/limited disapproval action does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* v. *U.S. EPA,* 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates Reform Act

Under sections 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must

prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or Tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the limited approval/limited disapproval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or Tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or Tribal governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Order 13175, Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications." This final rule does not have Tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on Tribal governments, 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. Thus, Executive Order 13175 does not apply to this rule.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045, because it approves a State rule implementing a Federal standard.

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

This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use "voluntary consensus standards" (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective February 12, 2010.

K. Petitions for Judicial Review

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 March 15, 2010. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 11, 2009.

Laura Yoshii,

Acting 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 paragraph (c)(303)(i)(C)(*4*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(303) * * *

(i) * * *

(C) * * *

(*4*) Rule 3170, "Federally Mandated Ozone Nonattainment Fee," adopted on May 16, 2002.

* * * * *

[FR Doc. 2010–353 Filed 1–12–10; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No.0910091344–9056–02]

RIN 0648–XT71

Fisheries of the Exclusive Economic Zone Off Alaska; Chiniak Gully Research Area for Vessels Using Trawl Gear

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

ACTION: Temporary rule.

SUMMARY: NMFS is rescinding the trawl closure in the Chiniak Gully Research Area. This action is necessary to allow vessels using trawl gear to participate in directed fishing for groundfish in the Chiniak Gully Research Area.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), August 1, 2010, through 1200 hrs, A.l.t., September 20, 2010.

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

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

The Chiniak Gully Research Area is closed to vessels using trawl gear from August 1 to a date no later than September 20 under regulations at § 679.22(b)(6)(ii)(A). This closure is in support of a research project to evaluate the effects of commercial fishing on pollock distribution and abundance, as part of a comprehensive investigation of Stellar sea lion and commercial fishery interactions.

The regulations at § 679.22(b)(6)(ii)(B) provide that the Regional Administrator, Alaska Region, NMFS, (Regional Administrator) shall rescind the trawl closure if relevant research activities will not be conducted. The Regional Administrator has determined that research activities will not be conducted in 2010 in the Chiniak Gully Research Area. Therefore, the Regional Administrator is rescinding the trawl closure of the Chiniak Gully Research Area. All other closures remain in full force and effect.

Classification

Pursuant to 5 U.S.C. 553 (b)(B), the Assistant Administrator for Fisheries, NOAA (AA) finds good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment is unnecessary. Notice and comment is unnecessary because the rescission of the trawl closure is non-discretionary; pursuant to § 679.22(b)(6)(ii)(B), the Regional Administrator has no choice but to rescind the trawl closure once it is determined that research activities will not be conducted in the area.

Pursuant to 5 U.S.C. 553(d)(1), this rule is not subject to the 30–day delay in effective date requirement of 5 U.S.C. 553(d) since the rule relieves a restriction.

This action has been determined to be not significant for purposes of Executive Order 12866.

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

Dated: January 7, 2010.

Emily H. Menashes,

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

[FR Doc. 2010–495 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 75, No. 8
Wednesday, January 13, 2010

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 930

[Docket No. AO–370–A8; AMS–FV–06–0213; FV07–930–2]

Tart Cherries Grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin; Secretary's Decision and Referendum Order on Proposed Amendment of Marketing Agreement and Order No. 930

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule and referendum order.

SUMMARY: This decision proposes amendments to Marketing Agreement and Order No. 930 (order), which regulates the handling of tart cherries grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin, and provides growers and processors with the opportunity to vote in a referendum to determine if they favor the changes. Seven amendments were proposed by the Cherry Industry Administrative Board (Board), which is responsible for local administration of the order. These amendments would: Authorize changing the primary reserve capacity associated with the volume control provisions of the order; authorize establishment of a minimum inventory level at which all remaining product held in reserves would be released to handlers for use as free tonnage; establish an age limitation on product placed into reserves; revise the nomination and election process for handler members on the Board; revise Board membership affiliation requirements; and update order language to more accurately reflect grower and handler participation in the nomination and election process in districts with only one Board representative. In addition, the Agricultural Marketing Service (AMS) proposed to make any such changes as may be necessary to the order to conform to any amendment that may result from the hearing.

A Board proposal to revise the voting requirements necessary to approve a Board action is not recommended for adoption.

The amendments are designed to provide flexibility in administering the volume control provisions of the order and to update Board nomination, election, and membership requirements. The amendments are intended to improve the operation and administration of the order.

DATES: The referendum will be conducted from February 1, 2010, through February 13, 2010. The representative period for the purpose of the referendum will be July 1, 2008 through June 30, 2009.

FOR FURTHER INFORMATION CONTACT: Martin Engeler, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, Suite 102–B, Fresno, California 93721; telephone: (559) 487–5110, Fax: (559) 487–5906; or Marc McFetridge, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Stop 0237, Washington, DC 20250–0237; telephone: (202) 720–1509, Fax: (202) 720–8938, or e-mail: *Martin.Engeler@usda.gov* or *Marc.McFetridge@usda.gov.*

Small businesses may request information on this proceeding by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, e-mail: *Jay.Guerber@usda.gov.*

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of Hearing issued on February 5, 2007, and published in the February 7, 2007, issue of the **Federal Register** (72 FR 5646), and a Recommended Decision issued on May 7, 2009 and published in the May 12, 2009, issue of the **Federal Register** (74 FR 22112).

This action is governed by the provisions of sections 556 and 557 of title 5 of the United States Code and is therefore excluded from the requirements of Executive Order 12866.

Preliminary Statement

The proposed amendments are based on the record of a public hearing held on February 21 and 22, 2007, in Grand Rapids, Michigan, and March 1 and 2, 2007, in Provo, Utah, to consider such amendments to the order. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act", and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR Part 900).

Notice of this hearing was published in the **Federal Register** on February 7, 2007, and contained amendment proposals submitted by the Board.

The amendments included in this decision would:

1. Amend § 930.50 of the order to authorize changing the primary reserve capacity associated with the volume control provisions of the order.
2. Amend § 930.54 of the order to authorize establishment of a minimum inventory level at which all remaining product held in reserves would be released to handlers for use as free tonnage.
3. Amend § 930.55 to establish an age limitation on product placed into reserves.
4. Amend § 930.23 to revise the nomination and election process for handler members on the Board, including revisions to conform this section to amendment of § 930.20 regarding membership affiliation requirements.
5. Amend § 930.20 to revise Board membership affiliation requirements.
6. Amend § 930.23 to update order language to more accurately reflect grower and handler participation in the nomination and election process in Districts with only one Board representative.

In addition to the proposed amendments to the order, AMS proposed to make any such additional changes as may be necessary to the order to conform to any amendments that may result from the hearing. To the extent necessary, conforming changes have been made to the amendments.

A Board proposal to revise the voting requirements necessary to approve a Board action is not recommended for adoption.

Upon the basis of evidence introduced at the hearing and the record

thereof, the Administrator of AMS on May 7, 2009, filed a Recommended Decision and Opportunity to File Written Exceptions thereto by June 11, 2009.

Six exceptions were filed during the period provided. Five of the exceptions were filed by growers and processors of tart cherries, and one was filed on behalf of the Board. All of the exceptions expressed concern about Material Issue Number 6 regarding membership affiliation requirements. Five of the exceptions raised specific concerns with the changes AMS made in the Recommended Decision to the industry's proposed amendment under Material Issue Number 5 regarding the nomination and election process of Board members, and its application in conjunction with Material Issue Number 6. Two of the exceptions addressed Material Issue Number 4 regarding the proposal to change Board voting requirements. One exception addressed Material Issue Number 1 concerning changing the reserve capacity through informal rulemaking, Material Issue Number 2 concerning establishment of a minimum inventory level at which reserve product would be released to handlers as free tonnage, and Material Issue Number 3 concerning placing an age limitation on reserve products. The specific issues raised in these exceptions are discussed in the Findings and Conclusions; Discussions of Exceptions section of this document.

Small Business Considerations

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), AMS has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions so that small businesses will not be unduly or disproportionately burdened. Marketing orders and amendments thereto are unique in that they are normally brought about through group action of essentially small entities for their own benefit.

Small agricultural producers have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than $750,000. Small agricultural service firms, which include handlers regulated under the order, are defined as those with annual receipts of less than $7,000,000.

There are approximately 40 handlers and processors of tart cherries subject to regulation under the order and approximately 900 producers of tart cherries in the regulated area. A majority of the producers, processors, and handlers are considered small entities according to the SBA's definition.

The geographic region regulated under the order covers the States of Michigan, New York, Oregon, Pennsylvania, Utah, Washington, and Wisconsin. Acreage devoted to tart cherry production in the regulated area has declined in recent years. According to data presented at the hearing, bearing acreage in 1987–88 totaled 50,050 acres; by 2006–2007 it had declined to 37,200 acres. Michigan accounts for 74 percent of total U.S. bearing acreage with 27,700 bearing acres. Utah is second, with a reported 2,800 acres, or approximately eight percent of the total. The remaining States' acreage ranges from 700 to 2,000 acres.

Production of tart cherries can fluctuate widely from year to year. The magnitude of these fluctuations is one of the most pronounced for any agricultural commodity in the United States, and is due in large part to weather related conditions during the bloom and growing seasons. This fluctuation in supplies presents a marketing challenge for the tart cherry industry because demand for the product is relatively static. In addition, the demand for tart cherries is inelastic, which means a change in the supply has a proportionately larger change in the price level.

Authorities under the order include volume regulation, promotion and research, and grade and quality standards. Volume regulation is used under the order to augment supplies during short supply years with product placed in reserves during large supply years. This practice is intended to reduce the annual fluctuations in supplies and corresponding fluctuations in prices.

The Board is comprised of representatives from all producing areas based on the volume of cherries produced in those areas. The Board consists of a mix of handler and grower members, and a member that represents the public. Board meetings where regulatory recommendations and other decisions are made are open to the public. All members are able to participate in Board deliberations, and each Board member has an equal vote. Others in attendance at meetings are also allowed to express their views.

The Board appointed a subcommittee to consider amendments to the marketing order. The subcommittee met several times for this purpose, and ultimately recommended several amendments to the order. The Board subsequently requested that USDA conduct a hearing to consider the proposed amendments. The views of all participants were considered throughout this process.

In addition, the hearing to receive evidence on the proposed amendments was open to the public and all interested parties were invited and encouraged to participate and express their views.

The proposed amendments are intended to provide additional flexibility in administering the volume control provisions of the order, and to update Board nomination, election, and membership requirements. The amendments are intended to improve the operation and administration of the order. Record evidence indicates the proposals are intended to benefit all producers and handlers under the order, regardless of size.

Amendment 1—Adding the Authority To Change the Primary Reserve Capacity

This amendment would revise § 930.50 of the order to authorize changing the primary reserve capacity associated with the volume provisions of the order through informal rulemaking. Changing the reserve capacity currently requires amendment of the order through the formal rulemaking process.

The order establishes a fixed quantity of 50-million pounds of tart cherries and tart cherry products that can be held in the primary reserve. Any reserve product in excess of the 50-million-pound limitation must be placed in the secondary reserve.

Free tonnage product can be sold to any market outlet, but most shipments are sold domestically, which is considered the primary market. Reserve product can be used only in specific outlets which are considered secondary markets. These secondary markets include development of export markets, new product development, new markets, and government purchases.

When the order was promulgated, a 50-million-pound limitation was placed on the capacity of the primary reserve. Proponents of the current order proposed a limitation on the quantity of product that could be placed into the primary reserve. That limitation was incorporated into the order, and can only be changed through the formal rulemaking process.

Economic data presented when the order was promulgated indicated that a reserve program could benefit the industry by managing fluctuating supplies. Witnesses at the February and March 2007 hearing indicated the order

has been successful in this regard. However, the record indicated that the order could be more flexible in allowing modifications to the 50-million-pound limitation should conditions warrant such a change in the future.

If the reserve capacity was changed, costs associated with storing product in reserves could also change. In addition, to the extent such a change could affect supplies in the marketplace; returns to both growers and handlers could also be affected.

Any Board recommendation to change the reserve capacity would be required to be implemented through the informal rulemaking process. As part of the informal rulemaking process, USDA expects that any Board recommendation will include an analysis of the pertinent factors and issues, including the impact of a proposed regulation on producers and handlers. During that process, the Board would recommend a change to USDA, and only if the recommendation was accompanied by adequate justification would USDA proceed with the change.

Amendment 2—Adding the Authority To Establish a Minimum Inventory Level at Which Reserves Would Be Released

This amendment would revise § 930.54 of the order to provide the Board with the authority to establish a minimum inventory level at which reserves would be released and made available to handlers as free tonnage. This amendment would allow the Board to clear out the primary reserve and subsequently the secondary reserve when a specified minimum inventory level of tart cherries is reached. The specified minimum level would be established through the informal rulemaking process.

Under current order provisions, handlers cannot access the secondary reserve until the primary reserve is empty. Based on current language of the order, one handler who has not completely disposed of or otherwise fulfilled its reserve obligation can prevent access to the secondary reserve.

The amendment would allow the Board to clear out the primary reserve when inventory levels are at a minimum level in order to provide the industry access to secondary reserve inventories.

If the amendment were implemented, costs to both handlers and the Board could be reduced. Handlers incur costs in maintaining reserves. According to the record, these costs include the cost of storage, which can be in the range of $.01 per pound per month. Handlers also incur costs associated with tracking their own inventory levels. Witnesses stated that when inventory levels reach a minimal amount the costs of tracking inventory outweigh the benefit from carrying inventory in the primary reserve.

A significant portion of the Board staff's time is directed at tracking reserve inventory maintained at handlers' facilities. Hearing witnesses testified that while it is difficult to quantify the exact value of the Board staff's time to conduct these activities, the time could be better spent on other industry issues, and it is unnecessary to track minimal levels of inventory.

The amendment, if implemented, could have a positive impact on the market. As inventories are released from the reserves, products could be sold, generating revenue for the industry.

If implemented, this amendment is expected to reduce costs to handlers and the Board, thus having a positive economic impact.

Amendment 3—Establishing an Age Limitation on Products Placed Into Reserves

This amendment would revise § 930.55 to require that products placed in reserves must have been produced in the current or immediately preceding two crop years. If implemented, this amendment would allow the Board to place an age limit on products carried in the reserve. The purpose of the amendment would be to help ensure that products of saleable quality are maintained in reserve inventories.

Witness supported the amendment by stating that it would add credibility to product quality for all products carried in the reserve. Currently, handlers can carry products they have no intention of selling just to meet their reserve obligation. This amendment would require handlers to rotate product in their reserve inventory, thus preventing them from maintaining the same product in the reserve year after year. Product held in inventory tends to deteriorate over time. When reserve product is ultimately released for sale to meet market demand, this proposed amendment would help ensure the reserve product available is in saleable condition and can satisfy the market's needs. Assuring product is available to satisfy the market helps to foster long-term market stability.

In terms of costs, handlers may experience some minimal costs associated with periodically rotating product through their reserve inventory. It would be difficult to estimate such costs because they would vary depending upon each handler's operation. To the extent costs would be increased, they would be proportionate to each handler's share of the entire industry's reserve inventory. Each handler's reserve inventory obligation is based on the handler's share of the total crop handled. Thus, small handlers would not be disproportionately burdened.

It is anticipated that the benefits of providing a good quality product in reserves to ultimately supply markets when needed would outweigh any costs associated with implementation of this amendment.

Amendment 4—Revision of Nomination and Election Process for Handler Members on the Board

This amendment relates to nomination and election of Board members under § 930.23 of the order. It would require a handler to receive support from handlers that handled at least five percent of the average production of tart cherries in the applicable district in order to be a candidate and to be elected by the industry and recommended to the Secretary for Board membership. Under the current order, there is no accounting for handler volume in the nomination and balloting process. Each handler is entitled to one equal vote. This proposal would continue to allow each handler to have one vote, but would also require handler candidates to be supported by handlers representing at least five percent of the average production in the applicable district to be eligible to run for a Board position and to be elected by the industry for recommendation to the Secretary. This would help to ensure that handler members on the Board represent the interests of handlers in their district that account for at least a minimal percentage of the volume in the district. The amendment proposed by the Board was modified by AMS. The amendment as modified by AMS would not apply the five percent support requirements to candidates whose potential election could prevent a sales constituency conflict from occurring, as discussed under amendment number five. The modification would help to ensure that all qualified handlers could participate in the election process.

This proposed amendment is not anticipated to have a significant economic impact on small businesses. It only affects the nomination and election criteria for membership on the Board by adding volume as an element of support to help ensure that Board membership reflects the interests of its constituency. All qualified handlers, regardless of size, will continue to be able to participate in the nomination and election process. The process would continue to allow for both small and

large handlers to be represented on the Board.

Amendment 5—Revision of Board Membership Affiliation Requirements

This amendment would revise § 930.20 to allow more than one Board member to be affiliated with the same sales constituency from the same district, if such a conflict cannot be avoided.

Currently, § 930.20 does not allow more than one Board member to be affiliated with the same sales constituency from the same district under any circumstances. The purpose of this provision is to prevent any one sales constituency from having a controlling influence on Board issues and actions. However, a situation occurred in District 7, Utah, where this particular provision of the order did not allow the district from having two representatives on the Board, as it was entitled to under § 930.20 (b) of the order. In that situation, the only candidates willing to serve on the Board from Utah were affiliated with the same sales constituency. Thus Utah was only able, under the marketing order rules, to seat one of the two Board representatives it was entitled to.

The proposed amendment is designed to prevent this problem from occurring in the future by allowing more than one Board member affiliated with the same sales constituency to represent a district, if such a sales constituency conflict cannot be avoided. The hearing record is clear that the sales constituency provision should not prevent a district from having its allocated number of seats on the Board if there are eligible candidates willing to serve on the Board.

This amendment is not expected to have an economic impact on growers or handlers. It relates to representation on the Board, and is intended to help ensure each area covered under the order has the opportunity to achieve its allocated representation on the Board.

Amendment 6—Update Order Language To Accurately Reflect Grower and Handler Participation in the Nomination and Election Process in Districts With Only One Board Representative

This amendment to § 930.23 would revise and update order language to more accurately reflect grower and handler participation in the nomination and election process in districts with only one Board representative.

Sections 930.23(b)(5) and (c)(4) specifically reference Districts 5, 6, 8, and 9 in regard to the nomination and election process. Those were the districts entitled to one Board seat when the order was initially promulgated. However, districts that are entitled to one Board seat have changed over time due to shifts in production. Amending §§ 930.23(b)(5) and (c)(4) by removing the specific references to Districts 5, 6, 8, and 9 and replacing it with generic language to cover any district that is entitled to only one Board representative based on the representative calculation established in § 930.20 would update order language to better reflect the constantly changing tart cherry industry.

This amendment updates order language to remove incorrect references to district representation in the event production shifts occur. It has no economic impact on handlers, growers, or any other entities.

Interested persons were invited to present evidence at the hearing on the probable regulatory and informational impacts of the proposed amendments to the order on small entities. The record evidence is that some of the proposed amendments may result in some minimal cost increases while others will result in cost decreases. To the extent there are any cost increases, the benefits of the proposed changes are expected to outweigh the costs. In addition, changes in costs as a result of these amendments would be proportional to the size of businesses involved and would not unduly or disproportionately impact small entities. The informational impact of proposed amendments is addressed in the Paperwork Reduction Act discussion that follows.

USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule. These amendments are intended to improve the operation and administration of the order to the benefit of the industry.

A Board proposal to change the voting requirements necessary to approve a Board action is not being recommended for adoption.

Paperwork Reduction Act

Information collection requirements for Part 930 are currently approved by the Office of Management and Budget (OMB), under OMB Number 0581–0177, Tart Cherries Grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin. Implementation of these amendments would not trigger any changes to those requirements. It is possible that a change to the reporting requirements may occur in the future if the Board believes it would be necessary to assist in program compliance efforts. Should any such changes become necessary in the future, they would be submitted to OMB for approval.

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

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

Civil Justice Reform

The amendments to Marketing Order 930 proposed herein have been reviewed under Executive Order 12988, Civil Justice Reform. They are not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United Sates in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed no later than 20 days after the date of the entry of the ruling.

Findings and Conclusions; Discussion of Exceptions

The material issues, findings and conclusions, rulings, and general findings and determinations included in the Recommended Decision set forth in the May 12, 2009, issue of the **Federal Register** (74 FR 22112) are hereby approved and adopted subject to the following additions and modifications.

Material Issue Number 1—Authority To Change the Primary Reserve Capacity

Based on the briefs and exceptions filed, the findings and conclusions in Material Issue Number 1 of the Recommended Decision are amended by adding the following four paragraphs to read as follows:

One exception to the Recommended Decision concerning Material Issue Number 1 was filed by a grower and processor of tart cherries. The exception did not support amending the order to

authorize changing the capacity of the primary reserve pool through informal rulemaking. The exception stated that when the order was promulgated, a 50 million-pound limitation was established for the primary reserve, and that limitation was adequately justified at the time. Conversely, the proposed amendment was not adequately justified through documentation and economic testimony.

The proposed amendment in itself would not make a change to the reserve capacity. It would change the process by which a change to the reserve capacity could be made. Under the proposed amendment, such a change could be made through the informal rulemaking process rather than the formal rulemaking process that is currently required.

The hearing record supports that circumstances and conditions in the industry change over time which could warrant a change in the reserve capacity. If the proposed amendment is adopted and such circumstances occur, a change could be made through informal rulemaking. During that process, the Board would recommend a change to USDA, and only if the recommendation was accompanied by adequate justification would USDA proceed with the change.

The record supports allowing a change to the reserve capacity to be made through informal rulemaking rather than formal rulemaking. Thus, the exception concerning Material Issue Number 1 is denied.

Material Issue Number 2—Authority To Establish a Minimum Level at Which Reserves Would Be Released

Based on the briefs and exceptions filed, the findings and conclusions in Material Issue Number 2 of the Recommended Decision are amended by adding the following two paragraphs to read as follows:

One exception to the Recommended Decision concerning Material Issue Number 2 was filed by a grower and processor of tart cherries. The exception did not support amending the order to authorize establishing a minimum level at which cherries in the reserve would be released. The exception indicated that adequate justification for the proposed amendment was not provided. It further states that the Board did not present a reasonable definition of what the minimum level would be in order for the reserves to be released. The exception suggested that actual criteria for establishing a minimum level should be developed and incorporated into the proposed amendment.

This proposal would not establish a level at which reserves would be released. Informal rulemaking would be required to establish such a level. The Board would need to develop adequate justification in any recommendation it would make to USDA to implement a regulation that would authorize release of the reserve. The intent of the proposal is to provide additional flexibility in administering the reserve program, and could also reduce costs associated with tracking small amounts of reserve product. The record evidence indicates that these objectives may be achieved if the proposed amendment is adopted. For these reasons, the exception is denied.

Material Issue Number 3—Establishment of a Minimum Age Limitation on Product Placed Into Reserves

Based on the briefs and exceptions filed, the findings and conclusions in Material Issue Number 3 of the Recommended Decision are amended by adding the following three paragraphs to read as follows:

One exception to the Recommended Decision concerning Material Issue Number 3 was filed by a grower and processor of tart cherries. The exception stated that the age of fruit placed in reserves is not truly a regulation of fruit quality, and that handlers should be able to place whatever product they choose in the reserve. The exception states that handlers could still place poor quality product in reserves if the amendment is adopted.

According to the record evidence, the intent of this proposed amendment is to help maintain marketable products in the reserve. When reserves are ultimately released, they need to be in a condition to satisfy market demands.

While placing an age limitation on reserve products does not guarantee a specific level of quality, the record shows that product quality deteriorates over time. Placing an age limitation on product held in reserves will reduce the likelihood that product of a deteriorated quality will be carried in handlers' reserve inventories. Based on the record evidence, the proposed amendment should be implemented and the exception is therefore denied.

Material Issue Number 4—Voting Requirements

Based upon the briefs and exceptions filed, the findings and conclusions in Material Issue Number 4 of the Recommended Decision are amended by adding the following five paragraphs to read as follows:

Two exceptions to the Recommended Decision were filed regarding Material Issue Number 4. One exception was filed on behalf of the Board and the other was filed by a tart cherry producer and processor.

The exception filed on behalf of the Board was opposed to the conclusion in the Recommended Decision to not adopt the amendment as proposed by the Board. The proposal would have changed the voting requirements necessary for the Board to pass any action from two-thirds of the entire Board membership to two-thirds of the members present at a meeting. According to the exception, the stringent voting requirement was originally implemented because of a perception that an entity or entities or any particular dominant district in terms of representation on the Board may otherwise have too large an influence on Board actions. The exception stated that due to changes in industry structure, there is no longer a dominant entity or district in terms of Board representation, and a relaxation of the voting requirements would thus be appropriate. In addition, the exception stated that experience under the order has shown no evidence of control over the Board by any entity or region, and based on current industry demographics, no entity or region could gain such control. Finally, the exception states that safeguards exist under the order to protect the concerns of industry members against being adversely affected if the proposed changes to the voting requirements were adopted.

As stated in the Recommended Decision, the super-majority voting requirements were incorporated into the order to help ensure a high degree of support for issues at the Board level. These requirements were included in the order to help ensure minority interests were addressed and that the industry majority supported Board actions. These fundamentals are still relevant today. While it may be true that the industry demographics have changed since the order was promulgated, this does not establish a foundation that the current voting requirements are not working properly and should be changed. The record evidence does not show that the current voting requirements are having a negative impact on Board actions or the Board's ability to conduct business.

The other exception regarding Material Issue Number 4 expressed support for the determination in the Recommended Decision not to implement the proposed amendment.

The record supports leaving the current voting requirements under the

order in place, and the exception advocating a change to the Recommended Decision by adopting Material Issue Number 4 is therefore denied.

Material Issue Number 6—Revising Board Membership Affiliation Requirements

Based upon the briefs and exceptions filed, the findings and conclusions in Material Issue Number 6 of the Recommended Decision are amended by adding the following eight paragraphs to read as follows:

Six exceptions concerning Material Issue Number 6 were received. Five of the exceptions were from tart cherry growers and processors, and one was from the Board.

Five of the exceptions expressed concerns with the interaction of Material Issue Number 6 and Material Issue Number 5 as these two issues were discussed in the Recommended Decision. The amendment proposed by the Board and discussed in Material Issue Number 5 of the Recommended Decision would revise Board membership nomination procedures. The amendment would require a handler to receive support from handler(s) that handled at least five percent of the average production of tart cherries in the applicable district in order to be eligible to participate as a candidate in an election for Board membership. The proposed amendment would also require a handler to receive support from handler(s) that handled at least five percent of the average production of tart cherries in the applicable district in order to be elected by the industry and recommended to the Secretary for selection to the Board. The amendment proposed by the Board and discussed in Material Issue Number 6 of the Recommended Decision would revise Board membership affiliation requirements to allow more than one Board member per district to be affiliated with the same sales constituency if it cannot be avoided.

The Recommended Decision included adding a provision to the proposal in Material Issue Number 5 to conform to the proposed amendment to § 930.20 (g). The added provision would not apply the five percent support requirement for Board membership candidates in instances where such a requirement would result in a sales constituency conflict. (A sales constituency conflict is considered to exist if two persons from the same district are affiliated with the same sales constituency.)

The five exceptions that expressed concern with the interaction of Material Issues 5 and 6 were opposed to the provisions added in the Recommended Decision regarding not applying the five percent support requirement in certain instances. These exceptions stated that the five percent support requirement should apply in all situations, regardless of potential sales constituency conflicts. According to these exceptions, having support from handlers with a minimum of five percent of the volume of cherries handled in the district requirement is more important than avoiding a potential sales constituency conflict. These exceptions further state that avoiding a sales constituency conflict is not as big an issue now as it was when the order was promulgated because the structure of the industry has changed and one sales constituency could no longer gain control of the Board. The exceptions also state that this amendment should not apply in one District but not another.

One exception expressed the view that the proposed amendment to revise Board membership affiliation requirements to allow more than one Board member per district to be from the same sales constituency if it cannot be avoided, should only apply in situations that are identical to those currently prevailing in Utah. In Utah, a situation occurred where there were no candidates from a different sales constituency that were willing to serve on the Board. Consequently, Utah (District 7) was unable to fill a Board position for a period of time.

One of the exceptions indicated that if the five percent support requirement was not applied in certain instances, it would preclude other handler candidates from seeking nomination and election if their election would present a sales constituency conflict.

The Recommended Decision took into account both the merits of the proposed amendment requiring Board candidates to receive support from handlers handling at least five percent of the volume in the District to be nominated and elected to the Board and also the merits of the proposed amendment to allow a sales constituency conflict to exist in Board membership if such a situation cannot be avoided, in the interest of each District achieving its allocated representation on the Board. The added provision in Material Issue Number 5 recognizes the importance of both issues. The changes would not preclude any qualified handler from seeking his or her candidacy for nomination or election to the Board. Any qualified handler would be able to seek a Board position, including those who may present a sales constituency conflict with an existing Board member. The effect of the changes to the proposal would relieve those handlers that do not present a sales constituency conflict from the five percent support requirements. This would provide opportunity to avoid a sales constituency conflict among Board members if the handler without a sales constituency conflict were to win the election. In addition, this requirement would be the same in all districts. Although it currently appears to be an issue only in Utah at this time, as the record indicates and the exceptions note, changes and affiliations in the industry occur over time. It could possibly be an issue in another district in the future, and if so, it would be applied the same in all instances.

In order to address the issues raised as a result of the interaction of the provisions in proposals in Material Issue Numbers 5 and 6, and to maintain an open election process that allows all qualified handler candidates to participate, USDA believes the proposed provisions as presented in the Recommended Decision are appropriate. The exceptions are therefore denied.

Rulings on Exceptions

In arriving at the findings and conclusions and the regulatory provisions of this decision, the exceptions to the Recommended Decision were carefully considered in conjunction with the record evidence. To the extent that the findings and conclusions and the regulatory provisions of this decision are at variance with the exceptions, such exceptions are denied.

Marketing Agreement and Order

Annexed hereto and made a part hereof is the document entitled "Order Amending the Order Regulating the Handling of Tart Cherries Grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin." This document has been decided upon as the detailed and appropriate means of effectuating the foregoing findings and conclusions.

It is hereby ordered, that this entire decision be published in the **Federal Register**.

Referendum Order

It is hereby directed that a referendum be conducted in accordance with the procedure for the conduct of referenda (7 CFR part 900.400–407) to determine whether the annexed order amending the order regulating the handling of tart cherries grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin is approved or favored by

growers and processors, as defined under the terms of the order, who during the representative period were engaged in the production or processing of tart cherries in the production area.

The representative period for the conduct of such referendum is hereby determined to be July 1, 2008 through June 30, 2009.

The agents of the Secretary to conduct such referendum are hereby designated to be Kenneth G. Johnson and Patricia A. Petrella, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, Suite 2A04, Unit 155, 4700 River Road, Riverdale, MD 20737; telephone: (301) 734–5243, Fax: (301) 734–5275; E-mail *Kenneth.Johnson@ams.usda.gov or Patricia.Petrella@ams.usda.gov*.

List of Subjects in 7 CFR Part 930

Marketing agreements, Reporting and recordkeeping requirements, Tart cherries.

Dated: January 6, 2010.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

Order Amending the Order Regulating the Handling of Tart Cherries Grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin [1]

Findings and Determinations

The findings and determinations hereinafter set forth are supplementary to the findings and determinations that were previously made in connection with the issuance of the marketing agreement and order; and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) Findings and Determinations Upon the Basis of the Hearing Record

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended, (7 U.S.C. 601–612), and the applicable rules of practice and procedure effective thereunder (7 CFR part 900), a public hearing was held upon proposed amendment of Marketing Agreement and Order No. 930 (7 CFR part 930), regulating the handling of tart cherries grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin. Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The marketing agreement and order, as amended, and as hereby proposed to be further amended, and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

(2) The marketing agreement and order, as amended, and as hereby proposed to be further amended, regulate the handling of tart cherries grown in the production area in the same manner as, and are applicable only to, persons in the respective classes of commercial and industrial activity specified in the marketing agreement and order upon which a hearing has been held;

(3) The marketing agreement and order, as amended, and as hereby proposed to be further amended, are limited in their application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

(4) The marketing agreement and order, as amended, and as hereby proposed to be further amended, prescribe, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of tart cherries grown in the production area; and

(5) All handling of tart cherries grown in the production area as defined in the marketing agreement and order is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

Order Relative to Handling

It is therefore ordered, That on and after the effective date hereof, all handling of tart cherries grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin shall be in conformity to, and in compliance with the terms and conditions of the said order as hereby proposed to be amended as follows:

The provisions of the proposed marketing agreement and order amending the order contained in the Recommended Decision issued on May 7, 2009, and published in the **Federal Register** on May 12, 2009, will be and are the terms and provisions of this order amending the order and are set forth in full herein.

PART 930—TART CHERRIES GROWN IN THE STATES OF MICHIGAN, NEW YORK, PENNSYLVANIA, OREGON, UTAH, WASHINGTON, AND WISCONSIN

1. The authority citation for 7 CFR part 930 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Revise paragraph (g) of § 930.20 to read as follows:

§ 930.20 Establishment and Membership.

* * * * *

(g) In order to achieve a fair and balanced representation on the Board, and to prevent any one sales constituency from gaining control of the Board, not more than one Board member may be from, or affiliated with, a single sales constituency in those districts having more than one seat on the Board; *Provided*, That this prohibition shall not apply in a district where such a conflict cannot be avoided. There is no prohibition on the number of Board members from differing districts that may be elected from a single sales constituency which may have operations in more than one district. However, as provided in § 930.23, a handler or grower may only nominate Board members and vote in one district.

* * * * *

3. In § 930.23 revise paragraphs (b)(2) and (b)(5), redesignate paragraph (c)(3) as paragraph (c)(3)(i), add a new paragraph (c)(3)(ii), and revise paragraph (c)(4) to read as follows:

§ 930.23 Nomination and Election.

* * * * *

(b) * * *

(2) In order for the name of a handler nominee to appear on an election ballot, the nominee's name must be submitted with a petition form, to be supplied by the Secretary or the Board, which contains the signature of one or more handler(s), other than the nominee, from the nominee's district who is or are eligible to vote in the election and that handle(s) a combined total of no less than five percent (5%) of the average production, as that term is used § 930.20, handled in the district. *Provided*, that this requirement shall not apply if its application would result in a sales constituency conflict as provided in § 930.20(g). The requirement that the petition form be signed by a handler other than the nominee shall not apply in any district where fewer than two handlers are eligible to vote.

* * * * *

(5) In districts entitled to only one Board member, both growers and handlers may be nominated for the

[1] This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

district's Board seat. Grower and handler nominations must follow the petition procedures outlined in paragraphs (b)(1) and (b)(2) of this section.

* * * * *

(c) * * *

(3)(i) * * *

(ii) To be seated as a handler representative in any district, the successful candidate must receive the support of handler(s) that handled a combined total of no less than five percent (5%), of the average production, as that term is used in § 930.20, handled in the district; *Provided*, that this paragraph shall not apply if its application would result in a sales constituency conflict as provided in § 930.20(g).

(4) In districts entitled to only one Board member, growers and handlers may vote for either the grower or handler nominee(s) for the single seat allocated to those districts.

* * * * *

4. Revise paragraph (i) of § 930.50 to read as follows:

§ 930.50 Marketing policy.

* * * * *

(i) *Restricted Percentages.* Restricted percentage requirements established under paragraphs (b), (c), or (d) of this section may be fulfilled by handlers by either establishing an inventory reserve in accordance with § 930.55 or § 930.57 or by diversion of product in accordance with § 930.59. In years where required, the Board shall establish a maximum percentage of the restricted quantity which may be established as a primary inventory reserve such that the total primary inventory reserve does not exceed 50-million pounds; *Provided*, That such 50-million-pound quantity may be changed upon recommendation of the Board and approval of the Secretary. Any such change shall be recommended by the Board on or before September 30 of any crop year to become effective for the following crop year, and the quantity may be changed no more than one time per crop year. Handlers will be permitted to divert (at plant or with grower diversion certificates) as much of the restricted percentage requirement as they deem appropriate, but may not establish a primary inventory reserve in excess of the percentage established by the Board for restricted cherries. In the event handlers wish to establish inventory reserve in excess of this amount, they may do so, in which case it will be classified as a secondary inventory reserve and will be regulated accordingly.

* * * * *

5. Add a new paragraph (d) to § 930.54 to read as follows:

§ 930.54 Prohibition on the use or disposition of inventory reserve cherries.

* * * * *

(d) Should the volume of cherries held in the primary inventory reserves and, subsequently, the secondary inventory reserves reach a minimum amount, which level will be established by the Secretary upon recommendation from the Board, the products held in the respective reserves shall be released from the reserves and made available to the handlers as free tonnage.

6. Revise paragraph (b) of § 930.55 to read as follows:

§ 930.55 Primary inventory reserves.

* * * * *

(b) The form of the cherries, frozen, canned in any form, dried, or concentrated juice, placed in the primary inventory reserve is at the option of the handler. The product(s) placed by the handler in the primary inventory reserve must have been produced in either the current or the preceding two crop years. Except as may be limited by § 930.50(i) or as may be permitted pursuant to §§ 930.59 and 930.62, such inventory reserve portion shall be equal to the sum of the products obtained by multiplying the weight or volume of the cherries in each lot of cherries acquired during the fiscal period by the then effective restricted percentage fixed by the Secretary; *Provided*, That in converting cherries in each lot to the form chosen by the handler, the inventory reserve obligations shall be adjusted in accordance with uniform rules adopted by the Board in terms of raw fruit equivalent.

* * * * *

[FR Doc. 2010–315 Filed 1–12–10; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0027; Directorate Identifier 2008–NM–204–AD]

RIN 2120–AA64

Airworthiness Directives; Sicma Aero Seat 9140, 9166, 9173, 9174, 9184, 9188, 9196, 91B7, 91B8, 91C0, 91C2, 91C3, 91C4, 91C5, and 9301 Series Passenger Seat Assemblies; and Sicma Aero Seat 9501311–05, 9501301–06, 9501311–15, 9501301–16, 9501441–30, 9501441–33, 9501311–55, 9501301–56, 9501441–83, 9501441–95, 9501311–97, and 9501301–98 Passenger Seat Assemblies; Installed on Various Transport Category Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as: Cracks have been found on seat backrest links P/N (part number) 90–000200–104–1 and 90–000200–104–2. These cracks can significantly affect the structural integrity of seat backrests. Failure of the backrest links could result in injury to an occupant during emergency landing conditions. The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by March 1, 2010.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Sicma Aero Seat, 7, Rue Lucien Coupet, 36100 ISSOUDUN, France; telephone +33 (0) 2 54 03 39 39; fax +33 (0) 2 54 03 39 00; e-mail: *customerservices@sicma.zodiac.com;* Internet *http://www.sicma.zodiac.com/en/*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Lee, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7161; fax (781) 238–7170.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2010–0027; Directorate Identifier 2008–NM–204–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We have lengthened the 30-day comment period for proposed ADs that address MCAI originated by aviation authorities of other countries to provide adequate time for interested parties to submit comments. The comment period for these proposed ADs is now typically 45 days, which is consistent with the comment period for domestic transport ADs.

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

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, has issued French Airworthiness Directive 2001–605(AB), dated December 12, 2001 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> Cracks have been found on seat backrest links P/N (part number) 90–000200–104–1 and 90–000200–104–2. These cracks can significantly affect the structural integrity of seat backrests. Therefore a life limit is introduced on the links. On 9g seats also affected by this problem, stronger unlimited life limits have been developed and their installation has been rendered mandatory. However, on 16g seats the affected links have a direct influence on certification dynamic tests and cannot be replaced by similar stronger links without performing again all dynamic tests for each seat part number.

Failure of the backrest links could result in injury to an occupant during emergency landing conditions. The required actions include a general visual inspection for cracking of backrest links, replacement with new links if cracking is found, and eventual replacement of all links with new links.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Sicma Aero Seat has issued Service Bulletin 90–25–012, Issue 4, dated December 19, 2001, including Annex 1, Issue 1, dated July 9, 2001. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

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

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect 70,073 seats on 163 products of U.S. registry. We also estimate that it would take 1 work-hour per seat to comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour. Required parts would cost about $0 per seat. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $5,605,840, or $80 per seat.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on

the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Sicma Aero Seat: Docket No. FAA–2010–0027; Directorate Identifier 2008–NM–204–AD.

Comments Due Date

(a) We must receive comments by March 1, 2010.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Sicma Aero Seat 9140, 9166, 9173, 9174, 9184, 9188, 9196, 91B7, 91B8, 91C0, 91C2, 91C3, 91C4, 91C5, and 9301 series passenger seat assemblies; and Sicma Aero Seat 9501311–05, 9501301–06, 9501311–15, 9501301–16, 9501441–30, 9501441–33, 9501311–55, 9501301–56, 9501441–83, 9501441–95, 9501311–97, and 9501301–98 passenger seat assemblies; identified in Annex 1, Issue 1, dated July 9, 2001, of Sicma Aero Seat Service Bulletin 90–25–012, Issue 4, dated December 19, 2001; that have backrest links part numbers (P/Ns) 90–000200–104–1 and 90–000200–104–2; and that are installed on, but not limited to the airplanes identified in Table 1 of this AD, certificated in any category.

TABLE 1—CERTAIN AFFECTED MODELS

Manufacturer	Model
Airbus	A330–200 and –300 Series Airplanes.
Airbus	A340–200, –300, –500 and –600 Series Airplanes.
The Boeing Company.	777–200, –300, –300ER, and –200LR Series Airplanes.

Note 1: This AD applies to Sicma Aero Seat passenger seat assemblies as installed on any airplane, regardless of whether the airplane has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance according to paragraph (g)(1) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Subject

(d) Air Transport Association (ATA) of America Code 25: Equipment/Furnishings.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Cracks have been found on seat backrest links P/Ns (part numbers) 90–000200–104–1 and 90–000200–104–2. These cracks can significantly affect the structural integrity of seat backrests. Therefore a life limit is introduced on the links. On 9g seats also affected by this problem, stronger unlimited life limits have been developed and their installation has been rendered mandatory. However, on 16g seats the affected links have a direct influence on certification dynamic tests and cannot be replaced by similar stronger links without performing again all dynamic tests for each seat part number.

Failure of the backrest links could result in injury to an occupant during emergency landing conditions. The required actions include a general visual inspection for cracking of backrest links, replacement with new links if cracking is found, and eventual replacement of all links with new links.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) At the later of the times specified in paragraphs (f)(1)(i) and (f)(1)(ii) of this AD, do a general visual inspection for cracking of the backrest links, P/Ns 90–000200–104–1 and 90–000200–104–2, in accordance with Part One "Checking Procedure" of Sicma Aero Seat Service Bulletin 90–25–012, Issue 4, dated December 19, 2001:

(i) Before 6,000 flight hours on the backrest link since new.

(ii) Within 900 flight hours or 5 months after the effective date of this AD, whichever occurs later.

(2) If, during the inspection required by paragraph (f)(1) of this AD, cracking is found between the side of the backrest link and the lock-out pin hole but the cracking does not pass this lock-out pin hole (refer to Figure 2 of Sicma Aero Seat Service Bulletin 90–25–012, Issue 4, dated December 19, 2001): Within 600 flight hours or 3 months after doing the inspection, whichever occurs first, replace both backrest links of the affected seat with new backrest links having the same part number (P/N 90–000200–104–1 or 90–000200–104–2), in accordance with Part Two "Replacement Procedure" of Sicma Aero Seat Service Bulletin 90–25–012, Issue 4, dated December 19, 2001.

(3) If, during the inspection required by paragraph (f)(1) of this AD, cracking is found that passes beyond the lock-out pin hole (refer to Figure 2 of Sicma Aero Seat Service Bulletin 90–25–012, Issue 4, dated December 19, 2001): Before further flight, replace both backrest links of the affected seat with new backrest links having the same part numbers (P/N 90–000200–104–1 or 90–000200–104–2), in accordance with Part Two "Replacement Procedure" of Sicma Aero Seat Service Bulletin 90–25–012, Issue 4, dated December 19, 2001.

(4) If no cracking is found during the inspection required by paragraph (f)(1) of this AD: At the later of the times specified in paragraphs (f)(4)(i) and (f)(4)(ii) of this AD, replace the links, P/Ns 90–000200–104–1 and 90–000200–104–2, with new backrest links having the same part numbers (P/N 90–000200–104–1 or 90–000200–104–2), in accordance with Part Two "Replacement Procedure" of Sicma Aero Seat Service Bulletin 90–25–012, Issue 4, dated December 19, 2001.

(i) Before 12,000 flight hours on the backrest links, P/Ns 90–000200–104–1 and 90–000200–104–2, since new.

(ii) Within 900 flight hours or 5 months after the effective date of this AD, whichever occurs later.

(5) Actions done before the effective date of this AD in accordance with Sicma Aero Seat Service Bulletin 90–25–012, Issue 3, dated October 3, 2001, are acceptable for compliance with the corresponding actions of this AD.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: The MCAI specifies doing repetitive inspections for cracking of links having over 12,000 flight hours since new until the replacement of the link is done. This AD does not include those repetitive inspections because we have reduced the required time for replacing those links. This AD requires replacement of the link before 12,000 flight hours since new, or within 900 flight hours or 5 months of the effective date of this AD, whichever occurs later.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Boston Aircraft Certification Office, FAA, has the authority to

approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Jeffrey Lee, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7161; fax (781) 238–7170. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office.

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

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI French Airworthiness Directive 2001–605(AB), dated December 12, 2001, and Sicma Aero Seat Service Bulletin 90–25–012, Issue 4, dated December 19, 2001, including Annex 1, Issue 1, dated July 9, 2001, for related information.

Issued in Renton, Washington, on January 5, 2010.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010–484 Filed 1–12–10; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 312

Children's Online Privacy Protection Rule Safe Harbor Proposed Self-Regulatory Guidelines; i-SAFE, Inc. Application for Safe Harbor

AGENCY: Federal Trade Commission (FTC or Commission)

ACTION: Notice announcing submission of proposed "safe harbor" guidelines and requesting public comment.

SUMMARY: The Federal Trade Commission publishes this notice and request for public comment concerning proposed self-regulatory guidelines submitted by i-SAFE, Inc. under the safe harbor provision of the Children's Online Privacy Protection Rule.

FOR FURTHER INFORMATION CONTACT: Mamie Kresses, Attorney, (202) 326-2070, Division of Advertising Practices, Federal Trade Commission, Washington, D.C. 20580.

DATES: Written comments must be received by March 1, 2010.

ADDRESSES: Interested parties are invited to submit written comments electronically or in paper form, by following the instructions in the Invitation To Comment part of the **SUPPLEMENTARY INFORMATION** section below. Comments in electronic form should be submitted by using the following weblink: (*https://public.commentworks.com/ftc/iSAFEsafeharbor*) (and following the instructions on the web-based form). Comments in paper form should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex E), 600 Pennsylvania Avenue, NW, Washington, DC 20580, (202) 326-2252.

SUPPLEMENTARY INFORMATION:

Section A. Background

On October 20, 1999, the Commission issued its final Rule[1] pursuant to the Children's Online Privacy Protection Act, 15 U.S.C. 6501, *et seq*, which became effective on April 21, 2000.[2] The Rule requires certain website operators to post privacy policies, provide notice, and obtain parental consent prior to collecting, using, or disclosing personal information from children. The Rule contains a "safe harbor" provision enabling industry groups or others to submit to the Commission for approval self-regulatory guidelines that would implement the Rule's protections.[3]

Pursuant to Section 312.10 of the Rule, iSAFE has submitted proposed self-regulatory guidelines to the Commission for approval. The full text of the proposed guidelines is available on the Commission's website, at (*www.ftc.gov/bcp/isafesafeharborapplication.pdf*).

Section B. Questions on the Proposed Guidelines

The Commission is seeking comment on various aspects of the proposed guidelines, and is particularly interested in receiving comment on the questions that follow. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted. Responses to these questions should cite the numbers and subsection of the questions being answered. For all comments submitted, please provide any relevant data, statistics, or any other evidence, upon which those comments are based.

1. Please provide comments on any or all of the provisions in the proposed guidelines. For each provision commented on please describe (a) the impact of the provision(s) (including any benefits and costs), if any, and (b) what alternatives, if any, iSAFE should consider, as well as the costs and benefits of those alternatives.

2. Do the provisions of the proposed guidelines governing operators' information practices provide "the same or greater protections for children" as those contained in Sections 312.2-312.8 of the Rule?[4] Where possible, please cite the relevant sections of both the Rule and the proposed guidelines.

3. Are the mechanisms used to assess operators' compliance with the guidelines effective?[5] If not, please describe (a) how the proposed guidelines could be modified to satisfy the Rule's requirements, and (b) the costs and benefits of those modifications.

4. Are the incentives for operators' compliance with the guidelines effective?[6] If not, please describe (a) how the proposed guidelines could be modified to satisfy the Rule's requirements, and (b) the costs and benefits of those modifications.

5. Do the guidelines provide adequate means for resolving consumer complaints? If not, please describe (a) how the proposed guidelines could be modified to resolve consumer complaints adequately, and (b) the costs and benefits of those modifications.

Section C. Invitation to Comment

All persons are hereby given notice of the opportunity to submit written data, views, facts, and arguments addressing the proposed self-regulatory guidelines. The Commission invites written comments to assist it in ascertaining the facts necessary to reach a determination as to whether to approve the proposed guidelines. Written comments must be received on or before March 1, 2010, and may be submitted electronically or in paper form. Comments should refer to "iSAFE Safe Harbor Proposal, P094504" to facilitate the organization of comments. Please note that your comment – including your name and your state – will be placed on the public record of this proceeding, including on the publicly accessible FTC website, at

[1] 64 FR 59888 (1999).

[2] 16 C.F.R. Part 312.

[3] *See* 16 C.F.R. § 312.10; 64 FR at 59906-59908, 59915.

[4] *See* 16 C.F.R. § 312.10(b)(1); 64 FR at 59915.

[5] *See* 16 C.F.R. § 312.10(b)(2); 64 FR at 59915.

[6] *See* 16 C.F.R. § 312.10(b)(3); 64 FR at 59915.

(*http://www.ftc.gov/os/publiccomments.shtm*).

Because comments will be made public, they should not include any sensitive personal information, such as any individual's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential. . . ," as provided in Section 6(f) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c).[7]

Because paper mail addressed to the FTC is subject to delay due to heightened security screening, please consider submitting your comments in electronic form. Comments filed in electronic form should be submitted by using the following weblink: (*https://public.commentworks.com/ftc/iSAFEsafeharbor*) (and following the instructions on the web-based form). To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the weblink (*https://public.commentworks.com/ftc/iSAFEsafeharbor*). If this document appears at (*http://www.regulations.gov/search/Regs/home.html#home*), you may also file an electronic comment through that website. The Commission will consider all comments that regulations.gov forwards to it. You may also visit the FTC Website at (*http://www.ftc.gov*) to read the document and the news release describing it.

A comment filed in paper form should include the "iSAFE Safe Harbor Proposal, P094504" reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex E), 600 Pennsylvania Avenue, NW, Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC website, to the extent practicable, at (*http://www.ftc.gov/os/publiccomments.shtm*). As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Website. More information, including routine uses permitted by the Privacy Act may be found in the FTC's privacy policy, at (*http://www.ftc.gov/ftc/privacy.shtm*).

By direction of the Commission.

Donald S. Clark

Secretary

[FR Doc. 2010–291 Filed 1–12–10: 8:45 am]

BILLING CODE 6750–01–S

[7] The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[REG–137036–08]

RIN 1545–BI21

Section 3504 Agent Employment Tax Liability

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to employment tax liability of agents authorized by the Secretary under section 3504 of the Internal Revenue Code (Code) to perform acts required of employers with respect to taxes under the Federal Unemployment Tax Act on wages paid for home care services, as defined in these regulations. These proposed regulations affect employers who are home care service recipients, as defined in these regulations, and their designated agents. These regulations also propose amendments to modify the existing regulations under section 3504 to be consistent with the organizational structure of the Internal Revenue Service (IRS), and to update the citation to the Internal Revenue Code of 1986.

DATES: Written or electronic comments must be received by April 13, 2010.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–137036–08), Room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington DC 20044. Submissions may be hand delivered Monday through Friday, between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–137036–08), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Additionally, taxpayers may submit comments electronically via the Federal eRulemaking Portal at *http://www.regulations.gov.* (Indicate IRS and REG–137036–08.)

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, contact Selvan Boominathan at (202) 622–0047; concerning the submission of comments or requests for a hearing, contact Oluwafunmilayo (Funmi) Taylor, at (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Federal, State, and local government programs seek to help elderly or disabled individuals maintain their independence by funding home health care and other personal services. See, for example, Deficit Reduction Act of 2005, Public Law 109–171, se. 6071, 120 Stat. 4, 102–110 (2006) (authorizing the Secretary of Health and Human Services to, among other things, award grants to states to "[i]ncrease the use of home and community-based, rather than institutional, long-term care services.") The government agencies that administer the programs seek to assist the service recipients with employment tax compliance by helping the service recipients to designate agents to report, file, and pay employment taxes on their behalf. The IRS and the Treasury Department are proposing changes to the regulations under section 3504, the section under which a third party can be authorized to act as an agent for an employer, to permit designated agents to provide comprehensive assistance to these service recipients who are employers.

1. Employment Taxes in General

Employers are generally required to withhold income tax and Federal

Insurance Contributions Act (FICA) taxes from their employees' wages under sections 3402(a) and 3102(a), respectively, and are separately liable for the employer's share of FICA taxes and Federal Unemployment Tax Act (FUTA) taxes under sections 3111 and 3301, respectively (collectively referred to herein as "employment taxes"). Sections 3102(b), 3111, 3301, and 3403 provide that the employer is the person liable for the withholding and payment of employment taxes; additionally, the employer is required to make tax deposits, file employment tax returns, and file and furnish Forms W–2, *Wage and Tax Statement,* to employees (collectively referred to herein as "employment tax obligations"). An *employer* is generally defined as the person for whom an individual performs services as an employee. See Sections 3121(d), 3306(a), and 3401(d).

FUTA tax is imposed under section 3301 on each employer in an amount equal to a percentage of wages paid by the employer with respect to employment. FUTA tax is imposed on the employer in an amount equal to 6.2 percent of wages. Under section 3306(b), wages of an employee subject to the FUTA tax are limited to $7,000 per calendar year. Section 3302 provides for a credit against FUTA tax in the amount of contributions paid by the employer into an unemployment fund maintained during the taxable year under the unemployment law of a State. The credit is limited to an amount equal to 90 percent of the FUTA tax.

2. Domestic Service Employment

The employment tax obligations of an employer are modified with respect to domestic services provided in a private home of the employer. Employers are not required to withhold income taxes on wages paid for domestic services, but may enter into a voluntary withholding agreement to withhold income taxes from one or more domestic employees. See sections 3401(a)(3) and 3402(p). An employer is not liable for FICA taxes with respect to cash wages for domestic services as long as the cash wages are less than an applicable dollar threshold amount, which is adjusted annually. Sections 3121(a)(7)(B) and 3121(x). When the cash wages equal or exceed the threshold amount, all of the cash wages (including amounts below the threshold) paid to that employee by the employer are subject to FICA taxes. For example, the FICA wage threshold for domestic services for 2009 is $1,700. This threshold applies separately to each employer with respect to each employee. An employer is liable for FUTA taxes with regard to domestic services if the employer paid aggregate wages of $1,000 or more (for all domestic employees) in any calendar quarter in the current or prior year. Section 3306(c)(2).

3. Agency Relationship Under Code Section 3504

Section 3504 of the Code authorizes the Secretary of the Treasury to promulgate regulations to authorize an agent to perform certain specified acts required of employers. Under section 3504, all provisions of law (including penalties) applicable with respect to employers are applicable to the agent and remain applicable to the employer. Accordingly, both the agent and employer are liable for the employment taxes and penalties associated with the employer's employment tax obligations undertaken by the agent. Section 31.3504–1 of the Employment Tax Regulations provides that the IRS may authorize an agent to undertake the employment tax obligations of an employer with respect to income tax withholding and FICA taxes. The agent is required to file only one return for each tax return period using the agent's own employer identification number (EIN) regardless of the number of employers for whom the agent acts. The current regulations do not authorize an agent to undertake the employment tax obligations of an employer with respect to the FUTA tax. Thus, an authorized agent can act on behalf of the employer for income tax withholding and FICA tax purposes, but the employer must continue to meet its employment tax obligations with respect to FUTA tax.

4. Home Care Service Recipients

Federal, State, and local governments fund programs to provide elderly or disabled individuals with services to assist them with health care or other personal needs in their homes or communities. Following an evolution in policy that seeks to empower the individuals receiving services to have autonomy, these programs generally give the service recipients discretion in selecting the service providers and directing their activities. See Deficit Reduction Act of 2005 section 6071(d)(2)(C)(ii), 120 Stat. at 108 (providing that the Secretary of Health and Human Services shall give preference when awarding grants to state applications proposing to provide eligible individuals with the opportunity to receive home and community-based long-term care services as self-directed services); also see "Roadmap to Medicaid Reform," Centers for Medicare and Medicaid Services, available at *http://www.cms.hhs.gov/smdl/downloads/Rvltcneeds.pdf.* The programs authorize the use of certain intermediaries to serve as agents to disburse payments to service providers on the service recipient's behalf. The federal, State, or local government agencies that administer these programs screen intermediaries before they are entrusted with funds to pay for the services. Intermediaries can be public or private entities. Many are nonprofit organizations. The IRS addressed questions with regard to certain intermediaries working with state or local government agencies in previous guidance. See Notice 2003–70, 2003 CB 916. See § 601.601(d)(2).

The service recipient is generally the employer of the individuals providing the services for employment tax purposes. However the Service recognizes that there are some government programs under which parents, grandparents, or guardians who are engaged in providing care for a disabled child or grandchild receive funding that do not give rise to an employment relationship between the service recipient and the care provider. Although the services generally constitute domestic services under section 3401(a)(3) such that income tax withholding is not required, FICA tax and FUTA tax must still be paid subject to the applicable thresholds, and some service recipients and their service providers may agree to voluntarily withhold income tax under section 3402(p). In recent years, many home care service recipients have applied to designate the intermediary that arranges to pay their service providers as an agent under section 3504 so that the intermediary can withhold, report, and pay income tax withholding and FICA tax on the service recipient's behalf. Designating these intermediaries as agents reduces the administrative burden on the service recipient who may not otherwise have an obligation to report, file, or pay employment taxes. The intermediaries have access to training in compliance with employment tax requirements and have the payroll information from the payments they make to the service providers. An intermediary that is designated as an agent can efficiently handle reporting, filing, and paying income tax withholding and FICA on behalf of multiple service recipients on a single return. A service recipient can complete the application to designate the intermediary as agent at the time the recipient enrolls with the intermediary.

Under the current regulations, a service recipient can designate an intermediary as agent to handle income

tax withholding and FICA but cannot designate an intermediary as agent to pay FUTA tax and file FUTA returns. As a result, separate FUTA returns must be prepared for thousands of individual service recipients reporting small amounts of wages and FUTA tax.

Explanation of Provisions

These proposed regulations would amend the current regulations to allow a home care service recipient to designate an agent under section 3504 to report, file, and pay all employment taxes, including FUTA. This change will allow an intermediary to file a single FUTA return on behalf of multiple home care service recipients as the intermediary does currently with respect to income tax withholding and FICA.

Specifically, the proposed regulation would amend the employment tax regulations under section 3504 to provide that the IRS may authorize a party to act as agent on behalf of employers who are home care service recipients with respect to FUTA taxes imposed on wages paid for home care services, provided that the party has been authorized to act as an agent for those home care service recipients for income tax withholding and FICA tax purposes. The agent is permitted to act for FUTA tax purposes only on behalf of employers who are home care service recipients, and not for any other type of employer on whose behalf the agent is authorized to act for income tax withholding and FICA tax purposes. Additionally, the agent is permitted to act as an agent for FUTA tax purposes only with respect to wages paid for home care services rendered to the home care service recipient.

These regulations propose to define the term *home care service recipient* as an individual who is an enrolled participant in a program administered by a Federal, State, or local government agency that provides Federal, State, or local government funds to pay, in whole or in part, for the provision of home care services, as defined in the proposed regulations. A participant qualifies as a home care service recipient while enrolled in such a program and until the end of the calendar year in which the participant ceases to be enrolled in the program. In all such programs, intermediaries who are engaged to assist beneficiaries to receive and distribute funds on the beneficiaries' behalf are reviewed and approved by a state or local government agency.

These regulations propose to define *home care services* to include health care and personal attendant care services rendered to a home care service recipient in his home or local community. Services provided outside the home care service recipient's private home may qualify as home care services for purposes of these regulations even if the services do not qualify as domestic service in a private home of the employer for purposes of sections 3121(a)(7), 3306(c)(2), and 3401(a)(3), so long as the services are provided within the service recipient's local community.

Because section 3504 provides that all provisions of law applicable to an employer apply to the agent, the agent can report on its aggregate FUTA tax return the state unemployment contributions paid into a state unemployment fund on the home care service recipient's behalf as a credit under section 3302 against the FUTA tax. The credit can be reported by the agent regardless of whether the state unemployment contributions are made under the name and state identifying number of the home care service recipient or the agent.

These regulations also propose amendments to modify the existing regulations under section 3504 to be consistent with the organizational structure of the IRS and to update the citation to the Internal Revenue Code of 1986.

Proposed Effective Date

These regulations are proposed to apply to wages paid on or after January 1 of the calendar year following the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register.** Taxpayers may rely on these proposed regulations for guidance pending the issuance of final regulations. Additionally, pursuant to section 7805(b)(7), taxpayers may apply these proposed regulations to all taxable years for which a valid designation as an agent has been in effect under § 31.3504–1(a) of the Employment Tax Regulations. Thus, prior to publication of a Treasury decision adopting these rules as final regulations, any party already authorized under section 3504 to serve as an agent for a home care service recipient, as defined in the proposed regulations, or with an application pending, will not need to file any additional application in order to expand the scope of the agency to cover FUTA taxes.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written or electronic comments that are submitted timely to the IRS. The Treasury Department and the IRS specifically request comments on the clarity of the proposed regulations and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing will be scheduled and held upon written request by any person who submits written comments on the proposed regulation. If a public hearing is scheduled, notice of the time and place for the hearing will be published in the **Federal Register.**

Drafting Information

The principal author of these proposed regulations is Selvan Boominathan, Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), Internal Revenue Service. However, personnel from other offices of the IRS and Treasury participated in their development.

List of Subjects in 26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Reporting and recordkeeping requirements, Railroad retirement, Social Security, Unemployment compensation.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 31 is proposed to be amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

Paragraph 1. The authority citation for part 31 continues to read in part as follows:

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

Par. 2. Section 31.3504–1 is revised to read as follows:

§ 31.3504–1 Designation of Agent by Application.

(a) *In general.* In the event wages as defined in chapter 21 or 24 of the Internal Revenue Code of 1986, or compensation as defined in chapter 22 of the Code, of an employee or group of employees, employed by one or more employers, is paid by a fiduciary, agent, or other person ("agent"), or if that agent has the control, receipt, custody, or disposal of those wages, or compensation, the Internal Revenue Service may, subject to the terms and conditions as it deems proper, authorize that agent to perform the acts required of the employer or employers under those provisions of the Code and the regulations which have application, for purposes of the taxes imposed by the chapter or chapters, in respect of the wages or compensation. If the agent is authorized by the Internal Revenue Service to perform such acts, all provisions of law (including penalties) and of the regulations applicable to an employer shall be applicable to the agent. However, each employer for whom the agent acts shall remain subject to all provisions of law (including penalties) and of the regulations applicable to an employer. Any application to authorize an agent to perform such acts, signed by the agent and the employer, shall be made on the form prescribed by the Internal Revenue Service and shall be filed with the Internal Revenue Service as prescribed in the instructions to the form and other applicable guidance.

(b) *Special rule for home care service recipients.* (1) *In general.* In the event a fiduciary, agent, or other person ("agent") is authorized pursuant to paragraph (a) of this section to perform the acts required of an employer under chapters 21 or 24 on behalf of one or more home care service recipients, as defined in paragraph (b)(3) of this section, the Internal Revenue Service may authorize that agent to perform the acts as are required of employers for purposes of the tax imposed by chapter 23 of the Internal Revenue Code of 1986 with respect to wages paid for home care services, as defined in paragraph (b)(2) of this section, rendered to the home care service recipient. Each home care service recipient for whom the agent performs the acts of an employer and each agent authorized under this section to perform the acts of an employer shall remain subject to all provisions of law (including penalties) and of the regulations applicable to an employer with respect to those wages paid.

(2) *Home care services.* For purposes of this section, the term *home care services* includes health care and personal attendant care services rendered in the home care service recipient's home or local community.

(3) *Home care service recipient.* For purposes of this section, the term *home care service recipient* means any individual who receives home care services, as defined in paragraph (b)(2) of this section, while enrolled, and for the remainder of the calendar year after ceasing to be enrolled, in a program administered by a Federal, state, or local government agency that provides Federal, state, or local government funds, to pay, in whole or in part, for the home care services for that individual.

(c) *Effective and applicability dates.* An authorization under paragraph (a) of this section in effect prior to the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register** continues to be in effect after that date. Paragraph (b) of this section applies to wages paid on or after January 1 of the calendar year following the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register.** However, pursuant to section 7805(b), taxpayers may rely on paragraph (b) of this section for all taxable years for which a valid designation is in effect under paragraph (a) of this section.

Linda M. Kroening,

Acting Deputy Commissioner for Services and Enforcement.

[FR Doc. 2010–415 Filed 1–12–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–1021]

RIN 1625–AA09

Drawbridge Operation Regulation; New Haven Harbor, Quinnipiac and Mill Rivers, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulation governing the operation of three bridges across the Quinnipiac and Mill Rivers at New Haven, Connecticut, to relieve the bridge owner from the burden of crewing the bridges during time periods when the bridges seldom receive requests to open while still providing for the reasonable needs of navigation.

DATES: Comments and related material must be received by the Coast Guard on or before February 12, 2010.

ADDRESSES: You may submit comments identified by docket number USCG–2009–1021 using any one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Fax:* 202–493–2251.
- *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.
- *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.

To avoid duplication, please use only one of these methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Judy Leung-Yee, Project Officer, U.S. Coast Guard; telephone 212–668–7165, e-mail *judy.k.leung-yee@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.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2009–1021), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (*http://www.regulations.gov*), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be

considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand delivery, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rules" and insert "USCG–2009–1021" in the "Keyword" box. Click "Search" then click on the balloon shape in the "Actions" column. 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 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 may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble 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–2009–1021" and click "Search." Click the "Open Docket Folder" in the "Actions" column. You may also visit either 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of 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 a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES.** Please explain why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register.**

Background and Purpose

The Ferry Street Bridge at mile 0.7, across the Quinnipiac River has a vertical clearance in the closed position of 25 feet at mean high water and 31 feet at mean low water.

The Grand Avenue Bridge at mile 1.3, across the Quinnipiac River has a vertical clearance in the closed position of 9 feet at mean high water and 15 feet at mean low water.

The Chapel Street Bridge at mile 0.4, across the Mill River has a vertical clearance of 7 feet at mean high water and 13 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.213.

The City of New Haven, the owner of the bridges, requested a change to the drawbridge operation regulations for the Ferry Street Bridge across Quinnipiac River at mile 0.7, the Grand Avenue Bridge across the Quinnipiac River at mile 1.3, and the Chapel Street Bridge at mile 0.4, across the Mill River, all at New Haven, Connecticut.

During the past four years the Ferry Street Bridge has undergone a major rehabilitation. During the rehabilitation project the movable spans were removed or left in the open position at various times allowing navigation to pass at all times.

Now that the Ferry Street Bridge is fully operational again, the bridge owner would like to change the drawbridge operation schedule for all its bridges, the Ferry Street Bridge, the Grand Avenue Bridge and the Chapel Street Bridge, to help reduce the burden of crewing these bridges during time periods when there have been few requests to open the bridges.

The waterway users are seasonal recreational craft, commercial fishing, and construction vessels.

The existing drawbridge operation regulation listed at 33 CFR 117.213, authorizes a roving crew concept that requires the draw of the Ferry Street Bridge to open on signal from October 1 through April 30, between 9 p.m. and 5 a.m. unless the draw tender is at the Grand Ave or Chapel Street bridges, in which case, a delay of up to one hour in opening is permitted.

The bridge owner would like to extend the above roving crew concept to be in effect year round.

As a result, the Coast Guard implemented a temporary test deviation (74 FR 27249) on June 9, 2009, to test the proposed changes to the drawbridge operation schedule in order to help us determine whether a permanent change to the schedule would satisfactorily accomplish the bridge owners goal and also continue to meet the reasonable needs of navigation.

The test period was in effect from May 1, 2009 through October 26, 2009. Satisfactory results were received from the test insofar as there were no adverse impacts to navigation. In addition, we received no objection to the operation schedule during or after the test period ended. As a result of the successful test, we are proposing to permanently change the drawbridge regulations for the three bridges.

The operation regulation schedule for the Tomlinson Bridge, which is owned by the Connecticut Department of Transportation, will not be changed by this action and will continue to operate as listed in the existing regulation.

Discussion of Proposed Rule

Under this proposed rule the Ferry Street Bridge, the Grand Avenue Bridge, and the Chapel Street Bridge would operate as follows:

The Ferry Street Bridge across Quinnipiac River at mile 0.7, would open on signal for all marine traffic; except that, from 7:30 a.m. to 8:30 a.m. and 4:45 p.m. to 5:45 p.m., weekdays except Federal holidays, the draw need not be opened for the passage of vessel traffic. From 9 p.m. to 5 a.m., the draw would open on signal if at least a one hour advance notice is given to the draw tender at the Chapel Street Bridge by calling (203) 946–7618.

The Grand Avenue Bridge across Quinnipiac River at mile 1.3, would open on signal for all marine traffic; except that, from 7:30 a.m. to 8:30 a.m. and 4:45 p.m. to 5:45 p.m., weekdays except Federal holidays, the draw need not be opened for the passage of vessel traffic. From 9 p.m. to 5 a.m. the draw would open on signal if at least a one hour advance notice is given to the draw tender at the Chapel Street Bridge by calling (203) 946–7618.

The Chapel Street Bridge across the Mill River at mile 0.4, would open on signal for all marine traffic; except that, from 7:30 a.m. to 8:30 a.m. and 4:45 p.m. to 5:45 p.m., weekdays except Federal holidays, the draw need not be opened for the passage of vessel traffic. From 9 p.m. to 5 a.m. the draw would open on signal if at least a one hour

advance notice is given to the draw tender by calling (203) 946–7618.

Under the existing regulation all the above bridges are allowed to remain closed from noon to 12:15 and from 12:45 to 1 p.m. in addition to the morning and afternoon rush hour time periods. The noon time closure periods, noon to 12:15 and 12:25 to 1 p.m., will be removed from all the above bridges, except the Tomlinson Bridge.

The Coast Guard is also removing obsolete language from the regulation as part of this action. Paragraphs (4)(b) through (4)(f) shall be removed because they are now listed under Subpart A—General Requirements, § 117.31 and § 117.15, and are redundant as a result.

Regulatory Analyses

We developed this proposed 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.

Regulatory Planning and Review

This proposed rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. This conclusion is based upon the fact that we tested the above drawbridge operation schedule and found that it met the reasonable needs of navigation.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This action will not have a significant economic impact on a substantial number of small entities for the following reasons. A test period was in effect from May 1, 2009 through October 26, 2009. Satisfactory results were received from the test insofar as there were no adverse impacts to navigation. In addition, we received no objection to the operation schedule during or after the test period ended and found that the operation schedule met the reasonable needs of navigation.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see* **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Commander (dpb), First Coast Guard District, Bridge Branch, One South Street, New York, NY 10004. The telephone number is (212) 668–7165. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

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 or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule 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.

Civil Justice Reform

This proposed 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.

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these

standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01, and Commandant Instruction M16475.lD which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment because it simply promulgates the operating regulations or procedures for drawbridges. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

2. Revise § 117.213 to read as follows:

§ 117.213 New Haven Harbor, Quinnipiac and Mill Rivers.

The draws of the Tomlinson Bridge, mile 0.0, the Ferry Street Bridge, mile 0.7, and the Grand Avenue Bridge, mile 1.3, across the Quinnipiac River, and the Chapel Street Bridge, mile 0.4, across the Mill River, shall operate as follows:

(a) The draw of the Tomlinson Bridge at mile 0.0, across the Quinnipiac River shall open on signal; except that, from 7:30 a.m. to 8:30 a.m., noon to 12:15 p.m., 12:45 p.m. to 1 p.m., and 4:45 p.m. to 5:45 p.m., Monday through Friday, except Federal holidays, the draw need not open for the passage of vessel traffic.

(b) The draw of the Ferry Street Bridge at mile 0.7, across Quinnipiac River, shall open on signal; except that, from 7:30 a.m. to 8:30 a.m. and 4:45 p.m. to 5:45 p.m., Monday through Friday, except Federal holidays, the draws need not open for the passage of vessel traffic. From 9 p.m. to 5 a.m. the draw shall open on signal if at least a one-hour advance notice is given by calling the number posted at the bridge.

(c) The draw of the Grand Avenue Bridge at mile 1.3, across the Quinnipiac River shall open on signal; except that, from 7:30 a.m. to 8:30 a.m. and 4:45 p.m. to 5:45 p.m., Monday through Friday, except Federal holidays, the draw need not open for the passage of vessel traffic. From 9 p.m. to 5 a.m. the draw shall open on signal if at least a one-hour advance notice is given by calling the number posted at the bridge.

(d) The draw of the Chapel Street Bridge at mile 0.4, across the Mill River shall open on signal; except that, from 7:30 a.m. to 8:30 a.m. and 4:45 p.m. to 5:45 p.m., Monday through Friday, except Federal holidays, the draw need not open for the passage of vessel traffic. From 9 p.m. to 5 a.m. the draw shall open on signal after at least a one-hour advance notice is given by calling the number posted at the bridge.

Dated: December 28, 2009.

Joseph L. Nimmich,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2010–435 Filed 1–12–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R2-ES-2009-0091; BFY2009-92210-1117-0000-B2]

Endangered and Threatened Wildlife and Plants; Determination That Designation of Critical Habitat is Prudent for the Jaguar

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of determination.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), under the Endangered Species Act of 1973, as amended (Act), have reconsidered our prudency determination concerning the designation of critical habitat for the jaguar (*Panthera onca*) and now find that designation of critical habitat is prudent. We are preparing a proposed designation of critical habitat for the jaguar in accordance with the Act this fiscal year and anticipate we will publish a proposed designation in January 2011.

DATES: To be considered in the proposed critical habitat designation, comments and information should be submitted to us by March 15, 2010.

ADDRESSES: You may submit comments by one of the following methods:

• Electronically: Go to the *Federal eRulemaking Portal*: *http://www.regulations.gov*. In the Keyword box, enter Docket No. [FWS-R2-ES-2009-0091], which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on "Send a Comment or Submission."

• By hard copy: Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS-R2-ES-2009-0091; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see Public Comment Procedures and Public Availability of Comments under **SUPPLEMENTARY INFORMATION** for more information).

FOR FURTHER INFORMATION CONTACT: Steve Spangle, Field Supervisor, Arizona Ecological Services Office, 2321 West Royal Palm Road, Suite 103, Phoenix, AZ 85021-4951; telephone (602) 242-0210; facsimile (602) 242-2513. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

The jaguar, a large member of the cat family (Felidae), is an endangered species that currently occurs from southern Arizona and New Mexico to southern South America. Jaguars in the United States are part of a population, or populations, that occur in Mexico. Below we present a summary of relevant information we used in making our determination that designating critical habitat in the United States for the jaguar is prudent. For more information regarding all aspects of the jaguar, refer to documents posted on our jaguar webpage (*http://www.fws.gov/southwest/es/arizona/Jaguar.htm*), and Jaguar Conservation Team documents and notes (*www.azgfd.gov/w_c/es/*

jaguar_management.shtml), and the literature cited there.

Jaguars in the United States historically occurred in California, Arizona, New Mexico, Texas, and possibly Louisiana (62 FR 39147; July 22, 1997). The last confirmed jaguar sightings in California, Texas, and Louisiana were in the late 1800s or early 1900s. While jaguars have been documented as far north as the Grand Canyon, sightings in the United States from 1996 to the present have occurred mainly within approximately 40 miles (mi) (64.4 kilometers (km)) of the international boundary of the United States and Mexico. Based on documented sightings in the late 20th century, occurrences in the United States at the time of the July 22, 1997, listing (62 FR 39147) were limited to southeastern Arizona and southwestern New Mexico.

Recently (1996 through 2009), four or possibly five jaguars have been documented in the United States (McCain and Childs 2008, p. 5; Service files). Of those, two jaguars were photographed in the United States in 1996: one on March 7 in the Peloncillo Mountains, located along the Arizona—New Mexico border (Glenn 1996; Brown and Lopez Gonzalez 2001, p. 6), and another on August 31 in the Baboquivari Mountains in southern Arizona (Childs 1998, p. 7; Brown and Lopez Gonzalez 2001, p. 6). In February 2006, a third jaguar was observed and photographed in Hidalgo County, New Mexico. Using camera traps, jaguars were photographed in the United States near the Arizona—Mexico border beginning in 2001, and as recently as February 2009. This survey effort resulted in the detection of the male jaguar originally observed in the Baboquivari Mountains in 1996 referred to above; and possibly a fifth jaguar that was unidentified and not determined as to sex. No females or kittens were detected as a result of this monitoring effort. Monitoring of jaguars with the use of camera traps in the United States has been geographically limited in scope (from the crest of the Baboquivari Mountains east to the San Rafael Valley and approximately 50 mi (80 km) north of the international boundary) (McCain and Childs 2008, p. 5). Therefore, we cannot make conclusions regarding the presence of other jaguars, including females and kittens, outside the scope of this monitoring effort.

We are not aware of any comprehensive rangewide population estimates for jaguars; however, Chávez and Ceballos (2006, p. 10) report the jaguar population in Mexico is estimated at less than 5,000, and Rabinowitz (as cited by Nowell and Jackson 1996, p. 121) estimated Belize's jaguar population at between 600 and 1,000 individuals. Experts reported 5,680 observations of jaguars (some of these are likely observations of the same animal) at 535 separate locations throughout the entire range during the last 10 years (Sanderson *et al.* 2002, p. 62). There are estimates of jaguar densities ranging from 1.7 to 4 adults per 38.6 square mi (100 square km) in Brazil, Peru, Colombia, and Mexico, with the highest density found in Belize (6-8 per 100 square km) (International Union for the Conservation of Nature (IUCN) 2008, p. 5).

Critical Habitat

Critical habitat is defined in section 3 of the Act as—(i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and, (ii) specific areas outside the geographical area occupied by a species at the time it was listed, upon a determination that such areas are essential for the conservation of the species. "Conservation" means the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

Section 4(a)(3) of the Act, as amended, and its implementing regulations at 50 CFR 424.12, require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time a species is determined to be endangered or threatened. According to our regulations in the Code of Federal Regulations (CFR) at (50 CFR 424.12(a)(1)) designation of critical habitat is not prudent when one or both of the following situations exist—(1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species.

Previous Federal Actions

In 1972, the jaguar was listed as endangered (37 FR 6476; March 30, 1972) in accordance with the Endangered Species Conservation Act of 1969, a precursor to the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*). Under the Endangered Species Conservation Act, the Service maintained separate listings for foreign species and species native to the United States. At that time, the jaguar was believed to be extinct in the United States; thus, the jaguar was only included on the foreign species list. The jaguar's range was described as extending from the international boundary of the United States and Mexico southward to include Central and South America (37 FR 6476). On July 22, 1997, we published a final listing rule that extended endangered status for the jaguar into the United States (62 FR 39147). For more information on previous Federal actions concerning the jaguar, please refer to the July 22, 1997, final listing rule (62 FR 39147).

The July 22, 1997, listing rule included a determination that designation of critical habitat for the jaguar was not prudent (62 FR 39147). At that time we determined that the greatest threat to the jaguar in the United States was from direct taking of individuals through shooting or other means. As a consequence, we determined that designating critical habitat for the jaguar was "not prudent," because "publication of detailed critical habitat maps and descriptions in the **Federal Register** would likely make the species more vulnerable to activities prohibited under section 9 of the Act," and therefore increase the degree of threat to the species.

In response to a complaint by the Center for Biological Diversity, we agreed to re-evaluate our 1997 prudency determination and make a new determination as to whether designation of critical habitat for the jaguar was prudent by July 3, 2006. In that subsequent finding (July 12, 2006; 71 FR 39335), we noted that since the time of our July 22, 1997, determination, the Jaguar Conservation Team, Arizona Game and Fish Department, publications, and other sources routinely have given specific and general locations of jaguars that have been sighted and currently are being documented in the United States through websites, public notifications, reports, books, and meeting notes. Publishing critical habitat maps and descriptions, as part of designating critical habitat, would not result in the species being more vulnerable in the United States than it is currently. We then assessed whether designation of critical habitat would be beneficial to the species. We found that no areas in the United States meet the definition of critical habitat and, as a result, designation of critical habitat for the jaguar would not be beneficial to the species. As a result, we again

determined that designation of critical habitat for the jaguar was not prudent (71 FR 39335). We did not consider designation of lands outside of the United States in this analysis, because, under the Act's implementing regulations, critical habitat cannot be designated in foreign countries (50 CFR 424.12(h)).

The Center for Biological Diversity again challenged the Service's decision that critical habitat was not prudent for the jaguar. On March 30, 2009, the United States District Court for the District of Arizona (Court) issued an opinion in *Center for Biological Diversity* v. *Kempthorne*, CV 07-372-TUC JMR (Lead) and *Defenders of Wildlife* v. *Hall*, CV08-335 TUC JMR (Consolidated) (D. Ariz., Mar. 30, 2009) that set aside our previous prudency determination and required that we issue a new determination as to "whether to designate critical habitat," i.e., whether such designation is prudent, by January 8, 2010. In this opinion, the Court noted, among other things, that the Service's regulations at 50 CFR 424.12(b) require that the Service "shall focus on the principal biological constituent elements within the defined area that are essential to the conservation of the species." Such elements include consideration of space for individual and population growth, and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing of offspring, germination, or seed dispersal; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.

Prudency Determination

As instructed by the Court, we have reevaluated our previous "not prudent" finding regarding critical habitat designation for the jaguar and the information supporting our previous findings. We have also evaluated information and analysis that has become available to us subsequent to the July 12, 2006, finding. As discussed in the **Background** section above, jaguars have been found in the United States in the past and may occur in the United States now or in the future. As such, there are physical and biological features that can be used by jaguars in the United States. Thus, in responding to the Court's order, and following a review of the best available information, including the ongoing conservation programs for the jaguar, we now determine that the designation of critical habitat for the jaguar would be beneficial. We also determine that designation of critical habitat will not be expected to increase the degree of threat to the species. As such, we no longer find that designation of critical habitat for the jaguar is not prudent under our regulations, and conversely, therefore determine that designation is prudent. We discuss below how we intend to proceed with developing a proposed designation of critical habitat for the jaguar.

How the Service Intends to Proceed

We intend to begin preparation of proposed rulemaking for the jaguar in Fiscal Year 2010 and publish a proposed critical habitat designation in January 2011. Based on the best available science, we will take the following steps to develop a proposal of critical habitat for the jaguar: (1) Determine the geographical area occupied by the species at the time of listing; (2) identify the physical or biological features essential to the conservation of the species; (3) delineate areas within the geographical area occupied by the species that contain these features, and identify the special management considerations or protections the features may require; (4) delineate any areas outside of the geographical area occupied by the species at the time of listing that are essential for the conservation of the species; (5) conduct appropriate analyses under section 4(b)(2) of the Act; and (6) invite the public to review and provide comments on the proposed critical habitat rule through a public comment period.

To aid us in completing these steps, we will use the best science available, including but not limited to Boydston and López González 2005, Brown and López González 2000, Brown and López González 2001, Carrillo *et al.* 2007, Cavalcanti 2008, Ceballos *et al.* 2006, Chávez and Ceballos 2006, Chávez *et al.* 2007a, Chávez *et al.* 2007b, Grigione *et al.* 2007, Grigione *et al.* 2009, Hatten *et al.* 2002, Hatten *et al.* 2005, Marieb 2005, McCain and Childs 2008, Medellin *et al.* 2002, Menke and Hayes 2003, Monroy-Vichis *et al.* 2007, Navarro Serment *et al.* 2005, Núxntilde;ez *et al.* 2002, Oropeza Hernández *et al.* 2009, Robinson 2006, Rosas Rosas 2006, Sanderson *et al.* 2002, and Sierra Institute 2000. We also solicit the public for additional information (see **Request for Public Information** section below) and will consult experts on the jaguar, including experts on the jaguar in the northern portion of its range.

While the proposed designation of critical habitat for the jaguar is under preparation, the areas occupied by jaguars in the United States will continue to be subject to conservation actions implemented under section 7(a)(1) of the Act, as well as consultation pursuant to section 7(a)(2) of the Act for Federal activities that may affect jaguars, as determined on the basis of the best available scientific information at the time of the action. In addition, the prohibition of taking jaguars under section 9 of the Act (e.g., prohibitions against killing, harming, harassing, and capturing jaguars) continues to apply, which addresses the single greatest threat to the species in the United States, as discussed in the final listing rule.

We will also continue to use our authorities to work with agencies and other partners in the United States, Mexico, and Central and South America to conserve and recover jaguars. We are working with the Jaguar Conservation Team and other partners to develop and implement a framework for the conservation of the northern jaguar populations, including providing recommendations on research needs and procedures in the United States, continuing education efforts, and providing recommendations regarding predator control in areas where jaguars may occur. We are also working with Mexican partners, such as Naturalia and La Comisión Nacional de áreas Protegidas (CONANP) and other partners on jaguar conservation in Mexico through the Trilateral Commission and other processes. The Service's Wildlife Without Borders program has funded and will likely continue to fund jaguar conservation projects throughout the range of the jaguar in Latin America. Mexico and countries in Central and South America, along with their nongovernmental partners, are continuing conservation efforts, including implementing research programs and developing conservation plans. Specifically, Federal and State agencies in Mexico are developing jaguar conservation plans; we intend to coordinate with Mexico in their development to maintain travel corridors for jaguars into the United States.

Request for Public Information

We intend that any designation of critical habitat for the jaguar be as accurate as possible. Therefore, we will continue to accept additional information and comments from all concerned governmental agencies, the scientific community, industry, or any other interested party concerning this finding. We are particularly interested in information concerning:

(1) The amount and distribution of jaguar habitat, both throughout its range and within the United States;

(2) The physical and biological features of jaguar habitat that are essential to the conservation of the species;

(3) Special management considerations or protections that the features essential to the conservation of the jaguar may require, including managing for the potential effects of climate change;

(4) Any areas that are essential to the conservation of the jaguar throughout its range and why;

(5) The areas in the United States that were occupied at the time of listing that contain features essential to the conservation of the species;

(6) The areas in the United States that were not occupied at the time of listing, but are essential to the conservation of the species and why;

(7) Land use designations and current or planned activities in jaguar habitats and their possible impacts on proposed critical habitat;

(8) Conservation programs and plans that protect the jaguar and its habitat; and

(9) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

Public Comment Procedures

To ensure that any final action resulting from this finding will be as accurate and as effective as possible, we request that you send relevant information for our consideration. The comments that will be most useful and likely to influence our decisions are those that you support by quantitative information or studies and those that include citations to, and analyses of, the applicable laws and regulations. Please make your comments as specific as possible and explain the bases for them. In addition, please include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

You must submit your comments and materials concerning this finding by one of the methods listed above in the **ADDRESSES** section. We will not accept comments sent by e-mail or fax or to an address not listed in **ADDRESSES**. If you submit a comment via *http://www.regulations.gov*, your entire comment—including any personal identifying information, such as your address, telephone number, or e-mail address—will be posted on the Web site. Please note that comments submitted to this Web site are not immediately viewable. When you submit a comment, the system receives it immediately. However, the comment will not be publicly viewable until we post it, which might not occur until several days after submission.

If you mail or hand-carry a hardcopy comment directly to us that includes personal information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. To ensure that the electronic docket for this finding is complete and all comments we receive are publicly available, we will post all hardcopy comments on *http://www.regulations.gov*.

In addition, comments and materials we receive, as well as supporting documentation used in preparing this finding, will be available for public inspection in two ways:

(1) You can view them on *http://www.regulations.gov*. In the Search Documents box, enter FWS-R2-ES-2009-0091, which is the docket number for this action. Then, in the Search panel on the left side of the screen, select the type of documents you want to view under the Document Type heading.

(2) You can make an appointment, during normal business hours, to view the comments and materials in person at the Arizona Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Public Availability of Comments

As stated above in more detail, before including your address, phone number, e-mail 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.

References Cited

A complete list of references cited is available on the Internet at Docket No. FWS-R2-ES-2009-0091 at *http://www.regulations.gov* and upon request from the Arizona Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Author(s)

The primary author of this notice is the staff of the U.S. Fish and Wildlife Service.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: December 30, 2009.

Eileen Sobeck,

Acting Assistant Secretary for Fish, Wildlife and Parks.

[FR Doc. 2010–479 Filed 1–12–10; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2008–0130; MO 92210–0–0008–B2]

Endangered and Threatened Wildlife and Plants; Partial 90-Day Finding on a Petition to List 475 Species in the Southwestern United States as Threatened or Endangered With Critical Habitat; Correction

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 90-day petition finding; correction.

SUMMARY: On Wednesday, December 16, 2009, we, the U.S. Fish and Wildlife Service, announced a 90-day finding on 192 species from a petition to list 475 species in the Southwest region of the United States as threatened or endangered under the Endangered Species Act of 1973, as amended (Act). In that notice, we used an incorrect docket number in one place and asked commenters submitting hardcopy comments to refer to this docket number in their comments. The correct docket number is [FWS–R2–ES–2008–0130]. However, comments we received under the incorrect docket number will be routed to the correct docket. If you already submitted a comment, even with the incorrect docket number, you need not resubmit it.

DATES: To allow us adequate time to conduct a status review, we request that we receive information on or before February 16, 2010.

ADDRESSES: You may submit information by one of the following methods:

- *Federal rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments to Docket no. FWS–R2–ES–2008–0130.
- *U.S. Mail or hand delivery:* Public Comments Processing, Attn: FWS–R2–ES–2008–0130, Division of Policy and Directives Management, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive,

Suite 222, Arlington, VA 22203. We will post all information received on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Request for Information section in our original notice—74 FR 66865—for more information).

FOR FURTHER INFORMATION CONTACT: Sarah Quamme, Listing Coordinator, Southwest Regional Ecological Services Office, 500 Gold Avenue, SW., Albuquerque, NM 87102; telephone 505–248–6920. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION: On Wednesday, December 16, 2009, we announced a 90-day finding on 192 species from a petition we received to list 475 species in the Southwest region of the United States as threatened or endangered under the Act (16 U.S.C. 1531 *et seq.*) (74 FR 66865). We found that the petition presented substantial information indicating that 67 of the 192 species may warrant listing as threatened or endangered. When we make a finding that a petition presents substantial information indicating that listing a species may be warranted, we are required to promptly review the status of the species (status review). For the status review to be complete and based on the best available scientific and commercial information, we requested information on each of the 67 species from governmental agencies, Native American Tribes, the scientific community, industry, and any other interested parties.

In that notice, we asked commenters to refer to an incorrect docket number when submitting comments via U.S. mail or hand delivery. The correct docket number is [FWS–R2–ES–2008–0130], and our instructions to persons submitting comments electronically included the correct docket number. All hardcopy comments received under the incorrect docket number will be routed to the correct docket. If you already submitted a comment, even with the incorrect docket number, you need not resubmit it. For more information about the species, background, and our finding, see our original notice at 74 FR 66865.

Sara Prigan,

Federal Register Liaison.

[FR Doc. 2010–454 Filed 1–12–10; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 0912281446–91447–01]

RIN 0648–XT32

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications

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

ACTION: Proposed rule.

SUMMARY: NMFS proposes a regulation to implement the annual harvest guideline (HG) and seasonal allocations for Pacific sardine in the U.S. exclusive economic zone (EEZ) off the Pacific coast for the fishing season of January 1, 2010, through December 31, 2010. This rule is proposed according to the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). The proposed 2010 acceptable biological catch (ABC) or maximum HG is 72,039 mt. 5,000 mt of this 72,039 mt would initially be set aside for use under an Exempted Fishing Permit (EFP), if issued, leaving the remaining 65,732 mt as the initial commercial fishing HG. That HG would be divided across the seasonal allocation periods in the following way: January 1–June 30, 22,463 mt would be allocated for directed harvest with an incidental set-aside of 1,000 mt; July 1–September 14, 25,861 mt would be allocated for directed harvest with an incidental set-aside of 1,000 mt; September 15–December 31, 11,760 mt would be allocated for directed harvest with an incidental set-aside of 1,000 mt with an additional 4,000 mt set aside to buffer against reaching the ABC. This rule is intended to conserve and manage Pacific sardine off the West Coast.

DATES: Comments must be received by February 2, 2010.

ADDRESSES: You may submit comments on this proposed rule identified by 0648–XT32 by any of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov*
- Mail: Rodney R. McInnis, Regional Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802.
- Fax: (562)980–4047

Instructions: No comments will be posted for public viewing until after the comment period has closed. All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields if you prefer to remain anonymous). You may submit attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the report "Assessment of Pacific Sardine Stock for U.S. Management in 2010" may be obtained from the Southwest Regional Office (see the Mailing address above).

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, Southwest Region, NMFS, (562) 980–4034.

SUPPLEMENTARY INFORMATION: The CPS FMP, which was implemented by publication of the final rule in the **Federal Register** on December 15, 1999 (64 FR 69888), divides management unit species into two categories: actively managed and monitored. Harvest guidelines for actively managed species (Pacific sardine and Pacific mackerel) are based on formulas applied to current biomass estimates. Biomass estimates are not calculated for species that are only monitored (jack mackerel, northern anchovy, and market squid).

During public meetings each year, the biomass for each actively managed species within the CPS FMP is presented to the Pacific Fishery Management Council's (Council) CPS Management Team (Team), the Council's CPS Advisory Subpanel (Subpanel) and the Council's Scientific and Statistical Committee (SSC). At that time, the biomass, the ABC and the status of the fisheries are reviewed and discussed. This information is then presented to the Council along with HG recommendations and comments from the Team, Subpanel and SSC. Following review by the Council and after hearing public comment, the Council makes its HG recommendation to NMFS.

In November 2009, the Council adopted and recommended to NMFS an ABC or maximum HG of 72,039 mt for the 2010 Pacific sardine fishing year. This ABC is based on a biomass estimate of 702,204 mt and the harvest control rule established in the CPS FMP. This ABC/HG is slightly higher than the ABC/HG for the 2009 fishing season,

which was 66,932 mt. The Council also recommended that 5,000 mt of the available 2010 ABC/HG be initially reserved for research activities that would be undertaken under a potential exempted fishing permit (EFP). In 2009, 2,400 mt was subtracted from the total HG for an EFP. The Council will hear proposals and comments on any potential EFPs at the March Council meeting and make a final recommendation to NMFS on whether or not to issue an EFP(s) for the 5,000 mt research set aside at their April 2010 Council meeting. NMFS will likely make a decision on whether or not to issue an EFP some time prior to the start of the second seasonal period (July 1, 2010). Any of the 5,000 mt that is not issued to an EFP will be rolled into the third allocation period's directed fishery. Any research set aside attributed to an EFP designed to be conducted during the closed fishing time in the second allocation period (prior to September 15), but not utilized, will roll into the third allocation period's directed fishery. Any research set aside attributed to an EFP designed to be conducted during closed fishing times in the third allocation, but not utilized, will not be re-allocated.

The Council recommended that the remaining 67,039 mt (HG of 72,039 mt minus proposed 5,000 mt EFP set aside) be used as the initial overall fishing HG and be allocated across the seasonal periods established by Amendment 11 (71 FR 36999). The Council also recommended an incidental catch set aside of 3,000 mt and a management uncertainty buffer of 4,000 mt. Subtracting this set aside from the initial overall HG establishes an initial directed harvest fishery of 60,039 mt and an incidental fishery of 3,000 mt. The purpose of the incidental fishery is to allow for the restricted incidental landings of Pacific sardine in other fisheries, particularly other CPS fisheries, if and when a seasonal directed fishery is closed.

The directed harvest levels and incidental set-aside would be initially allocated across the three seasonal allocation periods in the following way: January 1–June 30, 22,463 mt would be allocated for directed harvest with an incidental set aside of 1,000 mt; July 1–September 14, 25,861 mt would be allocated for directed harvest with an incidental set aside of 1,000 mt; September 15–December 31, 11,760 mt would be allocated for directed harvest with an incidental set aside of 1,000 mt. If during any of the seasonal allocation periods the applicable adjusted directed harvest allocation is projected to be taken, fishing would be closed to directed harvest and only incidental harvest would be allowed. For the remainder of the period, any incidental Pacific sardine landings would be counted against that period's incidental set-aside. The proposed incidental fishery would also be constrained to a 30 percent by weight incidental catch rate when Pacific sardine are landed with other CPS so as to minimize the targeting of Pacific sardine. In the event that an incidental set aside is projected to be attained, all fisheries will be closed to the retention of Pacific sardine for the remainder of the period. If the set-aside is not fully attained or is exceeded in a given seasonal period, the directed harvest allocation in the following seasonal period would automatically be adjusted to account for the discrepancy. Additionally, if during any seasonal period the directed harvest allocation is not fully attained or is exceeded, then the following period's directed harvest total would be adjusted to account for this discrepancy as well.

If the total HG or these apportionment levels for Pacific sardine are reached or are expected to be reached, the Pacific sardine fishery would be closed via appropriate rulemaking until it re-opens either per the allocation scheme or the beginning of the next fishing season. The Regional Administrator would publish a notice in the **Federal Register** announcing the date of such closures.

Detailed information on the fishery and the stock assessment are found in the report "Assessment of Pacific Sardine Stock for U.S. Management in 2010" (see **ADDRESSES**).

The formula in the CPS FMP uses the following factors to determine the HG:

1. *Biomass.* The estimated stock biomass of Pacific sardine age one and above for the 2010 management season is 702,204 mt.

2. *Cutoff.* This is the biomass level below which no commercial fishery is allowed. The FMP established this level at 150,000 mt.

3. *Distribution.* The portion of the Pacific sardine biomass estimated in the EEZ off the Pacific coast is 87 percent and is based on the average historical larval distribution obtained from scientific cruises and the distribution of the resource according to the logbooks of aerial fish-spotters.

4. *Fraction.* The harvest fraction is the percentage of the biomass above 150,000 mt that may be harvested. The fraction used varies (5–15 percent) with current ocean temperatures; a higher fraction for warmer ocean temperatures and a lower fraction for cooler temperatures. Warmer ocean temperatures favor the production of Pacific sardine. For 2010, the fraction used was 15 percent, based on three seasons of sea surface temperature at Scripps Pier, California.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable law, subject to further consideration after public comment.

These proposed specifications are exempt from review under Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities as follows:

The purpose of this proposed rule is to implement the 2010 HG for Pacific sardine in the U.S. EEZ off the Pacific coast. The CPS FMP and its implementing regulations require NMFS to set an annual HG for the Pacific sardine fishery based on the harvest formula in the FMP. The harvest formula is applied to the current stock biomass estimate to determine the ABC, from which the HG is then derived. The HG is determined using an environmentally-based formula accounting for the effect of ocean conditions on stock productivity.

The HG is apportioned based on the following allocation scheme: 35 percent of the HG is allocated coastwide on January 1; 40 percent of the HG, plus any portion not harvested from the initial allocation is then reallocated coastwide on July 1; and on September 15 the remaining 25 percent, plus any portion not harvested from earlier allocations will be released. If the total HG or these apportionment levels for Pacific sardine are reached at any time, the Pacific sardine fishery is closed until either it re-opens per the allocation scheme or the beginning of the next fishing season. There is no limit on the amount of catch that any single vessel can take during an allocation period or the year; the HG and seasonal allocations are available until fully utilized by the entire CPS fleet.

The small entities that would be affected by the proposed action are the vessels that compose the West Coast CPS finfish fleet. Approximately 109 vessels are permitted to operate in the sardine fishery component of the CPS fishery off the U.S. West Coast; 65 permits in the Federal CPS limited entry fishery off California (south of 39 N. lat.), and a combined 44 permits in Oregon and Washington's state Pacific sardine fisheries. This proposed rule has an equal effect on all of these small entities and therefore will impact a substantial number of these small entities in the same manner. These vessels are considered small business entities by the

U.S. Small Business Administration since the vessels do not have annual receipts in excess of $4.0 million. Therefore, there would be no economic impacts resulting from disproportionality between small and large business entities under the proposed action.

The profitability of these vessels as a result of this proposed rule is based on the average Pacific sardine ex-vessel price per mt. NMFS used average Pacific sardine ex-vessel price per mt to conduct a profitability analysis because cost data for the harvesting operations of CPS finfish vessels was unavailable.

For the 2009 fishing year the maximum HG was set at 66,932 mt. The majority of the HG was harvested during the 2009 fishing season with an estimated coastwide ex-vessel value of $12.5 million. Although the 2009 HG was 25 percent lower than the HG for 2008, due to an increase in ex-vessel price per pound of sardine, coastwide ex-vessel revenue for 2009 was less than $2 million different than revenue for 2008 and above the average ex-vessel revenue achieved from 2002–2007.

The proposed HG for the 2010 Pacific sardine fishing season (January 1, 2010 through December 31, 2010) is 72,039 mt. This HG is slightly higher than the HG for 2009 of 66,932 mt. If the fleet were to take the entire 2010 HG, and assuming a coastwide average ex-vessel price per mt of $187, the potential revenue to the fleet would be approximately $13.5 million. This would be higher than average coastwide ex-vessel value achieved from 2002–2009. Whether this will occur depends greatly on market forces within the fishery and on the regional availability of the resource to the fleets and the fleets' ability to find pure schools of Pacific sardine. A change in the market and/or the potential lack of availability of the resource to the fleets could cause a reduction in the amount of Pacific sardine that is harvested, in turn, reducing the total revenue to the fleet from Pacific sardine.

However, the revenue derived from harvesting Pacific sardine is only one factor determining the overall revenue of a majority of the CPS fleet and therefore the economic impact to the fleet from the proposed action can not be viewed in isolation. CPS finfish vessels typically harvest a number of other species, including anchovy, mackerel, squid, and tuna, making Pacific sardine only one component of a multi-species CPS fishery. A reliance on multiple species is a necessity because each CPS stock is highly associated to present ocean and environmental conditions. Because each species responds to such conditions in its own way, not all CPS stocks are likely to be abundant at the same time; therefore as abundance levels and markets fluctuate, the CPS fishery as a whole has endured by depending on a group of species.

Based on the disproportionality and profitability analysis above, this rule if adopted, will not have a significant economic impact on a substantial number of these small entities.

As a result, an Initial Regulatory Flexibility Analysis is not required and none has been prepared.

This action does not contain a collection-of-information requirement for purposes of the Paper Reduction Act.

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

Dated: January 7, 2010.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2010–496 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register

Vol. 75, No. 8

Wednesday, January 13, 2010

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

Helena National Forest, Montana, Stonewall Vegetation Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Helena National Forest is going to prepare an environmental impact statement for vegetation management actions north and west of the community of Lincoln, MT. Fire suppression and moist growing conditions through much of this century resulted in a loss of open forest conditions and seral species (aspen, ponderosa pine and western larch). This has created a more uniform landscape comprised of dense forests susceptible to insect and wildfire mortality (Douglas-fir and lodgepole pine). In addition, a large-scale mountain pine beetle epidemic has killed most of the mature lodgepole pine and ponderosa pine. These conditions are elevating fuel levels which pose a wildfire threat to nearby homes and communities in the wildland urban interface (WUI).

DATES: Comments concerning the scope of the analysis must be received by February 12, 2010. The draft environmental impact statement is expected August 2010 and the final environmental impact statement is expected January 2011.

ADDRESSES: Send written comments to Amber Kamps, Helena National Forest, 1569 Hwy. 200, Lincoln, MT 59639. Comments may also be sent via e-mail to *comments-northern-Helena@fs.fed.us,* or via facsimile to 406–449–5436.

It is important that reviewers provide their comments at such times and in such a way that they are useful to the Agency's preparation of the EIS. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

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.

FOR FURTHER INFORMATION CONTACT: Amber Kamps at 406–362–7000.

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

The landscape in this project area has become a more uniform dense forest susceptible to insect and wildfire mortality. The mountain pine beetle has caused widespread tree mortality. These conditions have elevated the fuel levels, which in turn pose a threat to nearby homes and communities in the wildland urban interface. The purpose and need for this project includes: improving the mix of vegetation and structure across the landscape so that it is diverse, resilient, and sustainable to wildfire and insects; modifying fire behavior to enhance community protection while creating conditions that allow the reestablishment of fire as a natural process on the landscape; enhancing and restoring aspen, western larch and ponderosa pine species and habitats; utilizing the economic value of trees through removal; and integrating restoration with socioeconomic considerations.

Proposed Action

Approximately 8,600 acres are proposed for treatment. The proposed action includes using both commercial and noncommercial treatments to achieve the desired condition. These actions would include: Regeneration harvests, intermediate harvests, precommercial thinnings, and prescribed burning. Implementing the proposed action could include the use of chainsaws, feller bunchers, and cable logging equipment.

The proposed action also includes using prescribed fire and tree slashing in two roadless areas (Bear Marshall Scapegoat Swan and Lincoln Gulch).

Approximately five miles of road would be built then obliterated immediately following timber removal. Commercial harvest and road construction would not occur in the two roadless areas.

Post treatment activities would include underburning, site preparation burning, jackpot burning, hand piling/burning, tree planting, and monitoring of natural regeneration.

In all the areas proposed, the opening size may exceed 40 acres due to the amount of mortality created by the bark beetles and the resulting need for regeneration.

Responsible Official

Helena National Forest Supervisor.

Nature of Decision To Be Made

The decisions to be made include: Whether to implement the proposed action or an alternative to the proposed action, what monitoring requirements would be appropriate to evaluate the implementation of this project, and whether a forest plan amendment would be necessary as a result of the decision for this project.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. In January 2010, a scoping package will be mailed, an open house will be scheduled, and Web site information will be posted.

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. The submission of timely and specific comments can affect a reviewer's ability to participate in subsequent administrative appeal or judicial review.

Dated: January 6, 2010.

Kevin T. Riordan,

Forest Supervisor.

[FR Doc. 2010–452 Filed 1–12–10; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Meeting; Federal Lands Recreation Enhancement Act (Title VIII, Pub. L. 108–447)

AGENCY: Pacific Northwest Region, Forest Service, USDA.

ACTION: Notice of Meeting.

SUMMARY: The Pacific Northwest Recreation Resource Advisory Committee will meet via a conference call. The purpose of the meeting is to review and provide recommendations on recreation fee proposals for facilities and services offered on lands managed by the Forest Service and Bureau of Land Management in Oregon and Washington, under the Federal Lands Recreation Enhancement Act of 2004.

DATES: The conference call will be held on February 2, 2010 from 12:30 p.m. to 4:30 p.m. A public input session will be provided at 1 p.m. on February 2, 2010. Comments will be limited to three minutes per person.

ADDRESSES: Individuals wishing to participate in the conference call or provide public comment should contact Jocelyn Biro, Recreation Program Coordinator (503) 808–2411 or *jbiro@fs.fed.us.* Send written comments to Dan Harkenrider, Designated Federal Official for the Pacific Northwest Recreation RAC, 902 Wasco Street, Suite 200, Hood River, OR 97031, 541–308–1700 or *dharkenrider@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Dan Harkenrider, Designated Federal Official, 902 Wasco Street, Suite 200, Hood River, OR 97031, 541–308–1700.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Recreation RAC discussion is limited to Forest Service and Bureau of Land Management staff and Recreation RAC members. However, persons who wish to bring recreation fee matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting. A public input session will be provided and individuals who have made written requests by January 29, 2010, to the Designated Federal Official will have the opportunity to address the Committee during the meeting on February 2, 2010, at 1 p.m.

The Recreation RAC is authorized by the Federal Land Recreation Enhancement Act, which was signed into law by President Bush in December 2004.

Dated: January 6, 2010.

Lenise Lago,

Deputy Regional Forester, Pacific Northwest Region.

[FR Doc. 2010–440 Filed 1–12–10; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Eastern Washington Cascades Provincial Advisory Committee and the Yakima Provincial Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of Meeting.

SUMMARY: The Eastern Washington Cascades Provincial Advisory Committee and the Yakima Provincial Advisory Committee will meet on February 3, 2010 at the Okanogan-Wenatchee National Forest Headquarters office, 215 Melody Lane, Wenatchee, WA. During this meeting information will be shared about Holden Mine clean-up operations, Stehekin River Corridor Implementation Plan/Environmental Impact Statement, and Bureau of Land Management Resource Management Plan update. All Eastern Washington Cascades and Yakima Province Advisory Committee meetings are open to the public.

FOR FURTHER INFORMATION CONTACT: Direct questions regarding this meeting to Becki Heath, Designated Federal Official, USDA, Okanogan-Wenatchee National Forest, 215 Melody Lane, Wenatchee, Washington 98801, phone 509–664–9200.

Dated: *January 6, 2010.*

Rebecca Lockett Heath,

Designated Federal Official, Okanogan-Wenatchee National Forest.

[FR Doc. 2010–513 Filed 1–12–10; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2009–0072]

Syngenta Biotechnology, Inc.; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has received a petition from Syngenta Biotechnology, Inc., seeking a determination of nonregulated status for corn designated as transformation event MIR162, which has been genetically engineered for insect resistance. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, we are soliciting comments on whether this genetically engineered corn is likely to pose a plant pest risk. We are also making available for public comment an environmental assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments we receive on or before March 15, 2010.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2009–0072*) to submit or view comments and to view supporting and related materials available electronically.
- Postal Mail/Commercial Delivery: Please send two copies of your comment to Docket No. APHIS–2009–0072, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2009–0072.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at (*http://www.aphis.usda.gov*).

FOR FURTHER INFORMATION CONTACT: Dr. Subray Hegde, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–0810, email: (*subray.hegde@aphis.usda.gov*). To obtain copies of the petition, draft environmental assessment or plant pest risk assessment, contact Ms. Cindy Eck at (301) 734–0667, email: (*cynthia.a.eck@aphis.usda.gov*). Those documents are also available on the Internet at (*http://www.aphis.usda.gov/brs/aphisdocs/07_25301p.pdf*), (*http://*

www.aphis.usda.gov/brs/aphisdocs/07_25301p_pea.pdf) and (*http://www.aphis.usda.gov/brs/aphisdocs/07_25301p_pra.pdf*).

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

On September 10, 2007, APHIS received a petition seeking a determination of nonregulated status (APHIS Petition Number 07–253–01p) from Syngenta Biotechnology, Inc., of Research Triangle Park, NC (Syngenta), for corn (*Zea mays* L.) designated as transformation event MIR162, which has been genetically engineered for insect resistance, stating that corn line MIR162 is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, the MIR162 corn line has been genetically engineered to express the VIP3Aa20 protein. The *VIP3Aa20* gene is based on the sequences from *Bacillus thuringiensis*, a common soil bacterium. The *VIP3Aa20* gene confers tolerance to certain lepidopteran (caterpillar) pests of corn. Expression of the *VIP3Aa20* gene is driven by the corn ubiquitin promoter (ZmUbilnt), and uses the terminator sequence from 35S RNA of cauliflower mosaic virus (CaMV). MIR162 corn also contains the *manA* gene from *E. coli*, which encodes the enzyme phosphomannose isomerase (PMI), and was used only as a selectable marker during transformant selection and confers no other benefits to the transformed corn plant. The *manA* gene is also driven by the ZmUbilnt promoter, and uses the Nopaline Synthase (NOS) gene from *Agrobacterium tumefaciens* as a terminator sequence. All of these sequences are well-characterized and are non-coding regulatory regions only. Therefore, these sequences will not cause the MIR162 corn line to promote plant disease.

A single copy of these genes and other DNA regulatory sequences were introduced into the corn genome with the transformation vector pNOV1300 using disarmed (non-plant pest causing) *A. tumefaciens* transformation. Plant cells containing the introduced DNA were selected by culturing them in sugar mannose. After the initial transformation, the antibiotic cefotoxime was included in the culture medium to kill any remaining *Agrobacterium*. Therefore, no part of the plant pest *A. tumefaciens* remained in Syngenta MIR162 corn due to the transformation method.

Syngenta's MIR162 corn line has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. The MIR162 corn line has been field tested in the United States since 1999 as authorized by USDA APHIS notifications and permits (see appendix A of the petition). In the process of reviewing the permits for field trials of the subject corn, APHIS determined that the vectors and other elements used to introduce the new genes were disarmed and that the trials, which were conducted under conditions of reproductive and physical confinement or isolation, would not present a risk of plant pest introduction or dissemination.

Field tests conducted under USDA APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These data are used by APHIS to determine if the new variety poses a plant pest risk. Syngenta has petitioned APHIS to make a determination that the MIR162 corn line and the progeny derived from its crosses with other nonregulated corn shall no longer be considered regulated articles under 7 CFR part 340.

APHIS has prepared an environmental assessment (EA) in which it presents two alternatives based on its analyses of data submitted by Syngenta, a review of other scientific data, and field tests conducted under APHIS oversight. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of the MIR162 corn line and it would continue to be a regulated article, or (2) grant nonregulated status to corn line MIR162 in whole.

In § 403 of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

The MIR162 corn line is subject to regulation by other Federal agencies. The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt from EPA regulation. In order to be registered as a pesticide under FIFRA, it must be demonstrated that when used with common practices, a pesticide will not cause unreasonable adverse effects in the environment. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA, and the U.S. Food and Drug Administration (FDA) enforce the tolerances set by EPA. Syngenta submitted the appropriate regulatory package to EPA on November 2, 2007, seeking an exemption from the requirement of a tolerance for residues from the Vip3Aa20 protein from *B. thuringiensis*. On August 6, 2008, EPA granted the exemption.

FDA's policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the **Federal Register** on May 29, 1992 (57 FR 22984–23005). Under this policy, FDA uses what is termed a consultation process to ensure that human and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of a bioengineered food. In compliance with the FDA policy, Syngenta submitted a food and feed safety and nutritional assessment

summary to FDA for their MIR162 corn line in 2007. FDA completed their consultation on MIR 162 corn on December 9, 2008, concluding that FDA had "no further questions concerning grain and forage derived from corn event MIR162."

National Environmental Policy Act

A draft EA has been prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status for the MIR162 corn line. The draft EA was prepared in accordance with (1) the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested or affected persons on the draft EA prepared to examine any potential environmental impacts of the proposed determination for the deregulation of the subject corn line, and the plant pest risk assessment. The petition, draft EA, and plant pest risk assessment are available for public review, and copies of the petition, draft EA, and plant pest risk assessment are available as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All public comments received regarding the petition, draft EA, and plant pest risk assessment will be available for public review. After reviewing and evaluating the comments on the petition, the draft EA, plant pest risk assessment and other data, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of the MIR162 corn line and the availability of APHIS' written regulatory and environmental decision.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 6th day of January 2010.

Cindy Smith

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010–407 Filed 1–12–10: 2:16 pm]

BILLING CODE 3410–34–S

COMMISSION ON CIVIL RIGHTS

Hearing on the Department of Justice's Actions Related to the New Black Panther Party Litigation and Its Enforcement of Section 11(b) of the Voting Rights Act

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of hearing.

DATE AND TIME: Friday, February 12, 2010; 9:30 a.m. EST.

PLACE: U.S. Commission on Civil Rights, 624 Ninth Street, NW., Room 540, Washington, DC 20425.

SUMMARY: Notice is hereby given pursuant to the provisions of the Civil Rights Commission Amendments Act of 1994, 42 U.S.C. 1975a, and 45 CFR 702.3, that public hearings before the U.S. Commission on Civil Rights will commence on Friday, February 12, 2010, beginning at 9:30 a.m. EST in Washington, DC at the Commission's offices located at 624 Ninth Street, NW., Room 540, Washington, DC 20425. An executive session not open to the public may be convened at any appropriate time before or during the hearing.

The purpose of this hearing is to collect information within the jurisdiction of the Commission, under 42 U.S.C. 1975a, related particularly to the Department of Justice's actions in the New Black Panther Party Litigation and enforcement of Section 11(b) of the Voting Rights Act.

The Commission is authorized to hold hearings and to issue subpoenas for the production of documents and the attendance of witnesses pursuant to 45 CFR 701.2. The Commission is an independent bipartisan, fact finding agency authorized to study, collect, and disseminate information, and to appraise the laws and policies of the Federal Government, and to study and collect information with respect to discrimination or denials of equal protection of the laws under the Constitution because of race, color, religion, sex, age, disability, or national origin, or in the administration of justice. The Commission has broad authority to investigate allegations of voting irregularities even when alleged abuses do not involve discrimination.

CONTACT PERSON FOR FURTHER INFORMATION: Lenore Ostrowsky, Acting Chief, Public Affairs Unit (202) 376–8591. TDD: (202) 376–8116.

Persons with a disability requiring special services, such as an interpreter for the hearing impaired, should contact Pamela Dunston at least seven days prior to the scheduled date of the hearing at 202–376–8105. TDD: (202) 376–8116.

Dated: January 8, 2010.

David Blackwood,

General Counsel.

[FR Doc. 2010–497 Filed 1–12–10; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–815]

Light–Walled Rectangular Pipe and Tube from Turkey: Extension of Time Limits for Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 13, 2010.

FOR FURTHER INFORMATION CONTACT: Tyler Weinhold or Robert James, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington DC 20230; telephone: (202) 482–1121 and (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

At the request of interested parties, on June 24, 2009, the Department published in the **Federal Register** a notice of initiation of this antidumping duty administrative review. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part*, 74 FR 30052, August 25, 2009. The review covers the period January 30, 2008, through April 30, 2009. The preliminary results for this administrative review is currently due no later than January 31, 2010.

Extension of Time Limits for Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to complete the

preliminary results of an administrative review within 245 days after the last day of the anniversary month of an order for which a review is requested. However, if it is not practicable to complete the review within these time periods, section 751(a)(3)(A) of the Act allows the Department to extend the 245 day time period for the preliminary results up to 365 days.

The Department has determined it is not practicable to complete this review within the statutory time limit because we require additional time to collect and analyze information needed for our preliminary results. Accordingly, the Department is extending the time limits for completion of the preliminary results of this administrative review until no later than May 31, 2010, which is 365 days from the last day of the anniversary month of these orders. We intend to issue the final results in this review no later than 120 days after publication of the preliminary results.

This notice is issued and published in accordance with sections 751(a)(3)(A) and 777(i)(1) of the Act.

Dated: January 7, 2010.

John M. Andersen,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010–493 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XT68

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meetings of the North Pacific Fishery Management Council Ecosystem Committee.

SUMMARY: The North Pacific Fishery Management Council (Council) Aleutian Islands Fishery Ecosystem Plan Team (AI Ecosystem Team) will meet in Seattle, WA, in the NMML conference room (room 2039), from 9 a.m. to 5 p.m., January 27–28, 2010. The Council's Ecosystem Committee will meet jointly with the AI Ecosystem Team on January 28 from 1 p.m. to 5 p.m.

DATES: The meetings will be held on January 27–28, 2010.

ADDRESSES: The meetings will be held at the Atlantic Fisheries Science Center (AFSC), 7600 Sand Point Way NE, Building 4, NMML conference room (room 2039), Seattle, WA.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff, telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The agenda is as follows:

AI Ecosystem Team agenda (January 27–28):

Review new information on AI ecosystem; Review FEP interactions and update as appropriate; Plan for further updates and amendments to the FEP.

Joint Ecosystem Committee and AI Ecosystem Team agenda (January 28, 1–5 p.m.):

Discuss AI Fishery Ecosystem Plan updates, and further action; Discuss NOAA's marine spatial planning framework, and provide recommendations for the Council.

The Agenda is subject to change, and the latest version will be posted at *http://www.alaskafisheries.noaa.gov/npfmc/*

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: January 7, 2010.

Tracey L. Thompson,

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

[FR Doc. 2010–401 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XT67

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) will hold a 3-day Council meeting to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Tuesday, January 26 through Thursday, January 28, 2010. The meeting will begin at 8:30 a.m. on each of the 3 meeting days.

ADDRESSES: The meeting will be held at the Sheraton Harborside Hotel, 250 Market Street, Portsmouth, NH 03801; telephone: (603) 431–2300 and fax: (603) 433–5649.

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:

Tuesday, January 26, 2010

Following introductions and any announcements, the Council will receive a series of brief reports from the Council Chairman and Executive Director, the NOAA Fisheries Northeast Regional Administrator, Northeast Fisheries Science Center and Mid-Atlantic Fishery Management Council liaisons, NOAA General Counsel, representatives of the U.S. Coast Guard and the Atlantic States Marine Fisheries Commission, as well as NOAA Enforcement. These reports will be followed by a review of any experimental fishery permit applications that have been received since the last Council meeting. During the morning session the Council also will review sector implementation as developed in the Northeast Multispecies (Groundfish) Fishery Management Plan (FMP) as part of a report to be provided by the National Marine Fisheries Service Regional Office staff from Gloucester, MA. After a lunch break, the Council will review and provide feedback to the Northeast Fisheries

Science Center on their performance monitoring and evaluation plan concerning existing and future catch share programs. The Council's Herring Committee will present an overview of the management measures proposed in Amendment 4 to the Atlantic Herring FMP, including the establishment of annual catch limits and accountability measures, and select final measures before submitting the action to NMFS. NOAA leadership will present a briefing on its Catch Shares Policy and conduct a question and answer session following the presentation.

Wednesday, January 27, 2010

The second day of the Council meeting will begin with a discussion about and possible reconsideration of Framework 21 to the Atlantic Sea Scallop FMP. Pending the outcome of this agenda item, the Council also may revisit Framework 44 to the Northeast Multispecies FMP to change the yellowtail flounder allocation to the scallop fleet in that action. Later, the Groundfish Committee will ask for approval of alternative rebuilding strategy options for the Georges Bank yellowtail flounder stock. The Chairman of the Scientific and Statistical Committee (SSC) will report on the committee's comments concerning a model developed by the Habitat Plan Development Team (PDT) to analyze alternatives to minimize adverse impacts of fishing activities. The SSC also will report on the process-related issues addressed at the last SSC meeting as well as the comments of SSC members on the published proposed rule concerning practices and procedures related to National Standard 2. The Habitat Committee will comment, where appropriate, about the model developed by its PDT, as well as on President Obama's Interagency Ocean Policy Task Force Report: *Interim Framework for Effective Coastal and Marine Spatial Planning*.

Thursday, January 28, 2010

The Council will begin the last day of the meeting with a discussion of several outstanding issues related to work priorities for 2010. The Northeast Fisheries Science Center staff will follow with two reports, one on the status of projected observer days-at-sea for the upcoming year in accordance with the Council's Standard Bycatch Reporting Methodology rules and another on the Vessel Calibration Workshop held late last year. The Council also intends to approve a range of alternatives to be analyzed in Amendment 3 to the Red Crab FMP. The action will include annual catch limits and accountability measures, and possibly a total allowable catch for the fleet. The day will conclude with an open period for public comments about items not listed on the agenda but related to Council business and any other outstanding issues that were postponed until the end of the meeting.

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided that 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.

Dated: January 11, 2010.

Tracey L. Thompson,

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

[FR Doc. 2010–623 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XT69

Fisheries of the Atlantic; Southeast Data, Assessment, and Review (SEDAR); Atlantic croaker and Atlantic menhaden; Public Meetings

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

ACTION: Notice of SEDAR Review Workshop for Atlantic croaker and Atlantic menhaden.

SUMMARY: The SEDAR assessment review of the Atlantic stocks of croaker and menhaden will be conducted at a Review Workshop. This is the twentieth SEDAR. See **SUPPLEMENTARY INFORMATION**.

DATES: The Review Workshop will take place March 8–12, 2010. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The Review Workshop will be held at the Hilton Garden Inn, 5265 International Boulevard, North Charleston, SC 29418; (800) 782–9444 or (843) 308–9330.

FOR FURTHER INFORMATION CONTACT: Dale Theiling, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; (843) 571–4366.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. The SEDAR 20 Review Workshop will be an independent peer review of the products from assessments of Atlantic stocks of croaker and menhaden conducted by the Atlantic States Marine Fisheries Commission (ASMFC). Products to be reviewed are reports from the ASMFC Data Workshop and ASMFC Stock Assessment Workshop for each stock. The Data Workshop Reports compile and evaluate potential datasets and recommend which datasets are appropriate for assessment analyses. The Stock Assessment Workshop Reports describe the fisheries, evaluate the status of the stock, estimate biological benchmarks, project future population conditions, and recommend research and monitoring needs. The product of the Review Workshop is a Peer Review Evaluation Report documenting Panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for the SEDAR 20 Review Workshop are appointed by the Atlantic States Marine Fisheries Commissions, NOAA Fisheries Southeast Fisheries Science Center, and the NOAA Center for Independent Experts. Review Workshop participants may include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; international experts; and staff of Councils, Commissions, and state and federal agencies.

SEDAR 20 Workshop Schedule:

March 8–12, 2010; SEDAR 20 Review Workshop

March 8, 2010: 1 p.m. - 8 p.m.; March 9–11, 2010: 8 a.m. - 8 p.m.; March 12, 2010: 8 a.m. - 1 p.m.

The Review Workshop is an independent peer review of the assessments developed during the ASMFC Data and Assessment Workshops. Workshop Panelists will review the assessment and document their comments and recommendations in a Peer Review Evaluation Report.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or otherauxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 10 business days prior to the workshop.

Dated: January 8, 2010

William D. Chappell,

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

[FR Doc. 2010–467 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XT70

Gulf of Mexico Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene public meetings.

DATES: The meetings will be held February 1 - 4, 2010.

ADDRESSES: The meetings will be held at the Battle House, 26 N. Royal Street, Mobile, AL 36602.

Council address: Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen Bortone, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Council

Wednesday, February 3, 2010

1 p.m. - The Council meeting will begin with a review of the agenda and approval of the minutes.

1:15 p.m. - 1:45 p.m. - The Council will receive a presentation on Catch Shares Task Force.

1:45 p.m. - 2:15 p.m. - They will receive a report of the Gulf of Mexico Alliance activities.

2:15 p.m. - 4:15 p.m. - They will receive public testimony on exempted fishing permits (EFPs), if any; final Regulatory Amendment for Reef Fish Total Allowable Catch; and the Council will hold an open public comment period regarding any fishery issue of concern. People wishing to speak before the Council should complete a public comment card prior to the comment period.

4:15 p.m. - 5:15 p.m. - The Council will review and discuss reports from the Sustainable Fisheries/Ecosystem Committee.

Thursday, February 4, 2010

8:30 a.m. - 12:45 p.m. - The Council will review and discuss reports from the committee meetings as follows: Reef Fish Management; Budget; Administrative Policy; Outreach and Education; Spiny Lobster/Stone Crab Management; Red Drum; Habitat Protection; Coastal Migratory Pelagics (Mackerel) Management; Shrimp Management; Advisory Panel Selection Committee; Scientific and Statistical Committee Selection Committee; and SEDAR Selection Committee.

12:45 p.m. - 1:15 p.m. - Other Business items will follow.

The Council will conclude its meeting at approximately 1:15 p.m.

Committees

Monday, February 1, 2010

8:30 a.m. - 9 a.m. - CLOSED SESSION - The Full Council will receive a litigation briefing.

9 a.m. - 9:20 a.m. - CLOSED SESSION (Full Council) - The SEDAR Selection Committee will appoint members to the SEDAR meetings for Spiny Lobster, Yellowedge Grouper and Tilefish and Greater Amberjack.

9:20 a.m. - 9:40 a.m. - CLOSED SESSION (Full Council) - The Scientific and Statistical Committee will appoint members to the Special Mackerel Scientific and Statistical Committee.

9:40 a.m. - 10 a.m. - CLOSED SESSION (Full Council) - The Advisory Panel Selection Committee will appoint members to the Mackerel Limited Access Privilege Program Advisory Panel.

10 a.m. - 12 p.m. - The Sustainable Fisheries/Ecosystem Committee will discuss the Options Paper for the Generic Annual Catch Limit/ Accountability Measures Amendment and review the proposed National Standard 2 Guidelines.

1:30 p.m. - 2 p.m. - The Budget Committee will review the 2010 funding.

2 p.m. - 4 p.m. - The Administrative Policy Committee will discuss modifications to Statement of Organization Practice and Procedures and Handbook Development.

4 p.m. - 4:45 p.m. - The Outreach and Education Committee will receive a report of the Outreach and Education Advisory Panel meeting.

4:45 p.m. - 5:45 p.m. - The Spiny Lobster/Stone Crab Committee will discuss the Options Paper for Spiny Lobster Amendment 10 and approve the Spiny Lobster SEDAR Terms of Reference.

-Recess-

Tuesday, February 2, 2010

8:30 a.m. - 4 p.m. - The Reef Fish Management Committee will receive a presentation on the Red Snapper update assessment; a report from the Standing and Special Reef Fish Scientific and Statistical Committee; a report from the Red Snapper Advisory Panel; a Draft Final Regulatory Amendment for Red Snapper Total Allowable Catch; an Options Paper for Amendment 32 Gag/ Red Grouper scoping meeting summaries; a report of the Limited Access Privilege Program Advisory Panel meeting; a presentation on Northeast Gulf of Mexico Reserves Program: Changes in Reef Fish Populations; and discuss approval of the schedules for SEDAR 22 (Yellowedge Grouper and Tilefish) and Greater Amberjack updates.

4 p.m. - 4:30 p.m. - The Red Drum Committee will discuss the Red Drum Fishery in the Exclusive Economic Zone.

4:30 p.m. - 5 p.m. - The Habitat Protection Committee will give a report of the Mississippi/Louisiana and the Texas Habitat Advisory Panel meetings.

-Recess-

Immediately Following Committee Recess - There will be an informal open public question and answer session.

Wednesday, February 3, 2010

8:30 a.m. - 9:30 a.m. - The Shrimp Management Committee will discuss the Texas Closure for 2010 from recommendations of the Shrimp Advisory Panel; report from the Standing and Special Shrimp Scientific and Statistical Committee Meetings and a report of Shrimp Effort in 2009.

9:30 a.m. - 11:30 a.m. - The Coastal Migratory Pelagics (Mackerel) Management Committee will discuss the Coastal Migratory Pelagics Scoping Meeting summaries and Options Paper for the Coastal Migratory Pelagics Amendment 18. The committee will also consider a control rule for Gulf group King and Spanish Mackerel.

Although other non-emergency issues not on the agendas may come before the Council and Committees for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions of the Council and Committees will be restricted to those issues specifically identified in the agendas and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take action to address the emergency. The established times for addressing items on the agenda may be adjusted as necessary to accommodate the timely completion of discussion relevant to the agenda items. In order to further allow for such adjustments and completion of all items on the agenda, the meeting may be extended from, or completed prior to the date/time established in this notice.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Tina O'Hern at the Council (see **ADDRESSES**) at least 5 working days prior to the meeting.

Dated: January 8, 2010.

William D. Chappell,

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

[FR Doc. 2010–468 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–945]

Prestressed Concrete Steel Wire Strand From the People's Republic of China: Postponement of Final Determination

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* January 13, 2010.

FOR FURTHER INFORMATION CONTACT: Alan Ray or Alexis Polovina, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–5403 or (202) 482–3927, respectively.

Postponement of Final Determination and Extension of Provisional Measures

On December 29, 2009, and January 4, 2010, Xinhua Metal Products Co., Ltd. ("Xinhua Metals") and Wuxi Jinyang Metal Products Co., Ltd. ("WJMP") requested that pursuant to the affirmative preliminary determination in this investigation, the Department postpone its final determination by 60 days under section 735(a)(2) of the Tariff Act of 1930, as amended ("the Act"). Xinhua Metals and WJMP also requested that the Department extend the application of the provisional measures prescribed under 19 CFR 351.210(e)(2) from a 4-month period to a 6-month period. In accordance with section 733(d) of the Act and 19 CFR 351.210(b), because (1) Our preliminary determination is affirmative, (2) the requesting exporters account for a significant proportion of exports of the subject merchandise, and (3) no compelling reasons for denial exist, we are granting the request and are postponing the final determination until no later than 135 days after the publication of the preliminary determination notice in the **Federal Register**, or May 7, 2010. Suspension of liquidation will be extended accordingly. This determination is issued and published in accordance with section 735(d) of the Act.

Dated: January 7, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010–491 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

[Docket No. 0911201414–0010–02]

Public Telecommunications Facilities Program: Notice of Availability of Funds

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of Availability of Funds; Catalog of Federal Domestic Assistance.

SUMMARY: On December 2, 2009, the National Telecommunications and Information Administration (NTIA) announced the closing date for receipt of applications for the Public Telecommunications Facilities Program (PTFP). NTIA now announces that $18 million has been appropriated for fiscal year (FY) 2010 grants.

DATES: Funds will be available for applications submitted by the originally announced deadline of 5 p.m., Eastern Standard Time (Closing Time), February 4, 2010, as well as applications for certain radio applications filed in response to the Federal Communications Commission (FCC) February 2010 FM Window that must be received prior to 5 p.m., Eastern Standard Time (Closing Time), February 26, 2010.

ADDRESSES: To obtain a printed application package, submit completed applications, or send any other correspondence, write to PTFP at the following address: NTIA/PTFP, Room H–4812, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, DC 20230. Application materials may be obtained electronically via the Internet at http://www.ntia.doc.gov/ptfp or http://www.grants.gov.

FOR FURTHER INFORMATION CONTACT: William Cooperman, Director, Public Broadcasting Division, telephone: (202) 482–5802; fax: (202) 482–2156. Information about the PTFP also can be obtained electronically via the Internet at www.ntia.doc.gov/ptfp.

SUPPLEMENTARY INFORMATION: On December 2, 2009, NTIA published a Notice of Closing Date for Solicitation of Applications for the FY 2010 PTFP grant round (the Notice). The Notice established Thursday, February 4, 2010, as the Closing Date for all applications except those applications that were related to the FCC FM Window. The Closing Date for the radio applications

related to the FM Window[1] must be received by Friday, February 26, 2010. The Notice indicated that:

[i]ssuance of grants is subject to the availability of FY 2010 funds. At this time, the Congress has passed the *Further Continuing Appropriations, 2010*, to fund operations of the PTFP through December 18, 2009. Further notice will be made in the **Federal Register** about the final status of funding for this program at the appropriate time.

On December 16, 2009, the Consolidated Appropriations Act, 2010 (the Act) was signed into law.[2] The Act appropriated $18 million for public telecommunications facilities planning and construction grants. These funds are now available to fund applications submitted in response to the **Federal Register** notice referenced above.

Dated: January 7,2010

Bernadette McGuire-Rivera,

Associate Administrator, Office of Telecommunications and Information Applications.

[FR Doc. 2010–453 Filed 1–12–10; 8:45 am]

BILLING CODE 3510–60–S

[1] Public Telecommunications Facilities Program: Closing Date, 74 FR 63120 (Dec. 2, 2009).

[2] *See* Pub. L. 111–117, 123 Stat. 3034 (Dec. 16, 2009).

DEPARTMENT OF DEFENSE

Office of the Secretary

Board of Regents of the Uniformed Services University of the Health Sciences

AGENCY: Uniformed Services University of the Health Sciences (USU), DoD.

ACTION: Quarterly meeting notice.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended) and the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended), this notice announces that the Board of Regents of the Uniformed Services University of the Health Sciences (USU) will meet on February 2, 2010. Subject to the availability of space, the meeting is open to the public.

DATES: The meeting will be held from 7:30 a.m. to 12:30 p.m. on Tuesday, February 2, 2010.

ADDRESSES: The meeting will be held at the Everett Alvarez Jr. Board of Regents Room (D3001), Uniformed Services University of the Health Sciences, 4301 Jones Bridge Road, Bethesda, Maryland 20814.

FOR FURTHER INFORMATION CONTACT: Janet S. Taylor, Designated Federal Official, 4301 Jones Bridge Road, Bethesda, Maryland 20814; telephone 301–295–3066. Ms. Taylor can also provide base access procedures.

SUPPLEMENTARY INFORMATION: Meetings of the Board of Regents assure that USU operates in the best traditions of academia. An outside Board is necessary for institutional accreditation.

Agenda

The actions that will take place include the approval of minutes from the Board of Regents Meeting held November 5, 2009; acceptance of reports from working committees; approval of faculty appointments and promotions; and the awarding of master's and doctoral degrees in the biomedical sciences and public health. The President, USU and the Vice President, USU Office of Research will also present reports. These actions are necessary for the University to pursue its mission, which is to provide outstanding health care practitioners and scientists to the uniformed services.

Meeting Accessibility

Pursuant to Federal statute and regulations (5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165) and the availability of space, this meeting is open to the public. Seating is on a first-come basis.

Written Statements

Interested persons may submit a written statement for consideration by the Board of Regents. Individuals submitting a written statement must submit their statement to the Designated Federal Official (see **FOR FURTHER INFORMATION CONTACT**). If such statement is not received at least 10 calendar days prior to the meeting, it may not be provided to or considered by the Board of Regents until its next open meeting. The Designated Federal Official will review all timely submissions with the Board of Regents Chairman and ensure such submissions are provided to Board of Regents Members before the meeting. After reviewing the written comments, submitters may be invited to orally present their issues during the February 2010 meeting or at a future meeting.

Dated: January 7, 2010.

Mitchell S. Bryman,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2010–393 Filed 1–12–10; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

National Defense University Board of Visitors (BOV); Open Meeting

AGENCY: National Defense University, DoD.

ACTION: Notice of open meeting.

SUMMARY: The National Defense University, Designated Federal Officer, has scheduled a meeting of the Board of Visitors (BOV). The BOV is a Federal Advisory Board that meets twice a year in proceedings that are open to the public.

DATES: The meeting will be held on April 15 (from 11:30 a.m. to 5 p.m.) and on April 16 (from 8 a.m. to 12:30 p.m.), 2010.

ADDRESSES: The meeting will be held at: Marshall Hall, Building 62, Room 155, the National Defense University, 300 5th Avenue, SW., Fort McNair, Washington, DC 20319–5066.

FOR FURTHER INFORMATION CONTACT: Ms. Dolores Hodge by phone (202) 685–2649, fax (202) 685–7707 or e-mail HodgeD@ndu.edu.

SUPPLEMENTARY INFORMATION: The future agenda will include discussion on Defense transformation, faculty development, facilities, information technology, curriculum development, post 9/11 initiatives as well as other operational issues and areas of interest affecting the day-to-day operations of the National Defense University and its components. The meeting is open to the public; limited space made available for observers will be allocated on a first come, first served basis. Written statements to the committee may be submitted at any time or in response to a stated planned meeting agenda by fax or e-mail (*see* **FOR FURTHER INFORMATION CONTACT**). The subject line of the e-mail should read: "Comment/Statement to the NDU BOV."

Dated: January 7, 2010.

Mitchell S. Bryman,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2010–395 Filed 1–12–10; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Acting Director, Information Collection Clearance Division, Regulatory Information

Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before March 15, 2010.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: January 8, 2010.

James Hyler,

Acting Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management.

Institute of Education Sciences

Type of Review: New.

Title: IES Research Training Program Surveys: Predoctoral Survey, Postdoctoral Survey, Special Education Postdoctoral Survey.

Frequency: Annually.

Affected Public: Individuals or households.

Reporting and Recordkeeping Hour Burden:

Responses: 695.
Burden Hours: 174.

Abstract: The surveys are for predoctoral and postdoctoral fellows taking part in the Institute of Education Sciences' three education training grant programs under which funds are provided to universities to support three types of training programs in the education sciences. The results of the survey will be used to both improve the fellowship programs as well as to provide information on the programs to policymakers, practitioners, and the public.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4197. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2010–514 Filed 1–12–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services (OSERS); Overview Information; National Institute on Disability and Rehabilitation Research (NIDRR)—Small Business Innovation Research Program (SBIR)—Phase I; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2010

Catalog of Federal Domestic Assistance (CFDA) Number: 84.133S–1.

Dates: Applications Available: January 13, 2010.

Deadline for Transmittal of Applications: March 15, 2010.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of this program is to stimulate technological innovation in the private sector, strengthen the role of small business in meeting Federal research or research and development (R/R&D) needs, increase the commercial application of the U.S. Department of Education (Department) supported research results, and improve the return on investment from federally funded research for economic and social benefits to the Nation.

Note: This program is in concert with NIDRR's Final Long-Range Plan for FY 2005–2009 (Plan).

The Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8166), can be accessed on the Internet at the following site: *http://www.ed.gov/about/offices/lists/osers/nidrr/policy.html.*

Through the implementation of the Plan, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of individuals with disabilities from traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for individuals with disabilities from underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

NIDRR Supports Manufacturing-Related Innovation (Executive Order 13329):

Executive Order 13329 states that continued technological innovation is critical to a strong manufacturing sector in the United States economy and ensures that Federal agencies assist the private sector in its manufacturing innovation efforts. The Department's SBIR program encourages innovative research and development (R&D) projects that are manufacturing-related, as defined by Executive Order 13329. Manufacturing-related R&D encompasses improvements in existing methods or processes, or wholly new processes, machines, or systems. The projects supported under the Department's SBIR program encompass a range of manufacturing-related R&D, including projects leading to the manufacture of such items as artificial intelligence or information technology devices, software, and systems. For more information on Executive Order

13329, please visit the following Web site: *http://www.sba.gov/sbir/execorder.html* or contact Lynn Medley at: *lynn.medley@ed.gov.*

Background

The Small Business Reauthorization Act of 2000 (Act) was enacted on December 21, 2000. The Act requires certain agencies, including the Department, to establish SBIR programs by reserving a statutory percentage of their extramural R&D budgets to be awarded to small business concerns through a uniform, highly competitive three-phase process.

The three phases of the SBIR program are:

Phase I: Phase I projects determine, insofar as possible, the scientific or technical merit and feasibility of ideas submitted under the SBIR program. An application for Phase I should concentrate on research that will contribute significantly to proving the scientific or technical feasibility of the approach or concept. Scientific or technical feasibility is a prerequisite to the Department's provision of further support in Phase II.

Phase II: Phase II projects expand on the results of and further pursue the development of Phase I projects. Phase II is the principal R/R&D effort of the SBIR program. Applications for Phase II projects must be more comprehensive than applications for Phase I projects; Phase II applications must outline the proposed effort in detail, including the commercial potential of projects or processes developed or researched during the Phase I project. Phase II applicants must be Phase I grantees with approaches that appear sufficiently promising as a result of their efforts in Phase I. Phase II awards are for periods of up to two years in amounts up to a maximum total of $500,000 over a period of two years.

Phase III: In Phase III, the small business grantee must use non-SBIR capital to pursue commercial applications of the R/R&D. Also, under Phase III, Federal agencies may award non-SBIR follow-on funding for products or processes that meet the needs of those agencies.

All SBIR projects funded by NIDRR must address the needs of individuals with disabilities and their families. (See 29 U.S.C. 762). Activities may include: conducting manufacturing-related R&D that encompasses improvements in existing methods or processes, or wholly new processes, machines, or systems; exploring the uses of technology to ensure equal access to education, employment, community environments, and information for individuals with disabilities; and improving the quality and utility of disability and rehabilitation research.

Priorities: Under this competition we are particularly interested in applications that address one of the following five priorities.

Invitational Priorities: For FY 2010 these priorities are invitational priorities. Under 34 CFR 75.105(c)(1) we do not give an application that meets one of these invitational priorities a competitive or absolute preference over other applications.

Each of the following priorities relate to innovative research utilizing new technologies to address the needs of individuals with disabilities and their families. Applicants who choose to respond to one of the invitational priorities must propose projects whose activities contribute to one of the following priorities:

(1) Increased independence of individuals with disabilities in the workplace, recreational settings, or educational settings through the development of technology to support access and promote integration of individuals with disabilities.

(2) Enhanced sensory or motor function of individuals with disabilities through the development of technology to support improved functional capacity.

(3) Enhanced workforce participation through the development of technology to support access to employment, promote sustained employment, and promote employment advancement for individuals with disabilities.

(4) Enhanced community participation and living for individuals with disabilities through the development of accessible information technology including Web access technology, software, and other systems and devices that promote access to information in educational, employment, and community settings, and voting technology that improves access for individuals with disabilities.

(5) Improved interventions and increased use of health-care resources through the development of technology to support independent access to health-care services in the community for individuals with disabilities.

Applicants should describe the approaches they expect to use to collect empirical evidence demonstrating the effectiveness of the technology they are proposing. This empirical evidence should facilitate the assessment of the efficacy and usefulness of the technology.

Note: NIDRR encourages applicants to adhere to universal design principles and guidelines. The term "universal design" is defined as "the design of products and environments to be usable by all people, to the greatest extent possible, without the need for adaptation or specialized design" (The Center for Universal Design, 1997). Universal design of consumer products minimizes or alleviates barriers that reduce the ability of individuals with disabilities to effectively or safely use standard consumer products. (For more information see *http://www.trace.wisc.edu/docs/consumer_product_guidelines/consumer.pcs/disabil.htm*).

Program Authority: The Small Business Act, Pub. L. 85–536, as amended (15 U.S.C. 631 and 638), and title II of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760, *et seq.*).

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 81, 82, 84, 85, 97, 98, and 99.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $1,125,000 for new Phase I awards.

Note: The estimated amount of funds available for new Phase I awards is based upon the estimated threshold SBIR allocation for OSERS, minus prior commitments for Phase II continuation awards.

Estimated Range of Awards: $70,000–$75,000.

Estimated Average Size of Awards: $75,000.

Maximum Award: We will reject any application that proposes a budget exceeding $75,000 for a single budget period of up to six months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register.**

Note: The maximum award amount includes direct and indirect costs and fees.

Estimated Number of Awards: 15.

Note: The Department is not bound by any estimates in this notice.

Maximum Project Period: We will reject any application that proposes a project period that exceeds a single budget period of up to six months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum project period through a notice published in the **Federal Register.**

III. Eligibility Information

1. *Eligible Applicants:* Entities that are, at the time of award, small business concerns as defined by the Small Business Administration (SBA). This definition is included in the application package.

If it appears that an applicant organization does not meet the eligibility requirements, we will request an evaluation by the SBA. Under circumstances in which eligibility is unclear, we will not make an SBIR award until the SBA makes a determination that the applicant is eligible under its definition of small business concern.

All technology, science, or engineering firms with strong research capabilities in any of the priority areas listed in this notice are encouraged to participate. Consultative or other arrangements between these firms and universities or other non-profit organizations are permitted, but the small business concern must serve as the grantee. For Phase I projects, at least two-thirds of the research and/or analytic activities must be performed by the proposing small business concern grantee.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Other:* The total of all consultant fees, facility leases or usage fees, and other subcontracts or purchase agreements may not exceed one-third of the total funding award.

IV. Application and Submission Information

1. *Address To Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *http://www.ed.gov/fund/grant/apply/grantapps/index.html.*

To obtain a copy from ED Pubs, write, fax, or call the following: Education Publications Center, P.O. Box 1398, Jessup, MD 20794–1398. Telephone, toll free: 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *http://www.ed.gov/pubs/edpubs.html* or at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.133S–1.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition. Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit the application narrative (Part III) to the equivalent of no more than 25 pages, excluding any documentation of prior multiple Phase II awards, if applicable, and required forms, using the following standards:

- A "page" is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Single space all text in the application narrative. Single space titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the coversheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the résumés, the bibliography, the letters of support; related application(s) or award(s); or documentation of multiple Phase II awards, if applicable. However, the page limit does apply to all of the application project narrative section (Part III).

We will reject your application if you exceed the page limit; or if you apply other standards and exceed the equivalent of the page limit.

The application package will provide instructions for completing all components to be included in the application. Each application must include a cover sheet (Standard Form 424); budget requirements (ED Form 524) and narrative budget justification; other required forms; an abstract, Human Subjects narrative, Part III project narrative; résumé of staff; and other related materials, if applicable.

3. *Content Restrictions:* If an applicant chooses to respond to more than one invitational priority, we request that the applicant submit a separate application for each priority. There is no limitation on the number of different applications that an applicant may submit under this competition. An applicant may submit separate applications for different priorities, or different applications under the same priority.

Applicants should consult NIDRR's Long-Range Plan when preparing their applications. The Plan is organized around the following research domains and arenas: (1) Community Living and Participation; (2) Health and Function; (3) Technology; (4) Employment; and (5) Demographics. Applicants should indicate, for each application, the domain or arena under which they are applying. In their applications, applicants should clearly indicate whether they are applying for a research grant in the area of (1) Community Living and Participation; (2) Health and Function; (3) Technology; (4) Employment; or (5) Demographics.

4. *Submission Dates and Times: Applications Available:* January 13, 2010.

Deadline for Transmittal of Applications: March 15, 2010.

Applications for grants under this competition must be submitted electronically using the Electronic Grant Application system (e-Application) accessible through the Department's e-Grants site. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV.7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under *For Further Information Contact* in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

5. *Intergovernmental Review:* This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

6. *Funding Restrictions:* We reference regulations outlining funding restrictions of the *Applicable Regulations* section of this notice.

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the SBIR Program—CFDA Number 84.133S–1—must be submitted electronically using e-Application, accessible through the Department's e-Grants Web site at: *http://e-grants.ed.gov.*

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

While completing your electronic application, you will be entering data online that will be saved into a database. You may not e-mail an electronic copy of a grant application to us.

Please note the following:

• You must complete the electronic submission of your grant application by 4:30:00 p.m., Washington, DC time, on the application deadline date. E-Application will not accept an application for this competition after 4:30:00 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process.

• The hours of operation of the e-Grants Web site are 6:00 a.m. Monday until 7:00 p.m. Wednesday; and 6:00 a.m. Thursday until 8:00 p.m. Sunday, Washington, DC time. Please note that, because of maintenance, the system is unavailable between 8:00 p.m. on Sundays and 6:00 a.m. on Mondays, and between 7:00 p.m. on Wednesdays and 6:00 a.m. on Thursdays, Washington, DC time. Any modifications to these hours are posted on the e-Grants Web site.

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

• You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. You must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified in this paragraph or submit a password protected file, we will not review that material.

• Your electronic application must comply with any page limit requirements described in this notice.

• Prior to submitting your electronic application, you may wish to print a copy of it for your records.

• After you electronically submit your application, you will receive an automatic acknowledgment that will include a PR/Award number (an identifying number unique to your application).

• Within three working days after submitting your electronic application, fax a signed copy of the SF 424 to the Application Control Center after following these steps:

(1) Print SF 424 from e-Application.

(2) The applicant's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard-copy signature page of the SF 424.

(4) Fax the signed SF 424 to the Application Control Center at (202) 245–6272.

• We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of e-Application Unavailability: If you are prevented from electronically submitting your application on the application deadline date because e-Application is unavailable, we will grant you an extension of one business day to enable you to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

(1) You are a registered user of e-Application and you have initiated an electronic application for this competition; and

(2)(a) E-Application is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) E-Application is unavailable for any period of time between 3:30 p.m. and 4:30:00 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgment of any system unavailability, you may contact either (1) the person listed elsewhere in this notice under *For Further Information Contact* (see VII. Agency Contact) or (2) the e-Grants help desk at 1–888–336–8930. If e-Application is unavailable due to technical problems with the system and, therefore, the application deadline is extended, an e-mail will be sent to all registered users who have initiated an e-Application. Extensions referred to in this section apply only to the unavailability of e-Application.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through e-Application because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to e-Application; and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Lynn Medley, U.S. Department of Education, 400 Maryland Avenue, SW., room 6027, Potomac Center Plaza (PCP), Washington, DC 20202–2700. FAX: (202) 245–7338.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.133S–1) LBJ Basement Level 1, 400 Maryland

Avenue, SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.133S–1) 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this grant notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

Selection Criteria: The selection criteria for this competition are from 34 CFR 75.210 of EDGAR and are listed in the application package.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* To evaluate the overall success of its research program, NIDRR assesses the quality of its funded projects through review of grantee performance and products. Each year, NIDRR examines a portion of its SBIR grantees to determine—

- The percentage of National Institute of Disability and Rehabilitation Research (NIDRR)-funded grant applications that receive an average peer review score of 85 or higher.

NIDRR uses information submitted by grantees as part of their Annual Performance Reports (APRs) for these reviews.

Department of Education program performance reports, which include information on NIDRR programs, are available on the Department's Web site: *http://www.ed.gov/about/offices/list/opepd/sas/index.html.*

VII. Agency Contact

For Further Information Contact: Lynn Medley, U.S. Department of Education, 400 Maryland Avenue, SW., room 6027, PCP, Washington, DC 20202–2700. Telephone: (202) 245–7338 or by e-mail: *lynn.medley@ed.gov.*

If you use a TDD, call the TDD number at (202) 205–4475.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the Federal Relay Service, toll free, at 1–800–877–8339.

Electronic Access to This Document: 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) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: 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 on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: January 8, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–482 Filed 1–12–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

January 04, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER97–4084–011.

Applicants: Denver City Energy Associates, L.P.

Description: Denver City Energy Associates, LP submits compliance filing under Order 697 and Request for Category 2 Seller Status.

Filed Date: 12/22/2009.

Accession Number: 20091230–0075.

Comment Date: 5 p.m. Eastern Time on Monday, February 22, 2010.

Docket Numbers: ER99–2984–014.
Applicants: Green Country Energy, LLC.
Description: Market Power Update of Green Country Energy, LLC.
Filed Date: 12/31/2009.
Accession Number: 20091231–5008.
Comment Date: 5 p.m. Eastern Time on Monday, March 01, 2010.

Docket Numbers: ER00–3614–013.
Applicants: BP Energy Company.
Description: Market Power Update of BP Energy Company.
Filed Date: 12/31/2009.
Accession Number: 20091231–5090.
Comment Date: 5 p.m. Eastern Time on Thursday, January 21, 2010.

Docket Numbers: ER02–1406–014; ER01–1099–013; ER99–2928–010.
Applicants: Acadia Power Partners, LLC; Cleco Power LLC; Cleco Evangeline LLC.
Description: Cleco Power LLC submits filing to supplement their updated market power analysis.
Filed Date: 12/30/2009.
Accession Number: 20091231–0102.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Docket Numbers: ER03–719–013; ER98–830–022; ER03–721–012.
Applicants: Millennium Power Partners, L.P., New Harquahala Generating Company, LLC, New Athens Generating Company, LLC.
Description: Revised notice of non-material change in status of New Athens Generating Company, LLC, et al.
Filed Date: 12/30/2009.
Accession Number: 20091230–5090.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Docket Numbers: ER05–1491–003.
Applicants: Vermont Yankee Nuclear Power Corporation.
Description: Vermont Yankee Nuclear Power Corporation submits compliance filing.
Filed Date: 12/24/2009.
Accession Number: 20091230–0034.
Comment Date: 5 p.m. Eastern Time on Thursday, January 14, 2010.

Docket Numbers: ER07–357–006.
Applicants: Fenton Power Partners I, LLC.
Description: Fenton Power Partners, I, LLC submits Substitute Second Revised Sheet 4 et al. to FERC Electric Tariff, Original Volume 1.
Filed Date: 12/08/2009.
Accession Number: 20091210–0102.
Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2009.

Docket Numbers: ER08–1225–007; ER08–1111–006; ER08–1226–005.
Applicants: Cloud County Wind Farm, LLC, Pioneer Prairie Wind Farm I, LLC, Arlington Wind Power Project LLC.
Description: Notice of change in status filing under part 35 of FERC's regulations of Arlington Wind Power Project LLC, et al.
Filed Date: 12/30/2009.
Accession Number: 20091230–5141.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Docket Numbers: ER09–1321–003.
Applicants: Blue Canyon Windpower V LLC.
Description: Notice of change in status filing under part 35 of FERC's regulations of Blue Canyon Windpower V LLC.
Filed Date: 12/30/2009.
Accession Number: 20091230–5089.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Docket Numbers: ER10–78–001.
Applicants: Orange Grove Energy, L.P.
Description: Orange Grover Energy, LP submits a sub. page of its proposed tariff to correct an incorrect page number and an amended version of attachment B etc.
Filed Date: 12/28/2009.
Accession Number: 20091230–0035.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–434–000.
Applicants: CPI USA North Carolina LLC.
Description: CPI USA North Carolina LLC submits a Notice of Succession informing the Commission that CPI adopts EPCOR USA NC's market-based rate tariff as its own etc.
Filed Date: 12/15/2009.
Accession Number: 20091217–0195.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–440–000.
Applicants: PacifiCorp.
Description: PacifiCorp submits the Fiber Communications Addition Agreement.
Filed Date: 12/16/2009.
Accession Number: 20091218–0211
Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: ER10–450–001; ER01–1044–014; ER00–3696–013; ER01–3109–014; ER02–506–013; ER03–1383–016; ER07–1000–005; ER09–1491–001; ER96–1947–027; ER98–2783–017; ER99–2157–014.
Applicants: Bluegrass Generation Company, LLC, Las Vegas Power Company, LLC, DeSoto County Generating Company, LLC, Griffith Energy LLC, Bridgeport Energy, LLC, Rocky Road Power, LLC, Riverside Generating Company, LLC, LS Power Marketing, LLC, Renaissance Power, LLC, Tilton Energy LLC, Arlington Valley, LLC.
Description: Notification of Change in Status of Arlington Valley, LLC, et al.
Filed Date: 12/30/2009.
Accession Number: 20091230–5082.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Docket Numbers: ER10–469–000.
Applicants: Northeast Utilities Service Company.
Description: NU Companies submits tariff sheets for the termination of two interconnection agreements.
Filed Date: 12/22/2009.
Accession Number: 20091224–0005.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–470–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc submits a Network Integration Transmission Service Agreement.
Filed Date: 12/22/2009.
Accession Number: 20091224–0004.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–471–000.
Applicants: Duke Energy Carolinas, LLC.
Description: Duke Energy Carolinas, LLC submits Rate Schedule 336, the Power Purchaser Agreements between Duke Energy Carolinas, LLC and Central Electric Power Cooperative, Inc.
Filed Date: 12/22/2009.
Accession Number: 20091224–0008.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–473–000.
Applicants: The United Illuminating Company.
Description: The United Illuminating Company submits Notice of Termination of the Localized Costs Sharing Agreement.
Filed Date: 12/22/2009.
Accession Number: 20091224–0002.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–474–000.
Applicants: San Diego Gas & Electric Company.
Description: San Diego Gas & Electric Co submits Ninth Revised Sheet No. 121 et al. to FERC Electric Tariff, Original Volume No. 11.
Filed Date: 12/22/2009.
Accession Number: 20091224–0003.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–475–000.
Applicants: PJM Interconnection, LLC.
Description: PJM Interconnection, LLC submits executed interconnection service agreement among PJM as the Transmission Provider et al. as the Interconnected Transmission Owner etc.

Filed Date: 12/22/2009.
Accession Number: 20091224–0082.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–478–000.
Applicants: PJM Interconnection, LLC.
Description: PJM Interconnection, LLC submits revised tariff sheets of the PJM Open Access Transmission Tariff.
Filed Date: 12/23/2009.
Accession Number: 20091224–0080.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 13, 2010.

Docket Numbers: ER10–479–000.
Applicants: California Independent System Operator Corporation.
Description: California Independent System Operator Corporation submits a proposed ISO Tariff amendment that will enable the ISO to procure incremental Ancillary Services from external Non-Dynamic System etc.
Filed Date: 12/22/2009.
Accession Number: 20091224–0079.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–480–000.
Applicants: PacifiCorp.
Description: PacifiCorp submits an updated Interconnection Agreement wit the State of California Department of Water Resources designated as First Revised Rate Schedule FERC 241.
Filed Date: 12/23/2009.
Accession Number: 20091224–0078.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 13, 2010.

Docket Numbers: ER10–482–000; ER10–483–000; ER10–484–000; ER10–485–000; ER10–486–000; ER10–487–000; ER10–488–000; ER10–489–000; ER10–490–000; ER10–491–000; ER10–492–000; ER10–493–000; ER10–494–000.
Applicants: Duke Energy Commercial Enterprises, Inc.; CinCap IV, LLC; CinCap V LLC; Cinergy Capital & Trading, Inc.; Cinergy Power Investments, Inc.; St. Paul Congeneration, LLC; Duke Energy Trading & Marketing, LLC; CinCap IV, LLC; Cincap V, LLC; Cinergy Capital & Trading, Inc.; Cinergy Power Investments, Inc.; St. Paul Cogeneration, LLC; Duke Energy Trading and Marketing, LLC.
Description: Duke Energy Commercial Enterprises, Inc submits FERC Electric notice of succession and clean copy of DECE's FERC Electric Rate Schedule 1 effective 11/25/09.
Filed Date: 12/22/2009.
Accession Number: 20091224–0077.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–497–000.
Applicants: Niagara Mohawk Power Corporation.
Description: Niagara Mohawk Power Corp submits a Notice of Cancellation of Service Agreement No. 41 et al.
Filed Date: 12/23/2009.
Accession Number: 20091224–0075.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 13, 2010.

Docket Numbers: ER10–511–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc submits an executed service agreement for Network Integration Transmission Service between Southwest Power Pool, Inc et al.
Filed Date: 12/29/2009.
Accession Number: 20091230–0074.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–512–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc submits an executed Meter Agent Service agreement with Lincoln Electric System etc.
Filed Date: 12/29/2009.
Accession Number: 20091230–0073.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–513–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc submits an executed service agreement for Firm Point-to-Point Transmission Service between Southwest Power Pool, Inc et al.
Filed Date: 12/29/2009.
Accession Number: 20091230–0072.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–514–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc submits their Adjacent Balancing Authority Coordination Agreement with the Big Rivers Electric Corporation etc.
Filed Date: 12/29/2009.
Accession Number: 20091230–0071.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–515–000.
Applicants: Xcel Energy Services Inc.
Description: Southwestern Public Service Company submits an executed copy of the Second Amended and Restated Transaction Agreement.
Filed Date: 12/28/2009.
Accession Number: 20091231–0038.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–516–000.
Applicants: South Carolina Electric & Gas Company.
Description: South Carolina Electric & Gas Company submits revised tariff sheets changing the transmission rates under SCE&G's Open Access Transmission Tariff.
Filed Date: 12/29/2009.
Accession Number: 20091231–0037.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–518–000.
Applicants: Southwest Power Pool, Inc.
Description: Southwest Power Pool, Inc submits an executed Service Agreement for Network Integration Transmission Service between SPP as Transmission Provider and Westar Energy.
Filed Date: 12/30/2009.
Accession Number: 20091231–0045.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Docket Numbers: ER10–523–000.
Applicants: New England Power Company.
Description: New England Power Company submits Amendments to Integrated Facilities Agreements and Service Agreements under FERC Electric Tariff, Original Volume 1.
Filed Date: 12/30/2009.
Accession Number: 20091231–0231.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Docket Numbers: ER10–524–000; ER10–525–000; ER10–526–000; ER10–527–000; ER10–528–000.
Applicants: Idaho Power Company; Deseret Generation & Transmission Co-op.; NorthWestern Corporation; PacifiCorp; Portland General Electric Company.
Description: Idaho Power Co et al submits Second Revised Rate Schedule FERC No. 152 et al.
Filed Date: 12/29/2009.
Accession Number: 20091231–0230.
Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–529–000.
Applicants: PJM Interconnection, LLC.
Description: PJM Interconnection, LLC submits amendments to Schedule 12–Appendix.
Filed Date: 12/30/2009.
Accession Number: 20091231–0240.
Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Docket Numbers: ER10–530–000.
Applicants: PJM Interconnection, LLC.
Description: PJM Interconnection, LLC submits an executed interconnection service agreement.
Filed Date: 12/31/2009.
Accession Number: 20091231–0241.
Comment Date: 5 p.m. Eastern Time on Thursday, January 21, 2010.

Docket Numbers: ER10–531–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc submits a Network Integration Transmission Service Agreement.

Filed Date: 12/30/2009.

Accession Number: 20091231–0242.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Docket Numbers: ER10–532–000.

Applicants: PJM Interconnection, LLC.

Description: PJM Interconnection, LLC submits an executed interconnection service agreement.

Filed Date: 12/30/2009.

Accession Number: 20091231–0244.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 20, 2010.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES10–21–000.

Applicants: AEP Texas North Company.

Description: Application by AEP Texas North Company Under Section 204 of the Federal Power Act for Authorization to Issue Securities.

Filed Date: 12/29/2009.

Accession Number: 20091229–5041.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH10–6–000.

Applicants: General Electric Company.

Description: Exemption Notification (Form FERC–65A) of General Electric Company.

Filed Date: 12/29/2009.

Accession Number: 20091229–5038.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: PH10–7–000.

Applicants: BlackRock, Inc.

Description: FERC 65A—Exemption Notification of Status as Passive Investors of BlackRock, Inc.

Filed Date: 12/31/2009.

Accession Number: 20091231–5093.

Comment Date: 5 p.m. Eastern Time on Thursday, January 21, 2010.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD10–9–000.

Applicants: North American Electric Reliability Corp.

Description: Errata Petition of the North American Electric Reliability Corporation for Approval of Corrected Reliability Standard FAC–010–2—System Operating Limits Methodology for the Planning Horizon.

Filed Date: 11/20/2009.

Accession Number: 20091120–5134.

Comment Date: 5 p.m. Eastern Time on Monday, January 25, 2009.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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Kimberly D. Bose,

Secretary.

[FR Doc. 2010–481 Filed 1–12–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

January 4, 2010.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP10–269–000.

Applicants: Rockies Express Pipeline LLC.

Description: Rockies Express Pipeline LLC submits Original Sheet No. 11C to FERC Gas Tariff, Second Revised Volume No. 1.

Filed Date: 12/28/2009.

Accession Number: 20091229–0057.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–270–000.

Applicants: Discovery Gas Transmission LLC,

Description: Discovery Gas Transmission LLC submits for filing its Fourth Revised Sheet 23, to become effective 5/1/09.

Filed Date: 12/29/2009.

Accession Number: 20091230–0050.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–271–000.

Applicants: Southern LNG Inc.

Description: Southern LNG, Inc submits for filing Third Revised Sheet 1 *et al.* to FERC Gas Tariff, Original Volume 1 to become effective 3/1/10.

Filed Date: 12/29/2009.

Accession Number: 20091230–0051.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–272–000.

Applicants: Millennium Pipeline Company, LLC.

Description: Millennium Pipeline Company, LLC submits Third Revised Sheet 51 *et al.* to FERC Gas Tariff, Original Volume 1.

Filed Date: 12/30/2009.

Accession Number: 20091230–0049.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–273–000.

Applicants: EnergyMark, LLC.

Description: Constellation NewEnergy—Gas Division, LLC *et al.* submits request for a temporary waiver of FERC's capacity release policies and regulations in order facilitate the acquisition.

Filed Date: 12/29/2009.

Accession Number: 20091230–0048.

Comment Date: 5 p.m.Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–274–000.

Applicants: Wyoming Interstate Company.

Description: Wyoming Interstate Company, Ltd submits for filing and acceptance a Fourteenth Revised Sheet 1 to its FERC Gas Tariff, Second Revised Volume 2.

Filed Date: 12/29/2009.

Accession Number: 20091230–0047.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–275–000.

Applicants: Wyoming Interstate Company, Ltd.

Description: Wyoming Interstate Company, Ltd submits for filing and acceptance a firm transportation service agreement with Devon Energy Production Company, LP.

Filed Date: 12/29/2009.

Accession Number: 20091230–0046.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–276–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: Iroquois Gas Transmission System, L.P. Measurement Variance/Fuel Use Factors utilized by Iroquois during July 1, 2009–December 31, 2009.

Filed Date: 12/30/2009.

Accession Number: 20091230–5088.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–277–000.

Applicants: National Fuel Gas Supply Corporation.

Description: National Fuel Gas Supply Corporation submits Non-conforming Service Agreements to FERC Gas Tariff, Fourth Revised Volume 2 with Crown Energy Services, Inc *et al.,* effective 1/29/10.

Filed Date: 12/30/2009.

Accession Number: 20091231–0024.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–278–000.

Applicants: Texas Eastern Transmission, LP

Description: Texas Eastern Transmission, LP submits Thirty-Third Revised Sheet 25 *et al.,* to FERC Gas Tariff, Seventh Revised Volume 1 and First Revised Volume 2, to be effective 2/1/10.

Filed Date: 12/30/2009.

Accession Number: 20091231–0025.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–279–000.

Applicants: Florida Gas Transmission Company, LLC.

Description: Florida Gas Transmission Company, LLC submits the Annual Accounting Report which details the activity of FGT's Cash-Out Mechanism.

Filed Date: 12/30/2009.

Accession Number: 20091231–0026.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–280–000.

Applicants: Rockies Express Pipeline LLC.

Description: Rockies Express Pipeline, LLC submits Original Sheet 11D to FERC Gas Tariff, Second Revised Volume 1, to be effective 1/1/10.

Filed Date: 12/30/2009.

Accession Number: 20091231–0027.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–281–000.

Applicants: Gulf South Pipeline Company, LP.

Description: Gulf South Pipeline Company, LP submits amendment to a negotiated rate letter agreement re the East Texas to Mississippi Expansion Project.

Filed Date: 12/30/2009.

Accession Number: 20091231–0028.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–282–000.

Applicants: Kinder Morgan Interstate Gas Trans. LLC.

Description: Kinder Morgan Interstate Gas Transmission, LLC submits Twenty Sixth Revised Sheet 4G.01 *et al.* to FERC Gas Tariff, Fourth Revised Volume 1A, to be effective 1/1/10.

Filed Date: 12/30/2009.

Accession Number: 20091231–0029.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–283–000.

Applicants: Northern Natural Gas Company.

Description: Northern Natural Gas Company submits 14 Revised Sheet 66B.35 to FERC Gas Tariff, Fifth Revised Volume 1, to be effective 1/1/10.

Filed Date: 12/30/2009.

Accession Number: 20091231–0030.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–284–000.

Applicants: Millennium Pipeline Company, LLC.

Description: Millennium Pipeline Company, LLC submits the Penalty Revenue Crediting Report to FERC Gas Tariff, Original Volume 1.

Filed Date: 12/30/2009.

Accession Number: 20091231–0031.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

Docket Numbers: RP10–285–000.

Applicants: Sea Robin Pipeline Company, LLC.

Description: Sea Robin Pipeline Company, LLC submits the Annual Flowthrough Crediting Mechanism to FERC Gas Tariff, Second Revised Volume 1.

Filed Date: 12/30/2009.

Accession Number: 20091231–0032.

Comment Date: 5 p.m. Eastern Time on Monday, January 11, 2010.

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Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–463 Filed 1–12–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

December 30, 2009.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC10–32–000.

Applicants: NSTAR Companies, Advanced Energy Systems, Inc., Medical Area Total Energy Plant, Inc., MATEP LLC, New MATEP, Inc.

Description: Application under Section 203 of the Federal Power Act for authorization of the sale of stock and disposition of facilities of Advanced Energy Systems, Inc., MATEP LLC, MATEP Inc., New MATEP Inc., and NSTAR.

Filed Date: 12/29/2009.

Accession Number: 20091229–5103.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER03–198–012.

Applicants: Pacific Gas and Electric Company.

Description: Pacific Gas and Electric Company submits its triennial market power update for the Southwest Region.

Filed Date: 12/23/2009.

Accession Number: 20091229–0058.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 13, 2010.

Docket Numbers: ER06–615–058; ER07–1257–012.

Applicants: California Independent System Operator Corporation.

Description: California Independent System Operator Corporation submits First Revised Sheet 116B *et al.* to FERC Electric Tariff, Fourth Replacement Volume 1 in compliance with the Commission's 12/3/09 Order.

Filed Date: 12/28/2009.

Accession Number: 20091230–0037.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER09–712–002; ER06–736–002; ER02–2263–010; ER01–2217–008; ER08–931–004; ER08–337–005.

Applicants: High Lonesome Mesa, LLC, Midway-Sunset Cogeneration Company, Southern California Edison Company, Sunrise Power Company, Walnut Creek Energy, LLC, Watson Cogeneration Company.

Description: Southwest EIX MBR Affiliates submits market power analysis and revised MBR Tariffs re the High Lonesome Mesa, LLC *et al.*

Filed Date: 12/22/2009.

Accession Number: 20091230–0065.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–78–001.

Applicants: Orange Grove Energy, L.P.

Description: Orange Grover Energy, LP submits a substitute page of its proposed tariff to correct an incorrect page number and an amended version of attachment B to the application *etc.*

Filed Date: 12/28/2009.

Accession Number: 20091230–0035.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–472–000.

Applicants: Katahdin Paper Company LLC.

Description: Katahdin Paper Co, LLC submits the Notice of Cancellation of Market-Based Rate Tariff and request for waiver of the prior notice requirement.

Filed Date: 12/22/2009.

Accession Number: 20091224–0001.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 12, 2010.

Docket Numbers: ER10–477–000.

Applicants: Consolidated Edison Company of New York, Inc.

Description: Consolidated Edison Company of New York, Inc submits a revised Master Services Agreement and Transaction Forms between Con Edison and Bayonne Energy Center, LLC.

Filed Date: 12/23/2009.

Accession Number: 20091224–0085.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 13, 2010.

Docket Numbers: ER10–501–000.

Applicants: Southern California Edison Company.

Description: Southern California Edison Company submits revised rate sheets reflection cancellation of the letter agreements.

Filed Date: 12/23/2009.

Accession Number: 20091228–0022.

Comment Date: 5 p.m. Eastern Time on Wednesday, January 13, 2010.

Docket Numbers: ER10–505–000.

Applicants: Dynegy Services Plum Point, LLC.

Description: Dynegy Services Plum Point, LLC submits an application for market-based rate authorization under Section 205 of the Federal Power Act *etc.*

Filed Date: 12/28/2009.

Accession Number: 20091229–0056.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–508–000.

Applicants: Nevada Power Company.

Description: NV Energy submits an executed Interconnection Agreement designated as Service Agreement 09–01804 between NPC and El Dorado Energy, LLC.

Filed Date: 12/28/2009.

Accession Number: 20091230–0040.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–509–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, LLC submits revised Interconnection Service Agreement with Richmond Energy, LLC *et al.* that supersedes the Original Service Agreement 2205.

Filed Date: 12/28/2009.

Accession Number: 20091230–0038.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Docket Numbers: ER10–510–000.

Applicants: Southern California Edison Company.

Description: Southern California Edison Company submits the unexecuted Brea Power II Standard Large Generator Interconnection Agreement, Service Agreement for Wholesale Distribution Service *etc.*

Filed Date: 12/28/2009.

Accession Number: 20091230–0036.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD09–7–002.

Applicants: North American Electric Reliability Corp.

Description: Compliance Filing of the North American Electric Reliability Corp. in Response to FERC's September 30, 2009 Order Approving Revised Reliability Standards for Critical Infrastructure Protection and Requiring Compliance Filing.

Filed Date: 12/29/2009.

Accession Number: 20091229–5104.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 19, 2010.

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Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–457 Filed 1–12–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

December 23, 2009.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP09–1037–002.

Applicants: Questar Pipeline Company.

Description: Questar Pipeline Company submits Second Substitute Eighth Revised Sheet 8 to its FERC Gas Tariff, First Revised Volume 1, to be effective 10/7/09.

Filed Date: 10/22/2009.

Accession Number: 20091023–0012.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 29, 2009.

Docket Numbers: RP10–234–001.

Applicants: Eastern Shore Natural Gas Company.

Description: Eastern Shore Natural Gas Company submits the corrected pagination for Sheet 236, filed as Original Sheet 236 to First Revised Sheet 236.

Filed Date: 12/16/2009.

Accession Number: 20091216–0125.

Comment Date: 5 p.m. Eastern Time on Monday, December 28, 2009.

Docket Numbers: RP10–178–001.

Applicants: Steuben Gas Storage Company.

Description: Steuben Gas Storage Co's filing of a revision to Order No. 712 and Order No. 587–T Compliance Filing under RP10–178.

Filed Date: 12/17/2009.

Accession Number: 20091218–0202.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 29, 2009.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in on or before 5 p.m. Eastern time on the specified comment date. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

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Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–460 Filed 1–12–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

December 28, 2009.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP10–254–000.

Applicants: East Tennessee Natural Gas, LLC.

Description: East Tennessee Natural Gas, LLC submits Eighth Revised Sheet 394 to its FERC Gas Tariff, Third Revised Volume 1 to be effective 1/13/10.

Filed Date: 12/18/2009.

Accession Number: 20091222–0048.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–255–000.

Applicants: Maritimes & Northeast Pipeline, LLC.

Description: Maritimes & Northeast Pipeline submits Original Sheet 9S *et al.* to its FERC Gas Tariff, First Revised Volume 1.

Filed Date: 12/18/2009.

Accession Number: 20091222–0047.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–256–000.

Applicants: Northwest Pipeline GP.

Description: Northwest Pipeline, GP submits Fifth Revised Sheet 395 *et al.* to its FERC Gas Tariff, Fourth Revised Volume 1.

Filed Date: 12/18/2009.

Accession Number: 20091222–0046.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–257–000.

Applicants: Rockies Express Pipeline LLC.

Description: Rockies Express Pipeline, LLC submits Original Sheet 11B to its FERC Gas Tariff, Second Revised Volume 1.

Filed Date: 12/18/2009.

Accession Number: 20091222–0045.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–258–000.

Applicants: Northern Natural Gas Company.

Description: Northern Natural Gas Company submits 12 Revised Sheet 66B.35 to its FERC Gas Tariff, Fifth Revised Volume 1.

Filed Date: 12/18/2009.

Accession Number: 20091222–0044.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–259–000.

Applicants: Transcontinental Gas Pipe Line Company,

Description: Transcontinental Gas Pipe Line Company, LLC submits First Revised Sheet 502 *et al.* to its FERC Gas Tariff, Fourth Revised Volume 1, to be effective 1/18/10.

Filed Date: 12/18/2009.

Accession Number: 20091222–0043.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–260–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Transcontinental Gas Pipe Line Company, LLC submits First Revised Sheet 336 *et al.* to its FERC Gas Tariff, Fourth Revised Volume 1 to be effective 1/18/10.

Filed Date: 12/18/2009.

Accession Number: 20091222–0042.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–261–000.

Applicants: Northern Natural Gas Company.

Description: Northern Natural Gas Company submits 13 Revised Sheet 66B.35 to FERC Gas Tariff, Fifth Revised Volume 1 to be effective 12/22/09.

Filed Date: 12/22/2009.

Accession Number: 20091222–0041.

Comment Date: 5 p.m. Eastern Time on Monday, January 04, 2010.

Docket Numbers: RP10–262–000.

Applicants: Gulf South Pipeline Company, LP.

Description: Gulf South Pipeline Co, LP submits First Revised Sheet No. 2500 to FERC Gas Tariff, Sixth Revised Volume No. 1.

Filed Date: 12/22/2009.

Accession Number: 20091223–0091.

Comment Date: 5 p.m. Eastern Time on Monday, January 04, 2010.

Docket Numbers: RP10–264–000.

Applicants: Natural Gas Pipeline Company of America LLC.

Description: Natural Gas Pipeline Company of America LLC submits an amendment to an existing Firm Transportation Rate Discount Agreement with The Board of Trustees of University of Illinois, to be effective 1/1/10.

Filed Date: 12/23/2009.

Accession Number: 20091224–0019.

Comment Date: 5 p.m. Eastern Time on Monday, January 04, 2010.

Docket Numbers: RP10–265–000.

Applicants: Equitrans, LP.

Description: Equitrans, LP submits Fifteenth Revised Sheet 11 to FERC Gas Tariff, Original Volume 1, to be effective 1/1/10.

Filed Date: 12/23/2009.

Accession Number: 20091224–0018.

Comment Date: 5 p.m. Eastern Time on Monday, January 04, 2010.

Docket Numbers: RP10–266–000.

Applicants: Sabine Pipe Line LLC.

Description: Sabine Pipe Line LLC submits Original Sheet No. 310B *et al.* to FERC Gas Tariff, Original Volume No. 1.

Filed Date: 12/22/2009.

Accession Number: 20091224–0020.

Comment Date: 5 p.m. Eastern Time on Monday, January 04, 2010.

Docket Numbers: RP10–267–000.

Applicants: Bear Creek Storage Company, LLC.

Description: Notice of name change for Bear Creek Storage Company to Bear Creek Storage Company, LLC of Bear Creek Storage Company.

Filed Date: 12/21/2009.

Accession Number: 20091221–5134.

Comment Date: 5 p.m. Eastern Time on Monday, January 04, 2010.

Docket Numbers: RP10–268–000.

Applicants: Kinder Morgan Interstate Gas Trans. LLC.

Description: Kinder Morgan Interstate Gas Transmission LLC Submits 2009 Reconciliation Filing.

Filed Date: 12/22/2009.

Accession Number: 20091222–5236.

Comment Date: 5 p.m. Eastern Time on Monday, January 04, 2010.

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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.

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The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–461 Filed 1–12–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

December 22, 2009.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP10–241–000.

Applicants: Questar Overthrust Pipeline Company.

Description: Questar Overthurst Pipeline Company submits Third Revised Sheet 1 *et al.* to its FERC Gas Tariff, Second Revised Volume 1–A, to be effective 2/1/10.

Filed Date: 12/16/2009.

Accession Number: 20091216–0126.

Comment Date: 5 p.m. Eastern Time on Monday, December 28, 2009.

Docket Numbers: RP10–242–000.

Applicants: MarkWest Pioneer, L.L.C.

Description: MarkWest Pioneer, LLC submits Second Revised Sheet No 76 *et al.* FERC Gas Tariff, Original Volume No 1.

Filed Date: 12/16/2009.

Accession Number: 20091217–0190.

Comment Date: 5 p.m. Eastern Time on Monday, December 28, 2009.

Docket Numbers: RP10–243–000.

Applicants: Rockies Express Pipeline LLC.

Description: Rockies Express Pipeline LLC submits Fourteenth Revised Sheet 10 *et al.* of its FERC Gas Tariff, Second Revised Volume 1, to be effective 12/17/09.

Filed Date: 12/16/2009.

Accession Number: 20091217–0191.

Comment Date: 5 p.m. Eastern Time on Monday, December 28, 2009.

Docket Numbers: RP10–244–000.
Applicants: Maritimes & Northeast Pipeline, L.L.C.
Description: Maritimes & Northeast Pipeline, LLC submits Sixth Revised Sheet No. 1 *et al.* to FERC Gas Tariff, First Revised Volume No. 1.
Filed Date: 12/17/2009.
Accession Number: 20091218–0201.
Comment Date: 5 p.m. Eastern Time on Tuesday, December 29, 2009.

Docket Numbers: RP10–245–000.
Applicants: Rockies Express Pipeline LLC.
Description: Rockies Express Pipeline LLC submits Original Sheet No. 11A *et al.* to its FERC Gas Tariff, Second Revised Volume No. 1.
Filed Date: 12/17/2009.
Accession Number: 20091218–0203.
Comment Date: 5 p.m. Eastern Time on Tuesday, December 29, 2009.

Docket Numbers: RP10–246–000.
Applicants: Texas Gas Transmission, LLC.
Description: Texas Gas Transmission, LLC submits Fifth Revised Sheet No. 35A to FERC Gas Tariff, Third Revised Volume No. 1.
Filed Date: 12/17/2009.
Accession Number: 20091218–0463.
Comment Date: 5 p.m. Eastern Time on Tuesday, December 29, 2009.

Docket Numbers: RP10–247–000.
Applicants: Equitrans, L.P.
Description: Equitrans, LP submits Third Revised Sheet 441 to be effective 1/17/10.
Filed Date: 12/18/2009.
Accession Number: 20091218–0480.
Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–248–000.
Applicants: Central Kentucky Transmission Company.
Description: Central Kentucky Transmission Company's submits Penalty Revenue Crediting Report.
Filed Date: 12/18/2009.
Accession Number: 20091218–0479.
Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–249–000.
Applicants: Columbia Gas Transmission, LLC.
Description: Columbia Gas Transmission, LLC submits petition for a limited waiver of Section 40.5 of the General Terms and Conditions of Columbia's FERC Gas Tariff, Third Revised Volume 1.
Filed Date: 12/18/2009.
Accession Number: 20091218–0478.
Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–250–000.
Applicants: Crossroads Pipeline Company.
Description: Crossroads Pipeline Company's submits Penalty Revenue Crediting Report.
Filed Date: 12/18/2009.
Accession Number: 20091218–0477.
Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–251–000.
Applicants: Columbia Gulf Transmission Company.
Description: Columbia Gulf Transmission Company submits Penalty Revenue Crediting Report.
Filed Date: 12/18/2009.
Accession Number: 20091218–0476.
Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–252–000.
Applicants: Columbia Gas Transmission, LLC.
Description: Columbia Gas Transmission, LLC submits Penalty Revenue Crediting Report.
Filed Date: 12/18/2009.
Accession Number: 20091218–0475.
Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Docket Numbers: RP10–253–000.
Applicants: Great Lakes Gas Transmission Limited Partnership.
Description: Great Lakes Gas Transmission Limited Partnership submits Seventh Revised Sheet 4A *et al.* to FERC Gas tariff, Second Revised Volume 1, to be effective 2/1/10.
Filed Date: 12/18/2009.
Accession Number: 20091218–0473.
Comment Date: 5 p.m. Eastern Time on Wednesday, December 30, 2009.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2010–462 Filed 1–12–10; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Filings

December 30, 2009.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP09–558–002.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Transcontinental Gas Pipe Line Company, LLC requests that the Commission reject as moot Original Sheet 89 and Original Sheet 90 to FERC Gas Tariff, Fourth Revised Volume 1, to be effective 12/15/09.
Filed Date: 12/22/2009.
Accession Number: 20091228–0028.
Comment Date: 5 p.m. Eastern Time on Monday, January 4, 2010.

Docket Numbers: RP09–687–003.
Applicants: Equitrans, L.P.
Description: Filing Motion of Equitrans, L.P. for Extension of Time to Comply with Order No. 587–T issued on December 22, 2009.
Filed Date: 12/22/2009.
Accession Number: 20091222–5204.

Comment Date: 5 p.m. Eastern Time on Monday, January 4, 2010.

Docket Numbers: RP10–147–002.

Applicants: Natural Gas Pipeline Company of America.

Description: Emergency Motion of Natural Gas Pipeline Company of America LLC for Limited Stay of Requirement to File Cost and Revenue Study.

Filed Date: 12/22/2009.

Accession Number: 20091222–5279.

Comment Date: 5 p.m. Eastern Time on Monday, January 4, 2010.

Docket Numbers: RP09–614–001.

Applicants: Cheniere Creole Trail Pipeline, LP.

Description: Request of Cheniere Creole Trail Pipeline LP for Limited Waiver of Order No. 712 Electronic Capacity Release Requirements.

Filed Date: 12/23/2009.

Accession Number: 20091223–4009.

Comment Date: 5 p.m. Eastern Time on Monday, January 4, 2010.

Docket Numbers: RP10–19–001.

Applicants: Columbia Gas Transmission, LLC.

Description: Columbia Gas Transmission, LLC submits Tenth Revised Sheet 28 *et al* to its FERC Gas Tariff, Third Volume 1, to be effective 11/1/09.

Filed Date: 12/23/2009.

Accession Number: 20091224–0074.

Comment Date: 5 p.m. Eastern Time on Monday, January 4, 2010.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed on or before 5 p.m. Eastern time on the specified comment date. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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 e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–459 Filed 1–12–10; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9094–9]

An Approach to Using Toxicogenomic Data in U.S. EPA Human Health Risk Assessments: A Dibutyl Phthalate Case Study

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA is announcing the availability of a final report titled, "An Approach to Using Toxicogenomic Data in U.S. EPA Human Health Risk Assessments: A Dibutyl Phthalate Case Study" (EPA/600/R–09/028F), which was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development (ORD).

Toxicogenomics is the application of genomic technologies (*e.g.*, transcriptomics, genome sequence analysis) to study effects of environmental chemicals on human health and the environment. Currently, EPA provides no guidance for evaluating and incorporating genomic data into risk assessment. This report describes an approach to evaluate toxicogenomic data for use in risk assessment and a case study for dibutyl phthalate (DBP). A multidisciplinary team of scientists developed the approach and performed the case study. In this approach, the genomic data and the human outcome and/or toxicity data are considered together to determine the relationship between genomic changes and toxicity or health outcomes and inform mechanisms and modes of toxicity. The DBP case study focuses on male reproductive developmental effects and the use of genomic data in qualitative aspects of the risk assessment because of the type of genomic data available for DBP. It is important to note that the case study presented in this report is a separate activity from any of the ongoing IRIS human health assessments for the phthalates.

The final report includes the development of exploratory methods for analyzing genomic data for application to risk assessment and some preliminary results. In addition, recommendations for risk assessors, research needs, and future directions for generating and applying genomic data in risk assessment are described. The approach and case study may be used as a template for evaluating and analyzing genomic data in future chemical assessments and the methods and research needs may be used by researchers performing genomic studies for use in risk assessment.

ADDRESSES: The document will be available electronically through the NCEA Web site at *www.epa.gov/ncea*. A limited number of paper copies will be available from the EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; *telephone:* 1–800–490–9198; *facsimile:* 301–604–3408; *e-mail: nscep@bps-lmit.com*. Please provide your name, your mailing address, the title and the EPA number of the requested publication.

FOR FURTHER INFORMATION CONTACT: The Information Management Team, National Center for Environmental Assessment (8601P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. *Telephone:* 703–347–8561; *fax:* 703–347–8691; *e-mail: nceadc.comment@epa.gov*.

Dated: October 27, 2009.

Peter W. Preuss,

Director, National Center for Environmental Assessment.

[FR Doc. 2010–486 Filed 1–12–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9102–5]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended ("Act"), 42 U.S.C. 7413(g), notice is hereby given of a proposed consent decree, to address a lawsuit filed by WildEarth Guardians in the United States District Court for the District of Colorado: *WildEarth Guardians* v. *Jackson*, No. 09–cv–01964–MSK–MEH (D. Colo.). Plaintiff filed a deadline suit

to compel the Administrator to respond to an administrative petition seeking EPA's objection to a CAA Title V operating permit issued by the Colorado Department of Public Health and Environment, Air Pollution Division, to the Public Service of Colorado to operate the Hayden Station power plant near Hayden, Colorado. Under the terms of the proposed consent decree, EPA has agreed to respond to the petition by March 25, 2010, or within 20 days of the entry date of this Consent Decree, whichever is later.

DATES: Written comments on the proposed consent decree must be received by *February 12, 2010.*

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2010–0007, online at *http://www.regulations.gov* (EPA's preferred method); by e-mail to *oei.docket@epa.gov*; mailed to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT: Amy Branning, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone: (202) 564–1744; fax number (202) 564–5603; e-mail address: *branning.amy@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree

This proposed consent decree would resolve a lawsuit alleging that the Administrator failed to perform a nondiscretionary duty to grant or deny, within 60 days of submission, an administrative petition to object to a CAA Title V permit issued by the Colorado Department of Public Health and Environment, Air Pollution Division, to the Public Service of Colorado to operate the Hayden Station power plant near Hayden, Colorado. Under the terms of the proposed consent decree, EPA has agreed to respond to the petition by March 25, 2010, or within 20 days of the entry date of this Consent Decree, whichever is later. In addition, the proposed consent decree states that within fifteen (15) business days following signature of its response EPA shall deliver notice of such action to the Office of the Federal Register for prompt publication. The proposed consent decree sets the attorneys' fees at $3,520.00, and states that, after EPA fulfills its obligations under the decree, the case shall be dismissed with prejudice.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree from persons who were not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this consent decree should be withdrawn, the terms of the decree will be affirmed.

II. Additional Information About Commenting on the Proposed Consent Decree

A. How Can I Get a Copy of the Consent Decree?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2010–0007) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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 OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *http://www.regulations.gov*. You may use the *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select "search".

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *http://www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and To Whom Do I Submit Comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment and with any disk or CD–ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *http://www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (e-mail) system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through *http://www.regulations.gov*,

your e-mail address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: January 7, 2010.

Richard B. Ossias,

Associate General Counsel.

[FR Doc. 2010–483 Filed 1–12–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0615; FRL–8433–2]

Pesticide Experimental Use Permits; Receipt of Applications; Comment Requests

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's receipt of applications 29964–EUP–I and 29964–EUP–O from Pioneer Hi-Bred International, Inc. requesting experimental use permits (EUPs) for seed blends of the plant-incorporated protectants (PIPs) [DAS–59122–7] *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material (vector PHP 17662) necessary for their production in Event DAS–59122–7 corn and [TC1507] *Bacillus thuringiensis* Cry1F protein and the genetic material (vector PHP8999) necessary for its production in Event TC1507 corn and [MON810] *Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material necessary for its production (Vector PV–ZMCT01) in Event MON810 corn (Organization for Economic Cooperation and Development (OECD) Unique Identifier MONØØ81Ø–6). The Agency has determined that the permits may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on these applications.

DATES: Comments must be received on or before February 12, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2009–0615, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington,VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2009–0615. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line 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 regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: *mendelsohn.mike@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons interested in agricultural biotechnology or those who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a

Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What Action is the Agency Taking?

Under section 5 of FIFRA, 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain EUPs before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water.

Pursuant to 40 CFR 172.11(a), the Agency has determined that the following EUP applications may be of regional and national significance, and therefore is seeking public comment on the EUP applications:

Submitter: Pioneer Hi-Bred International, Inc., (29964–EUP–I).

Pesticide Chemical: [DAS–59122–7] *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material (vector PHP 17662) necessary for their production in Event DAS–59122–7 corn (a maximum of 40.8 lbs Cry34Ab1 and 2.2 lbs Cry35Ab1) and [TC1507] *Bacillus thuringiensis* Cry1F protein and the genetic material (vector PHP8999) necessary for its production in Event TC1507 corn (a maximum of 2.6 lbs Cry1F).

Summary of Request: The 29964–EUP–I application is for a total of 36,670 acres in 11 states from March 1, 2010 to May 31, 2011 in order to continue research, testing, and evaluation of blended refuge concepts. 35,200 acres are proposed for testing under a grower evaluation protocol and will include seed blends of: 1) 5% Cry1F corn with 95% Cry34Ab1/35Ab1 x Cy1F corn, 2) 10% Cry1F corn with 95% Cry34Ab1/35Ab1 x Cy1F corn, 3) 95% Cry34Ab1/35Ab1 x Cy1F corn with 5% non-Bt corn, and 4) 90% Cry34Ab1/35Ab1 x Cy1F corn with 10% non-Bt corn. 1,470 acres are proposed for testing under a research trial protocol and will include the seed blends mentioned in this paragraph along with Cry34Ab1/35Ab1 x Cy1F corn and Cry34Ab1/35Ab1 corn as comparators and non-PIP corn as a control. States involved include: Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, Ohio, South Dakota, and Wisconsin.

Submitter: Pioneer Hi-Bred International, Inc. (29964–EUP–O).

Pesticide Chemical: [DAS–59122–7] *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material (vector PHP 17662) necessary for their production in Event DAS–59122–7 corn (a maximum of 0.630 lbs Cry34Ab1 and 0.040 lbs Cry35Ab1), [TC1507] *Bacillus thuringiensis* Cry1F protein and the genetic material (vector PHP8999) necessary for its production in Event TC1507 corn (a maximum of 0.110 lbs Cry1F), and [MON810] *Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material necessary for its production (Vector PV–ZMCT01) in Event MON810 corn (OECD Unique Identifier MONØØ81Ø–6) (a maximum of 0.011 lbs Cry1Ab).

Summary of Request: The 29964–EUP–O application is for 3,495.4 acres in 34 states from February 1, 2010 to June 30, 2011 in order to continue research, testing, and evaluation of blended refuge concepts. The following are proposed for testing: 1) 300.4 acres of a 95% blend of Cry1F x Cry1Ab corn and 5% non-Bt corn, 2) 295 acres of a blend of 90% Cry34Ab1/35Ab1 x Cy1F and 10% non-Bt corn, 3) 333.4 acres of a 95% blend of Cry1F x Cry1Ab x Cry34Ab1/35Ab1 corn and 5% non-Bt corn, 4) 328 acres of a 90% blend of Cry1F x Cry1Ab x Cry34Ab1/35Ab1 corn and 10% non-Bt corn, 5) 734.4 acres of other registered PIPs, 6) 300.4 acres of Cry1F x Cry1Ab corn, 7) 333.4 acres of Cry1F x Cry1Ab x Cry34Ab1/35Ab1 corn, and 8) 870.4 acres of non-PIP corn.

Four trial protocols will be conducted, including:

- Trait advancement trial (TAT).
- Agronomic observations.
- IRM/efficacy.
- University.

States involved include: Alabama, Arkansas, California, Colorado, Delaware, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Lousianna, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New York, North Carolina, North Dakota, Ohio, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, Washington, and Wisconsin.

A copy of the applications and any information submitted is available for public review in the docket established for these EUP applications as described under **ADDRESSES**.

Following the review of the applications and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP requests, and if issued, the conditions under which it is to be conducted. Any issuance of EUPs will be announced in the **Federal Register**.

List of Subjects

Environmental protection, Experimental use permits.

Dated: December 29, 2009.

W. Michael McDavit,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2010–334 Filed 1–12–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0917; FRL–8805–6]

Notice of Receipt of a Pesticide Petition Filed for Residues of Polymeric Polyhydroxy Acid in or on All Food Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the Agency's receipt of an initial filing of a pesticide petition proposing the establishment of a regulation for residues of the plant growth regulator, polymeric polyhydroxy acid, in or on all food commodities.

DATES: Comments must be received on or before February 12, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID)

number EPA–HQ–OPP–2009–0917 and the pesticide petition number (PP), by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2009–0917 and the pesticide petition number (PP 9F7645). EPA's policy is that all comments received will be included in the docket without change and may be made available on-line 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 regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT:

Menyon Adams, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8496; e-mail address: *adams.menyon@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What Action is the Agency Taking?

EPA is announcing receipt of a pesticide petition filed under section 408 of the Federal Food, Drug, and

Cosmetic Act (FFDCA), 21 U.S.C. 346a, proposing the establishment of a regulation in 40 CFR part 180 for residues of polymeric polyhydroxy acid in or on all food commodities. EPA has determined that the pesticide petition described in this notice contains data or information prescribed in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the pesticide petition. Additional data may be needed before EPA can make a final determination on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition that is the subject of this notice, prepared by the petitioner, is included in a docket EPA has created for this rulemaking. The docket for this petition is available on-line at *http://www.regulations.gov*.

As specified in FFDCA section 408(d)(3), (21 U.S.C. 346a(d)(3)), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment of a regulation for residues of the pesticide in or on all food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

PP 9F7645. Floratine Biosciences, Inc., 153 N. Main Street, Suite 100, Collierville, TN 38017, proposes to establish an exemption from the requirement of a tolerance for residues of the plant growth regulator, polymeric polyhydroxy acid, in or on all food commodities. The petitioner believes no analytical method is needed because this is an exemption from the requirement of a tolerance without any numerical limitation.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 5, 2010.

Keith A. Matthews,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2010–490; Filed 1–12–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0135; FRL–8804–9]

Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of request by registrants to voluntarily cancel certain pesticide registrations.

DATES: Unless a request is withdrawn by July 12, 2010 or February 12, 2010 for registrations for which the registrant requested a waiver of the 180–day comment period, orders will be issued canceling these registrations. The Agency will consider withdrawal requests postmarked no later than July 12, 2010 or February 12, 2010, whichever is applicable. Comments must be received on or before July 12, 2010 or February 12, 2010, for those registrations where the 180–day comment period has been waived.

ADDRESSES: Submit your comments and your withdrawal request, identified by docket identification (ID) number EPA–HQ–OPP–2009–0135, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Written Withdrawal Request, Attention: John Jamula, Information Technology and Resources Management Division (7502P).

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2009–0135. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line 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 regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available in regulations.gov. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: John Jamula, Information Technology and Resource Management Division, Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6426; e-mail address: *jamula.john@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to persons who produce or use pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What Action is the Agency Taking?

This notice announces receipt by the Agency of applications from registrants to cancel 81 pesticide products registered under section 3 or 24(c) of FIFRA. These registrations are listed in sequence by registration number (or company number and 24(c) number) in Table 1 of this unit:

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration no.	Product Name	Chemical Name
000228–00640	Imida E-Pro 0.50% Insecticide Plus Turf Fertilizer	Imidacloprid
000228–00641	Imida E-Pro 0.30% Insecticide Plus Turf Fertilizer	Imidacloprid
000228–00642	Imida E-Pro 0.25% Insecticide Plus Turf Fertilizer	Imidacloprid
000228–00643	Imida E-Pro 0.20% Insecticide Plus Turf Fertilizer	Imidacloprid
000228–00644	Imida E-Pro 0.15% Insecticide Plus Turf Fertilizer	Imidacloprid
000241 AR–04–0003	Beyond Herbicide	Imazamox
000264 LA–04–0002	Aztec 2.1% Granular Insecticide	Phostebupirim
		Cyfluthrin
000264 LA–04–0010	Aztec 4.67g Granular Insecticide	Cyfluthrin
		Phostebupirim
000264 MS–04–0001	Aztec 2.1% Granular Insecticide	Cyfluthrin
		Phostebupirim
000264 MS–04–0006	Aztec 4.67% Granular	Cyfluthrin
		Phostebupirim
000264 MS–06–0003	Defcon 2.1G	Cyfluthrin
		Phostebupirim
000264 TX–03–0010	Aztec 2.1% Granular Insecticide	Phostebupirim

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration no.	Product Name	Chemical Name
		Cyfluthrin
000264 TX–04–0024	Aztec 4.67% Granular Insecticide	Cyfluthrin
		Phostebupirim
000264 WA–94–0001	Rovral Fungicide	Iprodione
000538–00096	Scotts Lawn Disease Preventer	Pentachloronitrobenzene
000538–00116	Scotts Lawn Disease Preventer Plus Fertilizer	Pentachloronitrobenzene
000538–00194	Proturf Fertilizer Plus Fungicide VIII	Thiophanate-methyl
		Iprodione
000769–00978	Allpro Baracide 5ps Pelleted Herbicide	Simazine
		Sodium chlorate
		Prometon
		Boric acid (HBO2), sodium salt
000802–00593	Lilly/Miller Ready-To-Use Bug-Off	Piperonyl butoxide
		Pyrethrins
000829–00200	SA-50 Brand Sevin 10% Dust	Carbaryl
000961–00383	Par Ex Slow Release Fertilizer Plus Snow Mold Control	Pentachloronitrobenzene
002749 ID–05–0004	Sprout Nip Briquette	Chlorpropham
004822–00487	Snake 1	d-trans-Chrysanthemum monocarboxylic ester of dl-2-allyl-4-hydroxy-3-methyl-2-cyclopenten-1-
004822–00532	Raid Reach & Kill Indoor Ant & Roach Killer	Cypermethrin
005481 LA–01–0008	Aztec 4.67% Granular	Phostebupirim
		Cyfluthrin
005481 OR–00–0020	Orthene 97 Pellets	Acephate
005481 OR–97–0006	Orthene 75 S Soluble Powder	Acephate
005481 TX–04–0001	Aztec 4.67% Granular	Cyfluthrin
		Phostebupirim
005905 LA–06–0002	Defcon 2.1%G	Phostebupirim
		Cyfluthrin
007401–00163	Ferti - Lome A-C-G Insecticide & Fungicide	Malathion
		Pentachloronitrobenzene
007401–00372	Ferti-Loam Whitefly & Mealybug Killer	Aliphatic petroleum solvent
		Resmethrin
007401–00389	Hi-Yield Terraclor Fungicide	Pentachloronitrobenzene
007401–00433	3 Way Dust Garden Insecticide	Rotenone
		Sulfur
034704 CA–96–0009	Coastox Carbaryl Cutworm Bait	Carbaryl

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration no.	Product Name	Chemical Name
042964–00016	Aquinoc	Resmethrin
043813–00022	Fungaflor 100 SL	Imazalil sulphate
048273–00017	Marman Pcnb 75% WP	Pentachloronitrobenzene
053883–00204	IMI 0.22% G	Imidacloprid
053883–00206	IMI 0.22% G Rose, Flower & Shrub Insecticide	Imidacloprid
053883–00215	IMI 0.2 Plus	Imidacloprid
061483–00062	Vulcan Glazd Penta	Pentachlorophenol
062719–00222	Broadstrike + Treflan	Trifluralin
		Flumetsulam
062719–00286	Starane	Fluroxypyr 1-methylheptyl ester
062719 CA–05–0016	Kerb 50W	Propyzamide
062719 CA–07–0016	Intrepid 2F	Methoxyfenozide
062719 CA–86–0065	Kerb 50–W Herbicide (in Water Soluble Pouches)	Propyzamide
062719 CA–94–0013	Lorsban 4E-HF	Chlorpyrifos
062719 CA–94–0015	Lorsban 4E-HF	Chlorpyrifos
062719 CA–94–0016	Lorsban 4E-HF	Chlorpyrifos
062719 CA–95–0015	Lorsban-4E	Chlorpyrifos
062719 FL–94–0003	Lorsban 4E-HF	Chlorpyrifos
062719 HI–07–0002	Lorsban-4E	Chlorpyrifos
062719 ID–95–0013	Lorsban-4E	Chlorpyrifos
062719 ID–99–0019	Lorsban-4E	Chlorpyrifos
062719 LA–07–0002	Lorsban-4E	Chlorpyrifos
062719 MI–04–0004	Propiconazole EC	Propiconazole
062719 MS–06–0017	Lorsban-4E	Chlorpyrifos
062719 NC–07–0001	Lorsban-4E	Chlorpyrifos
062719 OR–05–0015	Lorsban-4E	Chlorpyrifos
062719 OR–94–0028	Lorsban 4E-HF	Chlorpyrifos
062719 OR–94–0030	Lorsban 4E-HF	Chlorpyrifos
062719 OR–94–0031	Lorsban 4E-HF	Chlorpyrifos
062719 OR–94–0033	Lorsban 4E-HF	Chlorpyrifos
062719 OR–95–0009	Lorsban-4E	Chlorpyrifos
062719 OR–97–0009	Lorsban-4E	Chlorpyrifos
062719 OR–99–0057	Lorsban-4E	Chlorpyrifos
062719 WA–04–0018	NAF-522	Glyphosate-isopropylammonium
062719 WA–05–0012	Lorsban-4E	Chlorpyrifos
062719 WA–94–0002	Lorsban 4E-HF	Chlorpyrifos

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration no.	Product Name	Chemical Name
062719 WA–97–0008	Lorsban-4E	Chlorpyrifos
062719 WA–97–0012	Lorsban-4E	Chlorpyrifos
062719 WA–99–0015	Lorsban-4E	Chlorpyrifos
067517–00002	Malathion Spray	Malathion
070506–00192	Knox Out NI	Diazinon
072871 MO–99–0005	Dylox 80 Turf and Ornamental Insecticide	Trichlorfon
083399–00004	SVP5	Dinotefuran
084467–00001	Proparmite Technical	Propargite
084467–00002	Antimite(tm)-6.5EC	Propargite
084467–00003	Proparmite (tm) -6EC	Propargite
084467–00004	Proparmite (tm)-30WSP	Propargite
084467–00005	Proparmite(tm)-6E	Propargite

A request to waive the 180–day comment period has been received for the following registrations: 000228–00640; 000228–00641; 000228–00642; 000228–00643;000228–00644; 000538–00096; 000538–00116; 000769–00978; 000961–00383; 004822–00487; 004822–00532; 007401–00163; 007401–00372; 007401–00389; 007401–00433; 043813–00022; 048273–00017; 061483–00062; 062719–00286; 067517–00002; 070506–00192; 084467–00001; 084467–00002; 084467–00003; 084467–00004; 084467–00005.

Unless a request is withdrawn by the registrant within 180 days of publication of this notice, orders will be issued canceling all of these registrations. Users of these pesticides or anyone else desiring the retention of a registration should contact the applicable registrant directly during this 180–day period.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number:

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company no.	Company Name and Address
000228	Nufarm Americas Inc., 150 Harvester Drive, Suite 200, Burr Ridge, IL 60527.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION—Continued

EPA Company no.	Company Name and Address
000241	BASF Corp., P.O. Box 13528, Research Triangle Park, NC 27709–3528.
00264	Bayer Cropscience LP, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709.
000538	The Scotts Co., 14111 Scottslawn Rd, Marysville, OH 43041.
000769	Value Gardens Supply, LLC, d/b/a Value Garden Supply, P.O. Box 585, Saint Joseph, MO 64502.
000802	Registrations By Design, Inc., Agent For: Lilly Miller Brands, P.O. Box 1019, Salem, VA 24153–3805.
000829	Southern Agricultural Insecticides, Inc., P.O. Box 218, Palmetto, FL 34220.
000961	Product & Regulatory Associates, LLC, Agent For: Lebanon Seaboard Corp., P.O. Box 351, Vorhees, NJ 08043.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION—Continued

EPA Company no.	Company Name and Address
002749	Aceto Agricultural Chemicals Corp., One Hollow Lane, Lake Success, NY 11042–1215.
004822	S.C. Johnson & Son Inc., 1525 Howe Street, Racine, WI 53403.
005481	Amvac Chemical Corp., d/b/a Amvac, 4695 Macarthur Ct., Suite 1250, NewP.O.rt Beach, CA 92660–1706.
005905	Helena Chemical Co, 7664 Moore Rd., Memphis, TN 38120.
007401	Mandava Associates, LLC, Agent For: Voluntary Purchasing Groups, Inc., 6860 N. Dallas Pkwy., Suite 200, Plano, TX 75024.
034704	Loveland Products, Inc., Attn: Mark R. Trostle P.O. Box 1286, Greeley, CO 80632–1286..
042964	Airkem Professional Products, Division of Ecolab, Inc., 370 North Wabasha Street, St. Paul, MN 55102.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION—Continued

EPA Company no.	Company Name and Address
043813	Janssen PMP, Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Rd, Titusville, NJ 08560–0200.
048273	Nufarm Inc., Agent For: Marman USA Inc., 150 Harvester Drive Suite 200, Burr Ridge, IL 60527.
053883	Control Solutions, Inc., 5903 Genoa-Red Bluff Rd., Pasadena, TX 77507–1041.
061483	KMG-Bernuth, Inc., 9555 W. Sam Houston Pkwy South, Suite 600, Houston, TX 77099.
062719	Dow Agrosciences LLC, 9330 Zionsville Rd 308/2E, IndianaP.O.lis, IN 46268–1054.
067517	Virbbac AH, Inc., Agent For: PM Resources Inc., P.O. Box 162059, Fort Worth, TX 76161.
070506	United Phosphorus, Inc., 630 Freedom Business Center, Suite 402, King Of Prussia, PA 19406.
072871	Missouri Aquaculture Association, P.O. Box 630, Jefferson City, MO 65102–6864.
083399	Summit Vetpharm, LLC, 301 Route 17 North (12th Floor), Rutherford, NJ 07070.
084467	UPI-Aceto, LLC, 630 Freedom Business Center, Suite 402, King Of Prussia, PA 19406.

III. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**, postmarked before July 12, 2010. This written withdrawal of the request for cancellation will apply only to the applicable FIFRA section 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

V. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in the **Federal Register** of June 26, 1991 (56 FR 29362) (FRL–3846–4). Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold, or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product. Exception to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in a special review action, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: December 29, 2009.

Katheryn S. Bouvé,

Acting Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2010–272 Filed 1–12–10; 8:45 am]

BILLING CODE 6560–50–S

FARM CREDIT SYSTEM INSURANCE CORPORATION

Meetings

AGENCY: Farm Credit System Insurance Corporation Board; Regular Meeting.

SUMMARY: Notice is hereby given of the regular meeting of the Farm Credit System Insurance Corporation Board (Board).

DATE AND TIME: The meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on January 21, 2010, from 9 a.m. until such time as the Board concludes its business.

FOR FURTHER INFORMATION CONTACT: Roland E. Smith, Secretary to the Farm Credit System Insurance Corporation Board, (703) 883–4009, TTY (703) 883–4056.

ADDRESSES: Farm Credit System Insurance Corporation, 1501 Farm Credit Drive, McLean, Virginia 22102.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available) and parts will be closed to the public. In order to increase the accessibility to Board meetings, persons requiring assistance should make arrangements in advance. The matters to be considered at the meeting are:

Open Session

A. Approval of Minutes

- December 10, 2009 (Open and Closed)

B. New Business

- Review of Insurance Premium Rates

Closed Session

- Update on System Institution Risk

Dated: January 7, 2010.

Roland E. Smith,

Secretary, Farm Credit System Insurance Corporation Board.

[FR Doc. 2010–406 Filed 1–12–10; 8:45 am]

BILLING CODE 6710–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection Being Submitted for Review to the Office of Management and Budget (OMB), Comments Requested

January 7, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number.

DATES: Persons wishing to comments on this information collection should submit comments on or before February 12, 2010. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget (OMB), via fax at (202) 395–5167, or via the Internet at Nicholas_A._Fraser@omb.eop.gov and to Judith B. Herman, Federal Communications Commission (FCC). To submit your PRA comments by e–mail send them to: PRA@fcc.gov.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to web page: http://www.reginfo.gov/public/do/PRAMain, (2) look for the section of the web page called "Currently Under Review", (3) click on the downward–pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, and (6) when the FCC list appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, OMD, 202–418–0214. For additional information about the information collection(s) send an e–mail to PRA@fcc.gov or contact Judith B. Herman, 202–418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control No: 3060–0719.

Title: Quarterly Report of IntraLATA Carriers Listing Payphone Automatic Number Identifications (ANIs).

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for–profit.

Number of Respondents: 400 respondents; 1,600 responses.

Estimated Time Per Response: 3.5 hours (8 hours for initial submission; 2 hours per subsequent submission – for an average of 3.5 hours per response).

Frequency of Response: Quarterly reporting requirement, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for this collection of information is contained in 47 U.S.C. sections 151, 154, 201–205, 215,218, 219, 220, 226 and 276.

Total Annual Burden: 5,600 hours.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: The Commission is not requesting respondents to submit confidential information to the Commission. If the respondent wishes confidential treatment of their information, they may request confidential treatment under 47 CFR 0.459 of the Commission's rules.

Need and Uses: The Commission is submitting this expiring information collection to the Office of Management and Budget (OMB) in order to obtain the full three year clearance from them. There is no change in the reporting, recordkeeping and/or third party disclosure requirements.

Pursuant to the mandate in section 276(b)(1)(A) of the Telecommunications Act of 1996 to "establish a per call compensation plan to ensure that all payphone service providers are fairly compensated for each and every completed intrastate and interstate call." IntraLATA carriers are required to provide to interexchange carriers (IXCs) a quarterly report listing payphone ANIs. Without provision of this report, resolution of disputed ANIs would be rendered very difficult. IXCs would not be able to discern which ANIs pertain to payphones and therefore would not be able to ascertain which dial–around calls were originated by payphones for compensation purposes. There would be no way to guard against possible fraud. Without this collection, lengthy investigations would be necessary to verify claims. The report allows IXCs to determine which dial–around calls are made from payphones. The data which must be maintained for at least 18 months after the close of the compensation period, will facilitate verification of disputed ANIs.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2010–396 Filed 1–12–10; 8:45 am]

BILLING CODE 6712–01–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection Being Submitted to the Office of Management and Budget (OMB) for Review, Comments Requested

January 7, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways of reducing the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with

a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number.

DATES: Persons wishing to comments on this information collection should submit comments on or before February 12, 2010. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget (OMB), via fax at (202) 395–5167, or via the Internet at Nicholas_A._Fraser@omb.eop.gov and to Judith B. Herman, Federal Communications Commission (FCC). To submit your PRA comments by e–mail send them to: PRA@fcc.gov.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to web page: http://www.reginfo.gov/public/do/PRAMain, (2) look for the section of the web page called "Currently Under Review", (3) click on the downward–pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, and (6) when the FCC list appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, OMD, 202–418–0214. For additional information about the information collection(s) send an e–mail to PRA@fcc.gov or contact Judith B. Herman, 202–418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control No: 3060–0743.

Title: Implementation of the Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996, CC Docket No. 96–128.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for–profit.

Number of Respondents: 4,471 respondents; 10,071 responses.

Estimated Time Per Response: .50 to 100 hours.

Frequency of Response: On occasion, monthly and quarterly reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for this collection of information is contained in 47 U.S.C. section 276 of the Telecommunications Act of 1996.

Total Annual Burden: 118,137 hours.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: The Commission is not requesting respondents to submit confidential information to the agency. However, if the respondents wish to request confidential treatment of their information, they may do so under 47 CFR 0.459 of the Commission's rules.

Need and Uses: This collection of information implements the following requirements under section 276 of the Telecommunications Act of 1996. They are: a) state showing of proof of market failure for exception to market–rate local coin call requirement; b) state review of adequacy of provision of public interest payphone; c) payphone providers' transmission of specific payphone coding digits; d) LEC verification of disputed ANIS and maintaining and making available the verification data; e) LEC timely notification of payphone disconnection; f) LEC indication on the payphone's monthly bill that the amount due is for payphone service; g) LEC tariff filing; h) reclassification of LEC–owned payphones; i) payphone provider's verification of its status to payer of compensation; j) payphone providers' posting of local coin call rate on each payphone placard; and k) LEC provision of emergency numbers to carrier–payers.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2010–402 Filed 1–12–10; 8:45 am]

BILLING CODE 6712–01–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection Being Submitted for Review to the Office of Management and Budget (OMB), Comments Requested

January 7, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number.

DATES: Persons wishing to comments on this information collection should submit comments on or before February 12, 2010. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget (OMB), via fax at (202) 395–5167, or via the Internet at Nicholas_A._Fraser@omb.eop.gov and to Judith B. Herman, Federal Communications Commission (FCC). To submit your PRA comments by e–mail send them to: PRA@fcc.gov.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to web page: http://www.reginfo.gov/public/do/PRAMain, (2) look for the section of the web page called "Currently Under Review", (3) click on the downward–pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, and (6) when the FCC list appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, OMD, 202–418–0214. For additional information about the information collection(s) send an e–mail to PRA@fcc.gov or contact Judith B. Herman, 202–418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control No: 3060–0952.

Title: Proposed Demographic Information and Notifications, Second

Further Notice of Proposed Rulemaking (FNPRM), CC Docket No. 98–147.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for–profit.

Number of Respondents: 1,400 respondents; 1,400 responses.

Estimated Time Per Response: 2 hours (2 filings per year).

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. sections 151–154, 201, 202, 251–254, 256, 271 and 303(r).

Total Annual Burden: 5,600 hours.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality.

Need and Uses: The Commission is submitting this expiring information collection to the Office of Management and Budget (OMB) as an extension (no change in the reporting and/or third party disclosure requirement). This submission is being made to the OMB in order to obtain the full three year clearance.

The Commission asked whether physical collocation in remote terminals presents technical or security concerns and, if so, whether these concerns warrant modification of its collocation rules. The Commission asked whether incumbent LECs should be required to provide requesting carriers with demographic and other information regarding particular remote terminals similar to the information available regarding incumbent LEC central offices. Requesting carriers use demographic and other information obtained from incumbent LECs to determine whether they wish to collocate at particular terminals.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2010–470 Filed 1–12–10; 8:45 am]

BILLING CODE 6712–01–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection Being Submitted for Review to the Office of Management and Budget (OMB), Comments Requested

January 8, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number.

DATES: Persons wishing to comments on this information collection should submit comments on or before February 12, 2010. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget (OMB), via fax at (202) 395–5167, or via the Internet at Nicholas_A._Fraser@omb.eop.gov and to Judith B. Herman, Federal Communications Commission (FCC). To submit your PRA comments by e–mail send them to: PRA@fcc.gov.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to web page: http://www.reginfo.gov/public/do/PRAMain, (2) look for the section of the web page called "Currently Under Review", (3) click on the downward–pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, and (6) when the FCC list appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, OMD, 202–418–0214. For additional information about the information collection(s) send an e–mail to PRA@fcc.gov or contact Judith B. Herman, 202–418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control No: 3060–0292.

Title: Section 69.605, Reporting and Distribution of Pool Access Revenues, Part 69, Access Charges.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for–profit.

Number of Respondents: 1,250 respondents; 15,000 responses.

Estimated Time Per Response: .75 hours (45 minutes) x 12 monthly reports.

Frequency of Response: Monthly and annual reporting requirements and third party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in 47 U.S.C. sections 154, 201, 202, 203, 205, 218 and 403.

Total Annual Burden: 11,250 hours.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality.

Need and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) during this comment period in order to obtain the full three year clearance from them. The Commission is submitting this collection as an extension (no change n the reporting and/or third party disclosure requirements.)

Section 69.605 states that access revenues and cost data shall be reported by participants in association tariffs to the association for computation of monthly pool revenues distributions in accordance with this subpart.

The association shall submit a report on or before February 1 of each calendar year describing the association's cost study review process for the preceding calendar year as well as the results of that process. For any revisions to cost study results made or recommended by the association that would change the respective carrier's calculated annual common line or traffic sensitive revenue requirement by ten percent or more, the report shall include the following information: 1) the name of the carrier; 2) a detailed description of the revisions; 3) the amount of the revisions; 4) the impact of the revisions on the carrier's calculated common line and traffic sensitive revenue

requirements; and 5) the carrier's total annual common line and traffic sensitive revenue requirement.

The information is used to compute charges in tariff for access service (or origination and termination) and to compute revenue pool distributions. Neither process could be implemented without the information.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2010–405 Filed 1–12–10; 8:45 am]

BILLING CODE 6712–01–S

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Advisory Committee on Community Banking; Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee on Community Banking, which will be held in Washington, DC. The Advisory Committee will provide advice and recommendations on a broad range of policy issues that have a particular impact on small community banks throughout the United States and the local communities they serve, with a focus on rural areas.

DATES: January 28, 2010, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The meeting will be held in the FDIC Board Room on the sixth floor of the FDIC Building located at 550 17th Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898–7043.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of the impact of the current environment on the ability of community banks to raise capital and increase lending, current examination issues, regulatory reform and other legislative proposals, as well as bank resolution issues. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present valid photo identification to enter the building. The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call (703) 562–6067 (Voice or TTY) at least two days before the meeting to make necessary arrangements. Written statements may be filed with the committee before or after the meeting.

This Community Banking Advisory Committee meeting will be Webcast live via the Internet at *http://www.vodium.com/goto/fdic/communitybanking.asp.* This service is free and available to anyone with the following systems requirements: *http://www.vodium.com/home/sysreq.html.* Adobe Flash Player is required to view these presentations. The latest version of Adobe Flash Player can be downloaded at *http://www.adobe.com/shockwave/download/download.cgi?P1_Prod_Version=ShockwaveFlash.* Installation questions or troubleshooting help can be found at the same link. For optimal viewing, a high speed Internet connection is recommended. The Community Banking Advisory Committee meeting videos are made available on-demand approximately two weeks after the event. For those unable to join the Webcast, this meeting is available through teleconference. Those audience members using this venue will be able to listen only. To access the teleconference, dial 1.888.917.8051, using the passcode FDIC. The Community Banking Advisory Committee meeting videos are made available on-demand approximately two weeks after the event.

Dated: January 8, 2010.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Committee Management Officer.

[FR Doc. 2010–465 Filed 1–12–10; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday, January 12, 2010, at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Darlene Harris,

Deputy Secretary of the Commission.

[FR Doc. 2010–162 Filed 1–12–10; 8:45 am]

BILLING CODE 6715–01–M

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

AGENCY: Federal Election Commission.

DATE AND TIME: Thursday, January 14, 2010, at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

Items To Be Discussed

CORRECTION AND APPROVAL OF MINUTES

DRAFT ADVISORY OPINION 2009–27: American Future Fund Political Action by its counsel, Jason Torchinsky.

DRAFT ADVISORY OPINION 2009–29: Retiree Support Group of Contra Costa County by its counsel, L. Douglas Pipes.

Management and Administrative Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Darlene Harris, Deputy Commission Secretary, at (202) 694–1040, at least 72 hours prior to the hearing date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Darlene Harris,

Deputy Secretary of the Commission.

[FR Doc. 2010–411 Filed 1–12–10; 8:45 am]

BILLING CODE 6715–01–M

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part

225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 5, 2010.

A. Federal Reserve Bank of San Francisco (Tracy Basinger, Director, Regional and Community Bank Group) 101 Market Street, San Francisco, California 94105-1579:

1. BW Acquisition, LLC, and Teach and Save, LLC (as a controlling owner of BW Acquisition, LLC), both of Fountain Green, Utah, to become bank holding companies by acquiring 57.7 percent of the voting shares of Utah Community Bancorp and thereby indirectly acquire Utah Community Bank, both of Sandy, Utah.

Board of Governors of the Federal Reserve System, January 8, 2010.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2010–448 Filed 1–12–10; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL TRADE COMMISSION

[File No. 091 0068]

Agrium Inc. and CF Industries Holding, Inc.; Analysis of the Agreement Containing Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order — embodied in the consent agreement — that would settle these allegations.

DATES: Comments must be received on or before January 22, 2010.

ADDRESSES: Interested parties are invited to submit written comments electronically or in paper form. Comments should refer to "Agrium and CF Industries, File No. 091 0068" to facilitate the organization of comments. Please note that your comment — including your name and your state — will be placed on the public record of this proceeding, including on the publicly accessible FTC website, at (*http://www.ftc.gov/os/publiccomments.shtm*).

Because comments will be made public, they should not include any sensitive personal information, such as an individual's Social Security Number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential. . . .," as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and Commission Rule 4.10(a)(2), 16 CFR 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c).[1]

Because paper mail addressed to the FTC is subject to delay due to heightened security screening, please consider submitting your comments in electronic form. Comments filed in electronic form should be submitted by using the following weblink (*https://public.commentworks.com/ftc/agriumcf*) and following the instructions on the web-based form. To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the weblink: (*https://public.commentworks.com/ftc/agriumcf*). If this Notice appears at (*http://www.regulations.gov/search/index.jsp*), you may also file an electronic comment through that website. The Commission will consider all comments that regulations.gov forwards to it. You may also visit the FTC website at (*http://www.ftc.gov/*) to read the Notice and the news release describing it.

A comment filed in paper form should include the "Agrium and CF Industries, File No. 091 0068" reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex D), 600 Pennsylvania Avenue, NW, Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

The Federal Trade Commission Act ("FTC Act") and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC website, to the extent practicable, at (*http://www.ftc.gov/os/publiccomments.shtm*). As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at (*http://www.ftc.gov/ftc/privacy.shtm*).

[1]The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

FOR FURTHER INFORMATION CONTACT: Robert S. Tovsky (202-326-2634), Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for December 23, 2009), on the World Wide Web, at (*http://www.ftc.gov/os/actions.shtm*). A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before the date specified in the **DATES** section.

Analysis of Agreement Containing Consent Order to Aid Public Comment

I. Introduction

The Federal Trade Commission ("Commission" or "FTC") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Agrium Inc. ("Agrium"), that will completely remedy the anticompetitive effects that would likely result from Agrium's proposed acquisition of CF Industries Holdings, Inc. ("CF"). Under the terms of the Consent Agreement, Agrium is required to, among other things, divest anhydrous ammonia ("AA") terminals in Ritzville, Washington, and Marseilles, Illinois to Terra Industries Inc. ("Terra") or another Commission-approved purchaser. Agrium is also required to divest its rights to market and distribute the AA produced by Rentech at Rentech's East Dubuque, Illinois manufacturing plant back to Rentech.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make it final.

II. Description of the Parties and the Proposed Acquisition

Agrium, a Calgary, Alberta-based company, is a major supplier of agricultural products and services in North and South America. It is also a leading global producer, distributor, and marketer of three primary groups of fertilizers: nitrogen, phosphate, and potash, as well as control release fertilizers and micronutrients. Agrium's operations in North America include four nitrogen fertilizer manufacturing plants and ten fertilizer storage and distribution terminals. Agrium's total net sales in 2008 were approximately $10 billion.

CF Industries Holdings, Inc. is headquartered in Deerfield, Illinois, and is the holding company for CF Industries, Inc., a major producer and distributor of nitrogen and phosphate fertilizers. CF owns two nitrogen fertilizer manufacturing plants and twenty-two fertilizer storage and distribution terminals in North America. Its customers include cooperatives and independent fertilizer retailers primarily located in the eastern and western cornbelt states. CF's total net sales in 2008 were approximately $3.9 billion.

On February 25, 2009, Agrium publicly announced that it had submitted a proposal to CF's board of directors to acquire CF for a total consideration of approximately $3.6 billion. Since then, Agrium has repeatedly extended its tender offer and CF's Board of Directors has consistently rejected these offers. Most recently, Agrium increased its offer to approximately $4.95 billion. This offer will expire on January 22, 2010. If CF accepts Agrium's tender offer, Agrium will hold 100 percent of the voting securities of CF, and CF will become a wholly owned subsidiary of Agrium.

III. The Proposed Complaint

The proposed complaint alleges that Agrium's acquisition of CF, if consummated, may substantially lessen competition or tend to create a monopoly in the distribution and sale of AA in the Pacific Northwest ("PNW") and two geographic areas in Northern Illinois in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Specifically, the acquisition would eliminate actual, direct, and substantial competition between Agrium and CF in the relevant markets; increase Agrium's ability to exercise market power unilaterally in the relevant markets; and substantially increase the level of concentration in the relevant markets and enhance the probability of coordination in the two markets in Northern Illinois.

AA is one of the three major forms of nitrogen fertilizer with the other two being urea and urea ammonia nitrate ("UAN"). Of the three nitrogen-based fertilizers, AA has the highest nitrogen content at 82 percent, while urea and UAN have 46 percent and 28 to 32 percent nitrogen content, respectively. AA also tends to be the least expensive nitrogen fertilizer on a per pound of nitrogen basis. Thus, AA can often be the most cost effective means to deliver nitrogen to the soil.

When deciding which type of nitrogen fertilizer to use, customers consider soil and topographical characteristics, equipment, and weather. AA is the most cost effective and efficient to use in dry areas where the topsoil is relatively thin. In moist conditions, there is a danger that AA will leach into the water table, thus becoming less effective, and that the heavy machinery required to apply AA would damage the field.

AA is applied as a fertilizer directly by injecting or "knifing" it into the soil. This process requires specialized equipment to transport, store, and apply the fertilizer. Customers who use AA have already made significant investments to acquire the necessary infrastructure and application equipment. Switching away from AA thus would require customers to: (a) abandon the investments they have already made to use AA; and (b) make additional investments to obtain the necessary infrastructure and application equipment to apply other nitrogen products. These investments are costly and switching from AA to one of the other nitrogen-based fertilizers would be time-consuming. Thus, existing customers are not likely to shift away from using AA.

The proposed complaint alleges that the three geographic areas in which to analyze the competitive effects of the transaction are the PNW and two adjacent areas in Northern Illinois. AA is transported from its site of production or from import terminals by barge, pipeline, rail, and truck to fertilizer storage terminals or, in limited situations, directly to fertilizer retailers. From there, AA is delivered by truck to local fertilizer retailers, where it is stored in smaller scale storage tanks.

The fertilizer retailers pump liquid AA from their storage tanks into smaller mobile nurse tanks. These nurse tanks are then towed to a farmer's field and hitched behind a tractor for application. Because fertilizer application seasons are highly compressed, fertilizer retailers expect a timely and reliable source of AA supply to meet customer demand during the peak of application season. As transportation costs can make it difficult for terminal owners to be price competitive and profitable, AA distributors must have adequate terminals or storage facilities within 100 to 140 miles of customer locations.

In the PNW, Agrium and CF are the only major suppliers of AA. Thus, the proposed acquisition would reduce the number of significant AA suppliers in the PNW from 2 to 1. In the two areas in Northern Illinois, Agrium and CF are two of only three significant suppliers of AA. As a result, the proposed acquisition would reduce the number of major AA suppliers in those areas from three to two.

As stated in the proposed complaint, entry would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of this acquisition. A new entrant would need: (1) sufficient AA storage capacity to supply customers; (2) a proper distribution infrastructure; and (3) a secure source of AA for the storage facility. For a new entrant to satisfy each of these steps requires significant sunk costs, onerous regulatory approvals and local permitting, and technical expertise. This does not take into account the cost and time it takes to achieve a significant market impact. Thus, it is unlikely that new entry or fringe expansion from another supplier would be timely, likely, or sufficient enough to thwart anticompetitive harm from the proposed acquisition.

IV. The Terms of the Agreement Containing Consent Orders

The Consent Agreement will remedy the Commission's competitive concerns about the proposed acquisition and preserve competition in each of the relevant markets. Under the terms of the Consent Agreement, Agrium would be required to divest: (1) the CF Ritzville, Washington AA terminal; (2) its Marseilles, Illinois AA terminal; and (3) its rights to market the AA produced by Rentech at Rentech's East Dubuque, Illinois, manufacturing plant. Agrium plans to divest the Ritzville and Marseilles terminals to Terra, but the proposed Decision and Order provides for a divestiture to another purchaser with a source of AA if Terra is unable to accomplish the divestitures. The Order also provides that Rentech will receive the rights to distribute and market the AA produced in its own manufacturing facility in East Dubuque. Pursuant to a settlement agreement between Agrium and the Canadian Competition Bureau, Terra will acquire a 50 percent interest in Agrium's nitrogen fertilizer production plant in Carseland, Alberta. The Carseland divestiture will give Terra an unencumbered supply of AA for the Ritzville, Washington terminal.

The Order to Hold Separate and Maintain Assets requires Agrium to maintain the assets to be divested and operate the Ritzville Terminal independently until the respective divestitures are completed.

A. Key Provisions of the Decision and Order

The proposed Decision and Order will allow for effective divestiture of the key assets that today allow CF to provide an independent competitive presence to Agrium in the relevant markets, and therefore will preserve the market structure. Paragraph II of the Decision and Order provides that Agrium divest the Ritzville Terminal and Carseland Facility Interest to Terra within forty-five days of Agrium's acquisition. This paragraph further states that in the event that the Ritzville Terminal divestiture cannot be made to Terra, Agrium will have one-hundred-twenty days from the date the Decision and Order becomes final to divest these assets to a Commission-approved acquirer that has a secure and stable, independent, long-term source of AA.

Paragraph III of the Decision and Order provides that Agrium divest the Marseilles Terminal to Terra within forty-five days of Agrium's acquisition of CF. If this does not occur, the Order requires that Agrium divest the Marseilles Terminal to a Commission-approved acquirer within one-hundred-twenty days from the date the Decision and Order becomes final. Paragraph IV requires Agrium to terminate its rights to distribute AA produced by Rentech pursuant to the Agrium/Rentech Distribution Agreement no later than five days after Agrium acquires CF.

The Decision and Order defines the scope of the assets to include the attributes of an ongoing business, such as necessary real property, tangible personal property, inventories, contracts, records of the business, accounts receivable permits, and all applicable regulatory registrations, permits, and applications. Pursuant to Paragraphs II.G and III.G of the proposed Decision and Order, Agrium also is required to provide necessary transition services to Terra or another Commission-approved acquirer. The purpose of this provision is to allow for a smooth transition of the terminal operations to the acquirer.

Paragraph V of the proposed Decision and Order requires that the Parties keep private, except where necessary under the agreement, confidential business information related to the divested terminals. Paragraph VI of the proposed Decision and Order provides for appointment of a divestiture trustee. Paragraph VII of the Decision and Order provides mechanisms for the retention of Ritzville Terminal and Marseilles Terminal employees by the Commission-approved acquirer.

Paragraph VIII of the proposed Decision and Order requires that the Parties provide the Commission with "advance written notification" of any intent to acquire assets or interests in terminals that store AA in any area affected by the proposed divestitures. Paragraphs IX-X define reporting obligations. Paragraph XI requires Agrium to provide the Commission access to company information and employees for purposes of determining or securing compliance with the Decision and Order. Paragraph XII states that the Decision and Order shall terminate ten years after the date on which the Order becomes final.

B. Key Provisions of the Order to Hold Separate and Maintain Assets

The Order to Hold Separate and Maintain Assets ("Hold Separate Order") requires that Agrium maintain the Marseilles Terminal, Ritzville Terminal, and Carseland Facility assets until such time as the assets are divested. The Hold Separate Order requires that Agrium establish a system to maintain confidential information until the divestitures are completed. It also gives the Commission the option to appoint a Monitor to ensure that Agrium complies with all of its obligations and performs all of its responsibilities as required by the Decision and Order and the Hold Separate Order. The Hold Separate Order incorporates the traditional provisions that allow the Monitor broad oversight of the assets, and requires the Monitor to report to the Commission on a regular basis. The Hold Separate Order also requires Agrium to maintain the Ritzville Terminal assets as an independent business pending divestiture. After the acquisition, the Commission can require Agrium to appoint a Manager to run the terminal on an independent basis pending the divestiture of the assets. Finally, the Hold Separate Order allows the Commission to appoint a Hold Separate

Trustee to operate the assets if the assets are not divested by the deadline set by the Commission.

The purpose of this analysis is to invite public comment on the proposed Consent Agreement, in order to aid the Commission in its determination of whether to make the proposed Consent Agreement final. This analysis is not intended to constitute an official interpretation of the proposed Consent Agreement nor is it intended to modify the terms of the proposed Consent Agreement in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2010–410 Filed 1–12–10; 8:45 am]

BILLING CODE 6750–01–S

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0086]

General Services Administration Acquisition Regulation; Submission for OMB Review; GSA Form 1364, Proposal To Lease Space

AGENCY: Acquisition Policy Division, GSA.

ACTION: Notice of request for comments regarding a reinstatement of an information collection requirement for an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve a revision to the reinstatement of a previously approved information collection requirement regarding GSA Forms 1364/1364A, Proposal to Lease Space (Not Required by Regulation). This form is used to obtain information about property being offered for lease to house Federal agencies. In the past, GSA also used a 1364A which requested information regarding how tenant improvements were financed by a prospective lessor. The new version of form combines the former 1364 and 1364A, and it also collects other financial aspects contained in an offer for analysis and negotiation into lease contracts (*e.g.* real estate taxes, adjustments for vacant space, offerors' design and construction fees). A request for public comments was published in the **Federal Register** at 74 FR 52811, on October 14, 2009. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: February 12, 2010.

FOR FURTHER INFORMATION CONTACT: Beverly Cromer, Procurement Analyst, Acquisition Policy Division, at telephone (202) 501–1448 or via e-mail to *Beverly.cromer@gsa.gov.*

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Regulatory Secretariat (MVPR), General Services Administration, 1800 F Street, NW., Room 4041, Washington, DC 20405. Please cite OMB Control No. 3090–0086, GSA Form 1364/1364A, Proposal to Lease Space (Not Required by Regulation), in all correspondence.

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration (GSA) has various mission responsibilities related to the acquisition and provision of real property management, and disposal of real and personal property. These mission responsibilities generate requirements that are realized through the solicitation and award of leasing contracts. Individual solicitations and resulting contracts may impose unique information collection/reporting requirements on contractors, not required by regulation, but necessary to evaluate particular program accomplishments and measure success in meeting program objectives.

B. Annual Reporting Burden

Respondents: 5733.
Responses Per Respondent: 1.
Hours Per Response: 5.0205.
Total Burden Hours: 28,783.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVPR), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 3090–0086, GSA Form 1364, Proposal to Lease Space, in all correspondence.

Dated: January 7, 2010.

Al Matera,

Director, Acquisition Policy Division.

[FR Doc. 2010–417 Filed 1–12–10; 8:45 am]

BILLING CODE 6820–61–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0246]

General Services Administration Regulation; Submission for OMB Review; Packing List Clause

AGENCY: Office of Acquisition Policy, GSA.

ACTION: Notice of request for reinstatement of and information collection requirement for an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve a reinstatement of a previously approved information collection requirement regarding the packing list clause. A request for public comments was published in the **Federal Register** at 74 FR 52811, October 14, 2009. No comments were received.

Public comments are particularly invited on: whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: February 12, 2010.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the GSA Desk Officer, OMB, Room 10236, NEOB, Washington, DC 20503, and a copy to the Regulatory Secretariat (MVPR), General Services Administration, 1800 F Street, NW., Room 4041, Washington, DC 20405. Please cite OMB Control No. 3090–0246, Packing List Clause, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Michael O. Jackson, Procurement Analyst, Contract Policy Branch, by telephone (202) 208–4949 or via e-mail at *michaelo.jackson@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

GSAR clause 552.211–77, Packing List, requires a contractor to include a packing list that verifies placement of an order and identifies the items shipped. In addition to information contractors would normally include on packing lists, the identification of cardholder

name, telephone number and the term "Credit Card" is required.

B. Annual Reporting Burden

Respondents: 4,000.
Responses per Respondent: 233.
Hours per Response: .00833.
Total Burden Hours: 7757.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVPR), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 3090–0246, Packing List Clause, in all correspondence.

Dated: January 7, 2010.

Al Matera,

Director, Acquisition Policy Division.

[FR Doc. 2010–418 Filed 1–12–10; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The Jackson Heart Study (JHS)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The Jackson Heart Study: Annual Follow-up with Third Party Respondents. *Type of Information Collection Request:* Revision of a currently approved collection (OMB NO. 0925–0491). *Need and Use of Information Collection:* This project involves contacting next-of-kin and family physicians of deceased participants who were part of the Jackson Heart Study exam. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in African American men and women. Recruitment of 5,500 JHS participants began in September 2000 and was completed in March 2004. 5,302 participants completed a baseline Exam 1 that included demographics, psychosocial inventories, medical history, anthropometry, resting and ambulatory blood pressure, phlebotomy and 24-hour urine collection, ECG, echocardiography, and pulmonary function. JHS Exam 2 began September 26 2005, followed by a more comprehensive Exam 3 that began in February 2009. The two new exams include some repeated measures from Exam 1 and several new components, including distribution of self-monitoring blood pressure devices. The continuation of the study allows continued assessment of subclinical coronary disease, left ventricular dysfunction, progression of carotid atherosclerosis and left ventricular hypertrophy, and responses to stress, racism, and discrimination as well as new components such as renal disease, body fat distribution and body composition, and metabolic consequences of obesity.

Frequency of Response: One-time. *Affected Public:* Individuals or households; Businesses or other for profit; not-for-profit institutions. *Type of Respondents:* Adults; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 400; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours per Response:* (84 hours/400 respondents) 0.21; and *Estimated Total Annual Burden Hours Requested:* 84. The annualized cost to respondents is estimated at $3,760, assuming $15 per burden hour for informants and $65 per burden hour for physicians. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN

Type of response	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Morbidity & Mortality AFU 3rd Party/Next-of-kin decedents	200	1	0.17	34
Morbidity & Mortality AFU 3rd Party Physicians	200	1	0.25	50
Total	400			84

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Cheryl Nelson, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892–7934, or call non-toll-free number 301–435–0451 or E-mail your request, including your address to: *NelsonC@nhlbi.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Suzanne Freeman,

NHLBI Project Clearance Liaison, National Institutes of Health.

Michael Lauer,

Director, DCVS, National Institutes of Health.

[FR Doc. 2010–419 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–10–0217]

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 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail 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

Vital Statistics Training Application, (OMB No. 0920–0217 exp. 7/31/2010)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the United States, legal authority for the registration of vital events, *i.e.,* births, deaths, marriages, divorces, fetal deaths, and induced terminations of pregnancy, resides individually with the States (as well as cities in the case of New York City and Washington, DC) and Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. These governmental entities are the full legal proprietors of vital records and the information contained therein. As a result of this State authority, the collection of registration-based vital statistics at the national level, referred to as the U.S. National Vital Statistics System (NVSS), depends on a cooperative relationship between the States and the Federal government. This data collection, authorized by 42 U.S.C. 242k, has been carried out by NCHS since it was created in 1960.

NCHS assists in achieving the comparability needed for combining data from all States into national statistics, by conducting a training program for State and local vital statistics staff to assist in developing expertise in all aspects of vital registration and vital statistics. The training offered under this program includes courses for registration staff, statisticians, and coding specialists, all designed to bring about a high degree of uniformity and quality in the data provided by the States. This training program is authorized by 42 U.S.C. 242b, section 304(a). In order to offer the types of training that would be most useful to vital registration staff members, NCHS requests information from State and local vital registration officials about their projected needs for training. NCHS also asks individual candidates for training to submit an application form containing name, address, occupation, work experience, education, and previous training. These data enable NCHS to determine those individuals whose needs can best be met through the available training resources. NCHS is requesting 3 years of OMB clearance for this project.

There is no cost to respondents in providing these data.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
State, local, and Territory Registration Officials	57	1	20/60	19
Training applicants	100	1	15/60	25
Total				44

Dated: January 7, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–510 Filed 1–12–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0605]

Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: IRB Continuing Review After Clinical Investigation Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled, "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review After Clinical Investigation Approval." The draft guidance announced in this notice is intended to assist institutional review boards (IRBs) in carrying out their continuing review responsibility by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations. The draft guidance should also help clinical investigators and sponsors better understand their responsibilities related to continuing review.

DATES: Although comments on any guidance can be submitted at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers a comment on this draft guidance before it begins work on the final version of the guidance, written or electronic comments on the draft guidance should be submitted by March 15, 2010. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., White Oak (WO) Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 (1–888–463–6332 or 301–796–3400); or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave. (WO Bldg. 66, rm. 4622), Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Sara Goldkind, Office of Good Clinical Practice (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 16–85, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled, "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review After Clinical Investigation Approval." This guidance is intended to assist IRBs in carrying out their continuing review responsibility under 21 CFR 56.108(a) and 56.109(f) by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations. The draft guidance should also help clinical investigators and sponsors better understand their responsibilities related to continuing review. When finalized, this guidance will supersede the Information Sheet, "Continuing Review After Study Approval" (September 1998, Office of Health Affairs, Food and Drug Administration).

To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services, Office for Human Research Protections (OHRP) and FDA have been actively working to harmonize the agencies' regulatory requirements and guidance for human subject research. This draft guidance document was developed as part of these efforts.

FDA is issuing this as a draft guidance because it has been substantially revised in response to numerous questions about the continuing review process from the IRB and research communities. Changes include more detailed discussion about what should be submitted to assist the IRB in conducting continuing review, discussion of the circumstances in which expedited review procedures may be used for continuing review, and guidance about how continuing review dates should be determined.

This draft guidance is part of the Information Sheet Guidance Initiative, announced in the **Federal Register** of February 3, 2006 (71 FR 5861), which describes FDA's intention to update the process for developing, issuing, and making available guidances intended for IRBs, clinical investigators, and sponsors. Known as "Information Sheets," these guidances have provided recommendations to IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by the FDA. The Information Sheet Guidance Initiative is intended to ensure that the Information Sheets are updated, consistent with the FDA's good guidance practices (GGPs). As part of the initiative, which will be ongoing, the agency plans to rescind Information Sheets that are obsolete, revise and reissue guidances that address current issues, and develop new guidance documents as needed.

The draft guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520) (PRA). The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115, which include the requirements for records of continuing review, have been approved under OMB Control No. 0910–0130; the collections of information in part 312 (21 CFR part 312) have been approved under OMB control number 0910–0014; and the collections of information in part 812 (21 CFR part 812) have been approved under OMB control number 0910–0078. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment, and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to these previously approved collections of information found in FDA regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov*, or *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm*

Dated: January 7, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–426 Filed 1–12–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Maternal and Child Health Bureau

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Non-competitive Supplemental Funding to Georgetown University.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing non-competitive supplemental funding under the Maternal Child Health Bureau, Title V program to ensure that Georgetown University, Maternal and Child Health Library can continue to provide much needed services to MCH professionals and members of the public.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Georgetown University.

Amount of the Non-Competitive Supplemental Funding: $137,500.

Project Period: The original project period for this grant is from January 1, 2005 through December 31, 2009.

Period of Supplemental Support: January 1, 2010 through March 31, 2010.

Authority: This activity is under the authority of Title V, Section 501(a)2 of the Social Security Act as amended, 42 U.S.C. 701.

Catalogue of Federal Domestic Assistance Number: 93.110.

Justification for Non-Competitive Supplemental Funding

The Maternal and Child Health (MCH) Library at Georgetown University serves as a national information and education resource library to help meet the changing needs of professionals, families with children, and the general public in the field of maternal and child health. The overall goal is to use information science and information technology to identify, collect, and organize information from the MCH field that is not readily available from other information sources and to make the information available for application by the MCH community in a timely, easy-to-access manner.

Due to an unanticipated delay in the issuance of the funding opportunity announcement for this grant program, the award of non-competitive funding for the period January 1, 2010, to March 31, 2010, to Georgetown University is necessary. In early fiscal year 2010, an open competition will take place for this grant program. The award of non-competitive supplemental funding for Georgetown University will enable the MCH Library to continue to provide this important service to MCH professionals and members of the public without disruption or delays until the results of the competition are known and a new award can be issued.

FOR FURTHER INFORMATION CONTACT: James A. Resnick, Public Health Analyst, Office of Data and Program Development, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857; phone 301–443–3222; e-mail: *JResnick@hrsa.gov*.

Dated: January 8, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–476 Filed 1–12–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Small Research Grants Review.

Date: February 4, 2010.

Time: 10 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael L. Bloom, PhD, MBA, Scientific Review Officer, National Institute of Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Blvd; Room 820, MSC 4872, Bethesda, MD 20892–4872, 301–594–4953, *Michael_Bloom@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–421 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Tumor Immunology and Immunotherapy.

Date: January 12, 2010.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lambratu Rahman, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301–451–3493, *rahmanl@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: AARR.

Date: January 14, 2010.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Robert Freund, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3200, MSC 7848, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing

limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–423 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NHLBI Systems Biology.

Date: January 20, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Ai-Ping Zou, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–435–1777, *zouai@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Biomarker Genomics/Proteomics.

Date: February 3, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Jonathan Arias, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301–435–2406, *ariasj@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

Date: February 4–5, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact: Michael Micklin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435–1258, *micklinm@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function B Study Section.

Date: February 4–5, 2010.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact: Arnold Revzin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7824, Bethesda, MD 20892, (301) 435–1153, *revzina@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: EPIC Members (b) Special Emphasis Panel.

Date: February 9, 2010.

Time: 11:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact: Bob Weller, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3160, MSC 7770, Bethesda, MD 20892, (301) 435–0694, *wellerr@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function A Study Section.

Date: February 11, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: George Washington University Inn, 824 New Hampshire Avenue, NW., Washington, DC 20037.

Contact: David R. Jollie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7806, Bethesda, MD 20892, (301) 435–1722, *jollieda@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroplasticity and Neurotransmitters Study Section.

Date: February 11–12, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: InterContinental Mark Hopkins Hotel, One Nob Hill, San Francisco, CA 94108.

Contact: Suzan Nadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301–435–1259, *nadis@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–425 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Study Team for the Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following meeting.

Name: Public Meeting of the Study Team for the Los Alamos Historical Document Retrieval and Assessment Project.

Time and Date: 9 a.m.–4 p.m., (Mountain Time), Thursday, January 28, 2010.

Place: OHKAY Casino/Resort/Conference Center (2 miles north of Espanola on US 84/285), P.O. Box 1270, Highway 68 Espanola, New Mexico 87506, telephone (505) 747–5523, facsimile (877) 747–5695. See following url/link for area map: *http://www.ohkay.com/contactus.html.*

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 200 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with the Department of Energy (DOE) and replaced by MOUs signed in 1996 and 2000, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC and ATSDR.

In addition, a memo was signed in October 1990 and renewed in November 1992, 1996, and in 2000, between the Agency for Toxic Substances and Disease Registry (ATSDR) and DOE. The MOU delineates the responsibilities and procedures for ATSDR's

public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or a Superfund). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This ChemRisk study group was charged with locating, evaluating, cataloguing, and copying documents that contain information about historical chemical or radionuclide releases from facilities at the Los Alamos National Laboratory since its inception. The purpose of this meeting is to update the report based on comments received to date, to discuss progress to date, provide a forum for community interaction, and serve as a vehicle for members of the public to express concerns and provide comments to CDC.

Matters To Be Discussed: Agenda items include an update presentation from the National Center for Environmental Health (NCEH) and its contractor regarding comments on the LAHDRA project's draft final report. The meeting will include an opening session and update in the morning session with an optional workshop in the afternoon in which attendees can express concerns and comments with subject matter experts.

There will be time for public input, questions, and comments throughout the workshop sessions. All agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: Phillip R. Green, Public Health Advisor, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE., (Mailstop F–58), Atlanta, Georgia 30341–3717, telephone (770) 488–3748, facsimile (770) 488–1539, e-mail address: *prg1@cdc.gov.*

Dated: January 7, 2010.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–501 Filed 1–12–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Special; Emphasis Panel Inflammatory Intervention.

Date: January 27, 2010.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Tamizchelvi Thyagarajan, PhD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892, (301) 594–0343, *tamizchelvi.thyagarajan.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: January 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–413 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Initial Review Group.

Date: February 18–19, 2010.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Weiqun Li, MD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Ste. 710, Bethesda, MD 20892, (301) 594–5966, *wli@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: January 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–429 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel, Predoctoral Individual National Research Service Award.

Date: February 19, 2010.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Weiqun Li, MD, Scientific Review Administrator, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Ste. 710, Bethesda, MD 20892, (301) 594–5966, *wli@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: January 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–428 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Hematopoietic Cellular Mechanisms.

Date: January 21–22, 2010.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

Contact Person: Bukhtiar H. Shah, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892. (301) 435–1233. *shahb@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, CMBK Conflicts.

Date: January 22, 2010.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Ryan G. Morris, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892. 301–435–1501. *morrisr@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group, Tumor Progression and Metastasis Study Section.

Date: February 4–5, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica, 530 West Pico Boulevard, Stella, Santa Monica, CA 90405.

Contact Person: Manzoor Zarger, MS, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892. (301) 435–2477. *zargerma@csr.nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group, Cellular and Molecular Biology of the Kidney Study Section.

Date: February 8, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Bonnie L. Burgess-Beusse, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892. 301–435–1783. *beusseb@mail.nih.gov*.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group, Clinical Oncology Study Section.

Date: February 8–9, 2010.

Time: 8 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Malaya Chatterjee, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892. 301–451–0131. *chatterm@csr.nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Skeletal Biology Development and Disease Study Section.

Date: February 10–11, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Priscilla B. Chen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892. (301) 435–1787. *chenp@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group, Biomedical Imaging Technology Study Section.

Date: February 10–12, 2010.

Time: 7 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Lee Rosen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892. (301) 435–1171. *rosenl@csr.nih.gov*.

Name of Committee: Vascular and Hematology Integrated Review Group, Erythrocyte and Leukocyte Biology Study Section.

Date: February 18, 2010.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Delia Tang, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7802, Bethesda, MD 20892. 301–435–2506. *tangd@csr.nih.gov*.

Name of Committee: Healthcare Delivery and Methodologies, Biomedical Computing and Health Informatics Study Section.

Date: February 18, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Katherine Bent, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3160, MSC 7770, Bethesda, MD 20892. 301–435–0695. *bentkn@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Risk Prevention and Health Behavior Across the Lifespan.

Date: February 18–19, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Claire E. Gutkin, PhD, MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7759, Bethesda, MD 20892. 301–594–3139. *gutkincl@csr.nih.gov*.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group, Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

Date: February 19, 2010.

Time: 8 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Rajiv Kumar, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122,

MSC 7802, Bethesda, MD 20892. 301–435–1212. *kumarra@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Healthcare Delivery and Methodologies.

Date: February 19, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Katherine Bent, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3160, MSC 7770, Bethesda, MD 20892. 301–435–0695. *bentkn@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–427 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel, Clinical Science—Review of NCCAM Clinical R21 and K Applications.

Date: February 25–26, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Laurie Friedman Donze, PhD, Scientific Review Officer, Office of Scientific Review, National Center for Complementary, and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–402–1030, *donzel@mail.nih.gov.*

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel, P50 Botanical Centers.

Date: March 3–5, 2010.

Time: 5 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Marriott Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20814.

Contact Person: Martina Schmidt, PhD, Scientific Review Officer, Office of Scientific Review, National Center for Complementary, and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–594–3456, *schmidma@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: January 7, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–424 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Genetic and Genomic Analyses of Xenopus.

Date: January 27, 2010.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, 6710 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact: Richard Panniers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular, Molecular and Integrative Reproduction Study Section.

Date: January 28, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Knecht, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435–1046, *knechtm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Healthcare Delivery and Methodologies; Nursing Science: Adults and Older Adults Study Section.

Date: February 2–3, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Karin F. Helmers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, 301–254–9975, *helmersk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict Applications: CMBK, PBKD and UKGD.

Date: February 2, 2010.

Time: 8 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting)

Contact: Najma Begum, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, MSC 7818, Bethesda, MD 20892, 301–435–1243, *begumn@csr.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Microscopic Imaging Study Section.

Date: February 3–4, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting)

Contact: Malgorzata Klosek, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge

Drive, Room 4188, MSC 7849, Bethesda, MD 20892, (301) 435–2211, *klosekm@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies; Nursing Science: Children and Families Study Section

Date: February 4, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact: Karin F. Helmers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, 301–254–9975, *helmersk@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Synapses, Cytoskeleton and Trafficking Study Section.

Date: February 4–5, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact: Jonathan K. Ivins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4186, MSC 7850, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Clinical and Integrative Diabetes and Obesity Study Section.

Date: February 4–5, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact: Nancy Sheard, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046–E, MSC 7892, Bethesda, MD 20892, (301) 435–1154, *sheardn@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies; Health Services Organization and Delivery Study Section.

Date: February 4–5, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact: Kathy Salaita, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7770, Bethesda, MD 20892, 301–451–8504, *salaitak@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Mechanisms of Emotion, Stress and Health Study Section.

Date: February 8, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Hotel Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact: Maribeth Champoux, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, MSC 7848, Bethesda, MD 20892, (301) 594–3163, *champoum@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular Aspects of Diabetes and Obesity Study Section.

Date: February 8–9, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Hotel Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Ann A. Jerkins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6154, MSC 7892, Bethesda, MD 20892, 301–435–4514, *jerkinsa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Applications in Mechanisms of Emotion, Stress and Health.

Date: February 8, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Hotel Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Jane A. Doussard-Roosevelt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biomedical Imaging and Bioengineering.

Date: February 9, 2010.

Time: 11:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting)

Contact Person: Dharam S. Dhindsa, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7854, Bethesda, MD 20892, (301) 435–1174, *dhindsad@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Nutrition and Metabolic Processes Study Section.

Date: February 11, 2010.

Time: 7 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Sooja K. Kim, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182, MSC 7892, Bethesda, MD 20892, (301) 435–1780, *kims@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Biomedical Sensing, Measurement and Instrumentation [SSMI] (SBIR/STTR)

Date: February 15, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Guo Feng Xu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–435–1032, *xuguofen@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: February 16–17, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica, 503 Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Yi-Hsin Liu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–451–1327, *liuyh@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Bacterial Pathogenesis Study Section.

Date: February 16, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Ritz-Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Richard G. Kostriken, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, (301) 402–4454, *kostrikr@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies; Biostatistical Methods and Research Design Study Section.

Date: February 17, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Denise Wiesch, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, (301) 435–0684, *wieschd@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–422 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of V–ATPase Inhibitor Compounds for the Treatment of Human Cancers and Osteoclastic Bone Diseases Excluding Rheumatoid Arthritis and Other Osteo-Specific Auto-Immune Diseases

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to the Australian Institute of Marine Science ("AIMS") located in Townsville, Queensland, Australia.

Intellectual Property

- U.S. Provisional Patent Application No. 60/398,092 filed July 24, 2002 entitled "Chondropsin-Class Antitumor V–ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E–191–2002/0–US–01];
- International Patent Application No. PCT/US03/23290 filed July 24, 2003 entitled "Chondropsin-Class Antitumor V–ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E–191–2002/0–PCT–02];
- U.S. Patent Application No. 10/521,930 filed April 18, 2005 entitled "Chondropsin-Class Antitumor V–ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E–191–2002/0–US–03];
- European Patent Application No. 03751813.1 filed February 16, 2005 entitled "Chondropsin-Class Antitumor V–ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E–191–2002/0–EP–04];
- Australian Patent Application No. 2003269924 filed February 4, 2005 entitled "Chondropsin-Class Antitumor V–ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E–191–2002/0–AU–05];
- Canadian Patent Application No. 2493821 filed January 24, 2005 entitled "Chondropsin-Class Antitumor V–ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E–191–2002/0–CA–06];
- U.S. Patent No. 7,521,475 issued April 21, 2009 entitled "Chondropsin-Class Antitumor V–ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E–191–2002/0–US–07];
- U.S. Patent Application No. 12/402,560 filed March 12, 2009 entitled "Chondropsin-Class Antitumor V–ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E–191–2002/0–US–08];
- U.S. Provisional Patent Application No. 60/220,270 filed July 24, 2000 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E–203–2000/0–US–01];
- International Patent Application No. PCT/US01/23633 filed July 24, 2001 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E–203–2000/0–PCT–02];
- US Patent No. 7,144,918 issued December 5, 2006 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E–203–2000/0–US–04];
- US Patent Application No. 11/435,189 filed May 16, 2006 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E–203–2000/0–US–08];
- Australian Patent No. 200112808 issued November 30, 2006 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E–203–2000/0–US–03];
- European Patent Application No. 01959257.5 filed July 24, 2001 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E–203–2000/0–EP–05];
- Canadian Patent Application No. 2415611 filed July 24, 2001 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E–203–2000/0–CA–06]; and
- Japanese Patent Application No. 514137/2002 filed July 24, 2001 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E–203–2000/0–JP–07].

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be for "use of Licensed Patent Rights for use and development of pharmaceutically suitable V–ATPase Inhibitor compounds for the treatment of human cancers, including osteosarcoma, and osteoclastic bone diseases, such as osteoporosis, osteopenia and Paget's disease, " in "all" geographic territories. For avoidance of doubt, the field of use will specifically exclude rheumatoid arthritis and other osteo-specific autoimmune diseases.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before February 12, 2010 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, PhD Licensing and Patenting Associate, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5587; Facsimile: (301) 435–4013; e-mail: *chatterjeesa@od.nih.gov*.

SUPPLEMENTARY INFORMATION: The technology describes the class of Chondropsin compounds and its derivatives. The compounds can be potentially developed into new therapeutics for cancer, osteoporosis, and Alzheimer's diseases.

Briefly, vacuolar type (H+) ATPase (V–ATPase) has been described as "a universal proton pump of eukaryotes". V–ATPase is responsible for maintaining internal acidity and is important in myriad of physiological functions, such as sorting of membrane proteins, proinsulin conversion, neurotransmitter uptake, and cellular degradation process. This technology describes a new chondropsin, Poecillastrin-A, a cytotoxic, 33-member ring, macrolide lactam, isolated from the sponge Poecillastra *sp.* It is structurally related to the chondropsin class of macrolide lactams. However, it possesses unique patterns of methylation and oxygenation, and it is the first member of this family of polyketide derivatives with a 33-membered macrocyclic ring. The in vitro anti-tumor activity of the compound is comparable to that of the chondropsins, however the new structural features found in Poecillastrin-A broaden the known structural diversity of this family of potent anti-proliferative and cytotoxic macrolide lantams. The chondropsins and poecillastrin A produce a distinctive pattern of differential cytotoxicity in the NCI's 60 cell antitumor screen that directly correlates with selective V–ATPase inhibitors.

This class of compounds and its' derivatives have the potential of being used as a therapeutics against several cancer types and may have applicability as highly selective anti-cancer small molecule inhibitors. Additionally, it has

the potential of being used for the treatment of several other diseases such as osteoporosis, and Alzheimer's diseases.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 29, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–420 Filed 1–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Accreditation of Commercial Laboratories and Approval of Commercial Gaugers

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing information collection: 1651–0053.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Accreditation of Commercial Laboratories and Approval of Commercial Gaugers. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (74 FR 58036) on November 10, 2009, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before February 12, 2010.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Accreditation of Commercial Laboratories and Approval of Commercial Gaugers.

OMB Number: 1651–0053.

Form Number: None.

Abstract: Commercial gaugers and laboratories seeking accreditation or approval must provide the information specified in 19 CFR 151.12 and/or 19 CFR 151.13 to CBP. CBP uses this information in deciding whether to approve individuals or businesses desiring to measure bulk products or to analyze importations

Current Actions: There are no changes to the information collection. This submission is being made to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses, Individuals.

Reporting

Estimated Number of Respondents: 200.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Total Responses: 200.

Estimated Time per Response: 75 minutes.

Estimated Total Burden Hours: 250.

Recordkeeping

Estimated Number of Recordkeepers: 200.

Estimated Time per Recordkeeper: 60 minutes.

Estimated Total Burden Hours: 200.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177, at 202–325–0265.

Dated: January 7, 2009.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2010–464 Filed 1–12–10; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2009–0299]

Terminate Long Range Aids to Navigation (Loran-C) Signal

AGENCY: U.S. Coast Guard, DHS.

ACTION: Notice; correction.

SUMMARY: The Coast Guard is correcting a notice that appeared in the **Federal Register** of January 7, 2010 (75 FR 998). The document announced termination of the Long Range Aids to Navigation (Loran-C) Signal commencing on or about February 8, 2010. The document had an incorrect word in the **DATES** section.

DATES: Effective January 13, 2010.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, contact Mr. Mike Sollosi, U.S. Coast Guard, Department of Homeland Security, telephone (202) 372–1545, *Mike.M.Sollosi@uscg.mil.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 7, 2010, in

FR Doc. 2010–83, on page 998 in the second column under **DATES,** correct "Transmission of the Loran-C signal and phased decommissioning of the Loran-C infrastructure will commence on or about February 8, 2010" to read: "Termination of the Loran-C signal and phased decommissioning of the Loran-C infrastructure will commence on or about February 8, 2010."

Dated: January 7, 2010.

Mark W. Skolnicki,

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

[FR Doc. 2010–439 Filed 1–12–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[L63330000–PH0000–LLWO270000; OMB Control Number 1004–0102]

Notice of Proposed Information Collection for 1004–0102

AGENCY: Bureau of Land Management, Interior.

ACTION: 60-Day Notice and Request for Comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is announcing its intention to request reinstatement of an approval to collect information that documents the payment of road use fees for the use of privately owned roads to haul timber sold in accordance with BLM sale contracts. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned the control number 1004–0102.

DATES: Comments on the proposed information collection must be received by March 15, 2010, to be assured of consideration.

ADDRESSES: Comments may be mailed to U.S. Department of the Interior, Bureau of Land Management, Mail Stop 401–LS, 1849 C St., NW., Washington, DC 20240. Comments may also be submitted electronically to *Jean_Sonneman@blm.gov.* Please attach "*Attn:* 1004–0102" to either form of comment.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request, contact Richard Watson, 303–236–0158. Persons who use a telecommunication device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) on 1–800–877–8339, 24 hours a day, seven days a week, to contact Mr. Watson.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320 (which implement provisions of the Paperwork Reduction Act, 44 U.S.C. 3501–352) 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 a collection of information that the BLM will be submitting to OMB for approval.

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 the BLM's submission of the information collection requests to OMB.

Before including your address, phone number, e-mail 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: Road Use Fees Paid Report.

OMB Control Number: 1004–0102.

Summary: Most purchasers of timber from BLM-managed lands use both federal and private roads to haul the timber. In such instances, the timber sale contract with the BLM requires the purchaser to pay private landowners for the use and/or maintenance of their roads. These fees represent the BLM's share of road construction and maintenance costs under reciprocal right-of-way agreements between the BLM and private landowners. *See* 43 U.S.C. 1762; 43 CFR subpart 2812. This information collection is a report that timber sale purchasers submit to the BLM to show that they have paid the fees required by their timber sale contracts. The BLM uses the report to ensure compliance with the timber sale contract, and to amortize road construction and maintenance costs among several road users.

Frequency of Collection: On occasion.

Description of Respondents: Timber sale purchasers that haul timber purchased from the BLM over privately owned roads that are included in reciprocal right-of-way agreements.

Total Annual Responses: 40.

Response Time: 20 minutes.

Total Annual Burden Hours for Respondents: 13 hours.

Jean Sonneman,

Acting Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2010–502 Filed 1–12–10; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

National Park Service

60-Day Notice of Intention To Request Clearance of Collection of Information; Opportunity for Public Comment

AGENCY: Department of Interior, National Park Service.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 and 5 CFR part 1320, Reporting and Record Keeping Requirements, the National Park Service (NPS) invites public comments on a new collection of information.

DATES: Public comments on this Information Collection Request (ICR) will be accepted on or before March 15, 2010.

ADDRESSES: Send comments to: Brian Mitchell, Northeast Temperate Inventory and Monitoring Network, NPS, 54 Elm Street, Woodstock, VT 05091; or via fax at 802–457–3405; or via e-mail at *brian_mitchell@nps.gov.* All responses to the Notice will be summarized and included in the request for the Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

To Request a Draft of Proposed Collection of Information Contact: Brian Mitchell, NPS, 54 Elm Street, Woodstock, VT 05091; or via phone at 802/457–3368; or via fax at 802/457–3368; or via e-mail at *brian_mitchell@nps.gov.* You are entitled to a copy of the entire ICR package free of charge once the package is submitted to OMB for review.

SUPPLEMENTARY INFORMATION:

Title: Citizen Science Phenology Monitoring in National Parks.

Form(s): None.

Type of Request: A new collection of information.

Description of Need: The Government Performance and Results Act (GPRA) of 1995 (Pub. Law 103–62) and the National Park Service (NPS) Strategic

Plan require that the NPS develop goals to improve program effectiveness and public accountability. This collection will encourage the public to collect data relevant to goal 1b: "The National Park Service contributes to knowledge about natural and cultural resources and associated values; management decisions about resources and visitors are based on adequate scholarly and scientific information". This collection is also consistent with the NPS Management Policies (2006), which emphasize the "use of qualitative and quantitative techniques to monitor key aspects of resources and processes at regular intervals" and furthermore state that "studies, research, and collection activities by non-NPS personnel involving natural and cultural resources will be encouraged and facilitated when they otherwise comport with NPS policies." More specifically, the goal of this collection is to engage the public in documenting the timing of biological events ("phenology") for a variety of species at numerous different locations. The data collected will help the NPS document how climate change is affecting the timing of biological events such as migration, flowering, and autumn foliage.

The proposed Internet- and paper-based surveys will ask the public to participate in the collection of these data on NPS lands. With sufficient participation, NPS will obtain critical information for determining trends in the timing of biological events for many species. In addition to documenting changes in timing of events, the data set will facilitate the identification of species most at risk from climate change and anthropogenic influences. Survey participants will provide their contact information and multiple observations of species at one or more sites. The contact information will be used for quality control and (at the request of the participant) to provide data summaries or reports and information about additional opportunities for assisting with NPS research and monitoring activities. The obligation to respond is voluntary.

Automated Data Collection: The information will be collected through an Internet site, as well as through paper forms available at public locations.

Description of respondents: Respondents are members of the public with an interest in contributing to climate change research in the National Parks.

Estimated average number of responses: 1,000 per year.

Frequency of Response: 5 per respondent.

Estimated average time burden per respondent: 30 minutes.

Estimated total annual reporting burden: 100 hours per year.

Comments are invited on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. Before including your address, phone number, e-mail 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.

December 23, 2009.

Cartina A. Miller,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2010–446 Filed 1–12–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[F–14909–B, F–14909–B2, F–19148–38; LLAK964000–L14100000–KC0000–P]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: As required by 43 CFR 2650.7(d), notice is hereby given that an appealable decision approving the surface estate in certain lands for conveyance pursuant to the Alaska Native Claims Settlement Act will be issued to Kuukpik Corporation. The lands are in the vicinity of Nuiqsut, Alaska, and are located in:

Umiat Meridian, Alaska

T. 10 N., R. 2 E.,
Secs. 1, 2, and 3;
Secs. 5 to 10, inclusive;
Secs. 16, 17, and 18;
Secs. 20, 21, and 29.
Containing approximately 8,751 acres.

T. 11 N., R. 2 E.,
Secs. 24, 25, and 26;
Secs. 34, 35, and 36.
Containing approximately 3,545 acres.

T. 11 N., R. 3 E.,
Secs. 7, 11, 13, and 18;
Secs. 19, 24, and 25.
Containing approximately 3,616 acres.

T. 11 N., R. 4 E.,
Secs. 19, 20, and 30.
Containing approximately 1,376 acres.
Aggregating approximately 17,288 acres.

The subsurface estate in these lands will be conveyed to Arctic Slope Regional Corporation when the surface estate is conveyed to Kuukpik Corporation. Notice of the decision will also be published four times in the Arctic Sounder.

DATES: The time limits for filing an appeal are:

1. Any party claiming a property interest which is adversely affected by the decision shall have until February 12, 2010 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4, Subpart E, shall be deemed to have waived their rights.

ADDRESSES: A copy of the decision may be obtained from: Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7504.

FOR FURTHER INFORMATION CONTACT: The Bureau of Land Management by phone at 907–271–5960, or by e-mail at *ak.blm.conveyance@ak.blm.gov.* Persons who use a telecommunication device (TTD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, seven days a week, to contact the Bureau of Land Management.

Michael Bilancione,

Land Transfer Resolution Specialist, Land Transfer Adjudication I Branch.

[FR Doc. 2010–449 Filed 1–12–10; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CACA 048649, LLCAD06000 L51010000 FX0000 LVRWB09B2520]

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed First Solar Desert Sunlight Solar Farm Project, Riverside County, CA and Possible Land Use Plan Amendment

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Palm Springs South Coast Field Office, Palm Springs, California, intends to prepare an Environmental Impact Statement (EIS) for First Solar Inc.'s application for a right-of-way authorization to develop a solar photovoltaic generating facility. The EIS may also support an amendment to the California Desert Conservation Area (CDCA) Plan (1980), as amended; by this notice the BLM is announcing the beginning of the scoping process to solicit public comments and identify issues.

DATES: This notice initiates the public scoping process for the EIS and possible plan amendment. Comments on issues may be submitted in writing until February 12, 2010. The date(s) and location(s) of any scoping meetings will be announced at least 15 days in advance through the local media, and the BLM Web site at: *http://www.blm.gov/ca/st/en/fo/palmsprings.html.* In order to be considered in the Draft EIS, all comments must be received prior to the close of the scoping period or 15 days after the last public meeting, whichever is later. The BLM will provide additional opportunities for public participation upon publication of the Draft EIS.

ADDRESSES: You may submit comments on issues and planning criteria related to the First Solar Desert Sunlight Solar Farm Draft EIS/Plan Amendment by any of the following methods:

- Web site: *http://www.blm.gov/ca/st/en/fo/palmsprings.html;*
- E-mail: *CAPSSolarFirstSolarDesertSunlight@blm.gov;*
- Fax: (760) 833–7199; or
- Mail: Allison Shaffer, Project Manager, Palm Springs South Coast Field Office, BLM, 1201 Bird Center Drive, Palm Springs, California 92262.

Documents pertinent to this proposal may be examined at the Palm Springs South Coast Field Office.

FOR FURTHER INFORMATION CONTACT: For further information or to have your name added to our mailing list, contact Allison Shaffer, BLM Project Manager, telephone (760) 833–7100; address Palm Springs South Coast Field Office, BLM, 1201 Bird Center Drive, Palm Springs, California 92262; e-mail *CAPSSolarFirstSolarDesertSunlight@blm.gov.*

SUPPLEMENTARY INFORMATION: The applicant, First Solar Inc., has requested a right-of-way authorization to develop a solar photovoltaic generating facility with a proposed output of 550 megawatts and a project footprint of approximately 4,410 acres. The proposed project would be located on BLM-administered lands in Riverside County approximately 6 miles north of the rural community of Desert Center, California. The overall site layout and generalized land uses would include a substation, an administration building, operations and maintenance facilities, a transmission line, and temporary construction lay down areas. The project's 230-kilovolt (kV) generation interconnection transmission line also would be located on BLM-administered lands and would utilize a planned 230- to 500-kV substation (referred to as the Red Bluff substation). The Red Bluff substation would connect the project to the Southern California Edison regional transmission grid. Should the project be approved, the interconnection transmission line would be about 9 miles to about 13 miles long, depending on the alternative selected. If approved, construction would begin in late 2010 and would take approximately 41 months to complete.

The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the process for developing the EIS. At present, the BLM has identified the following preliminary issues: Air quality, biological resources, recreation, cultural resources, water resources, geological resources, special management areas, land use, noise, paleontological resources, public health, socioeconomic, soils, traffic and transportation, visual resources, and other issues. Authorization of this proposal may require amendment of the CDCA Plan. By this notice, the BLM is complying with requirements in 43 CFR 1610.2(c) to notify the public of potential amendments to land use plans, based on the findings of the EIS. If a land use plan amendment is necessary, the BLM will integrate the land use planning process with the NEPA process for this project.

The BLM will use and coordinate the NEPA commenting process to satisfy the public involvement process for Section 106 of the National Historic Preservation Act (16 U.S.C. 470f) as provided for in 36 CFR 800.2(d)(3). Native American tribal consultations will be conducted and tribal concerns, including impacts on Indian trust assets, will be given appropriate consideration. Federal, State, and local agencies—along with other stakeholders who may be interested or affected by the BLM's decision on this project—are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate as a cooperating agency.

Before including your address, phone number, e-mail 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.

Thomas Pogacnik,

Deputy State Director, California.

Authority: 40 CFR 1501.7 and 43 CFR 1610.2.

[FR Doc. 2010–403 Filed 1–12–10; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

National Park Service

Termination of the Environmental Impact Statement for the General Management Plan, Gila Cliff Dwellings National Monument

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of termination of the Environmental Impact Statement for the General Management Plan, Gila Cliff Dwellings National Monument, New Mexico.

SUMMARY: The National Park Service (NPS) is terminating the Environmental Impact Statement (EIS) for the Gila Cliff Dwellings General Management Plan because it has determined that an Environmental Assessment (EA) is the more appropriate National Environmental Policy Act compliance document. A Notice of Intent to prepare the EIS for the Gila Cliff Dwellings General Management Plan was published on April 16, 2008 (**Federal Register** Vol. 73, No. 74). Scoping conducted for the plan indicated that there were no significant impacts or controversy identified by the public. A preliminary impact analysis indicated that the alternatives have limited potential to result in significant/major effects on the human environment as they focus on different ways of protecting resources, providing appropriate visitor experiences, and addressing joint NPS/Forest Service operations. For these reasons the NPS determined the proposal would not require an EIS.

DATES: The request to terminate the Environmental Impact Statement and proceed with an Environmental Assessment was approved by the Chief of the NPS Environmental Quality Division on November 4, 2009. The draft general management plan and Environmental Assessment is expected to be distributed for a 30 day public comment period early in 2011 and a decision is expected be made in the fall of 2011. The NPS will notify the public by mail, Web site, and other means, and will include information on where and how to obtain a copy of the GMP/EA, how to comment on the plan, and the dates of the public comment period.

FOR FURTHER INFORMATION CONTACT: Steve Riley, Superintendent, Gila Cliff Dwellings National Monument, HC 68 Box 100, Silver City, NM 88061. Telephone (575) 536–9461.

SUPPLEMENTARY INFORMATION: In place of the EIS, the NPS will prepare an Environmental Assessment (EA) that analyzes four alternatives (no-action and three action alternatives) that look at different ways of protecting resources, providing appropriate visitor experiences, and addressing joint NPS/Forest Service operations:

—Alternative 1 (No-Action) would continue the present management direction.

—Alternative 2 would emphasize and expand high-quality visitor services and experiences by providing more comprehensive interpretation of the Gila Headwaters area and its 2,000 years of human occupation.

—Alternative 3 would enhance visitor understanding and enjoyment of the Gila Headwaters' natural and cultural heritage by providing a more unified management approach to the two units of the monument.

—Alternative 4 would forge more personal connections between visitors and the ancient cultures and wilderness character of the monument.

Dated: November 12, 2009.

Michael D. Snyder,

Director, Intermountain Region, National Park Service.

[FR Doc. 2010–443 Filed 1–12–10; 8:45 am]

BILLING CODE 4312–FA–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–R–2009–N162; 40136–1265–0000–S3]

Lower Florida Keys Refuges, Monroe County, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability: final Comprehensive Conservation Plan and finding of no significant impact.

SUMMARY: We, the Fish and Wildlife Service (Service), announce our decision and the availability of the final CCP and finding of no significant impact (FONSI) for the Environmental Assessment for the Lower Florida Keys Refuges in accordance with the National Environmental Policy Act (NEPA) requirements. We completed a thorough analysis of impacts on the human environment, which are included in the Environmental Assessment (Appendix N of the CCP). The CCP will guide us in managing and administering the Lower Florida Keys Refuges for the next 15 years.

ADDRESSES: You may obtain a copy of the CCP by writing to: Ms. Anne Morkill, Refuge Manager, Florida Keys National Wildlife Refuge Complex, 28590 Watson Boulevard, Big Pine Key, FL 33043. You may also access and download the document from the Service's Web site: *http://southeast.fws.gov/planning.*

FOR FURTHER INFORMATION CONTACT: Ms. Anne Morkill; telephone: 305/872–2239; or Mary Morris, Natural Resource Planner; telephone 850/567–6202.

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we finalize the CCP process for the Lower Florida Keys Refuges. We started this process through a notice in the **Federal Register** on May 9, 2003 (68 FR 25058).

The Lower Florida Keys Refuges includes three wildlife refuges—Key West National Wildlife Refuge (Key West NWR), Great White Heron National Wildlife Refuge (Great White Heron NWR), and National Key Deer Refuge in Monroe County, Florida. These are a collection of low-lying, subtropical islands between the Gulf of Mexico and the Atlantic Ocean that protect all the vital habitats representative of the Florida Keys ecosystem, including the globally imperiled pine rockland and tropical hardwood hammock. These geologically and climatically distinct islands provide a haven for a diversity of native flora and fauna, including endemic, threatened, endangered, and candidate species.

Key West NWR

Located west of Key West and accessible only by boat, the refuge consists of the Marquesas Keys and 13 other keys distributed across over 375 square miles of open water. Key West NWR is among the first refuges established in the United States. President Roosevelt created the refuge in 1908 as a preserve and breeding ground for colonial nesting birds and other wildlife. The refuge encompasses 208,308 acres of land and water with only 1 percent (2,019 acres) being land. Most islands are dominated by mangrove plant communities.

The refuge provides habitat and protection for Federally listed species, including piping plovers and roseate terns. The refuge harbors the largest wintering population of piping plovers and the largest colony of white-crowned pigeons in the Florida Keys. It is a haven for over 250 species of birds, including 10 wading-bird species that nest in the refuge. Other notable imperiled species include sea turtles. More loggerhead and green sea turtle nests are found each year in Key West NWR than in any area of the Florida Keys except the Dry Tortugas. Waters within the refuge's administrative boundaries are important developmental habitat for these sea turtle species, as well as hawksbills and Kemp's ridley sea turtles. In 1975, Public Law 93–632 designated all islands in Key West NWR, except Ballast Key, which is privately owned, as a part of the National Wilderness Preservation System. These islands total 2,109 acres.

Great White Heron NWR

Great White Heron NWR was established in 1938, by Executive Order 7993 signed by President Roosevelt, as a haven for great white herons, migratory birds, and other wildlife. The refuge encompasses 117,683 acres of land and water with 6,300 acres of land, including 1,900 land acres which were designated Wilderness Areas in 1975, also under Public Law 93–632. While the islands are primarily mangroves, some of the larger islands contain pine rockland and tropical hardwood hammock habitats. This vast area, known locally as the "backcountry," provides critical nesting, feeding, and resting areas for more than 250 species of birds. We co-manage this area with the State through a "Management Agreement for Submerged Lands Within

the Boundaries of Key West and Great White Heron National Wildlife Refuges" (hereinafter referred to as Management Agreement).

Great white herons are a white color-phase of great blue herons. In the United States, nesting is restricted to extreme south Florida including the Florida Keys. The refuge was created to protect great white herons from extinction since the population was decimated by the demand for feathered hats. Protection of great white herons was successful, and these magnificent birds can be observed feeding on tidal flats throughout the refuge. The refuge islands are also used for nesting by 10 wading bird species, including the reddish egret, and by many neotropical migratory bird species.

National Key Deer Refuge

The National Key Deer Refuge was established on August 22, 1957, to protect and conserve Key deer and other wildlife resources. It comprises about 8,983 acres of land on several islands within the authorized approved acquisition boundary, as well as additional parcels located outside the boundary administered by the refuge. These lands host diverse habitats, most notably globally endangered tropical hardwood hammocks and pine rocklands. The refuge provides habitat for hundreds of endemic and migratory species, including 21 Federally listed species, such as Key deer, Lower Keys marsh rabbit, and silver rice rat. It contains a variety of plants endemic to the Florida Keys.

The refuge is an important stopping point for thousands of migrating birds each year and an important wintering ground for many North American bird species. Notable species include the piping plover and peregrine falcon. The mosaic of upland and wetland habitats found in the Florida Keys are critical breeding and feeding grounds for birds, and refuge land acquisition efforts strive to add to the lands already protected. Loggerhead, green, hawksbill, and Kemp's ridley sea turtles forage in the waters surrounding the refuge, but nesting is limited to refuge lands on Ohio Key, where a small number of loggerhead nests are laid annually. There are 2,278 acres of Wilderness Area designated on this refuge as of 1975 per Public Law 632.

Refuge Purposes

The purposes of the refuges come from the executive orders and subsequent laws Congress passed as it established each refuge. There are also specific purposes Congress designated for managing the Refuge System as a whole. Each of the three refuges has different enabling legislation and purposes. The CCP has been designed with consideration of the distinct purposes of each refuge. For the purposes of each refuge, refer to a notice in the **Federal Register** dated May 23, 2008 (73 FR 30139).

Alternatives, Including the Preferred Alternative

The Service developed three alternatives for managing the refuges over the next 15 years and chose Alternative B as the preferred alternative. A description of the three alternatives follows.

Alternative A—(Current Management—No Action)

The Lower Florida Keys Refuges have a high diversity of community types and endemic species, with many threatened, endangered, candidate, and other imperiled species. The primary mission of these refuges is to provide habitat for wildlife. The refuges currently have a small staff and funding source for the inventorying and monitoring of natural resources. Much effort has been put into some resources, such as Key deer and their habitat (pine rocklands), as a result of cooperative partnerships with academic and other research organizations. Certain species, such as great white herons, white-crowned pigeons, and sea turtles, have been studied over time by refuge biological staff. Under this alternative, these studies would continue.

Baseline data have yet to be established for some protected species, species suites, habitats, and cultural resources. The effects of natural catastrophic disturbances (*e.g.,* Hurricane Wilma in 2005) on the refuges' resources have not been fully assessed and the effect of climate change (*e.g.,* sea level rise) is not known.

We would protect threatened and endangered species through a variety of management tools, such as area closures, law enforcement, exotic plant control, etc. Working with partners, we would continue limited research and monitoring of focal species, such as Key deer, Lower Keys marsh rabbit, and some migratory birds. The National Key Deer Refuge's prescribed fire management program would continue with the objectives to reduce fuels and sustain the pine rockland ecosystem for the benefit of Key deer.

As funding and willing sellers are available, we would continue habitat conservation through land acquisition within the approved acquisition boundary and through lease agreements with other agencies for non-refuge lands that support the refuges' missions. Partnerships exist to promote land conservation. Exotic plant control to protect and maintain current habitat would occur at existing levels by relying on partnerships with the Nature Conservancy, the Florida Fish and Wildlife Conservation Commission, and Monroe County. A predator management program is currently under development on National Key Deer Refuge to reduce the effects of feral cat predation on the endangered Lower Keys marsh rabbit and other native wildlife.

Most ecologically sensitive areas and living resources are protected from disturbance or degradation through the use of closure areas, law enforcement, and the implementation of the Management Agreement. Impacts from concentrated, non-wildlife-dependent uses threaten a limited number of sites, particularly islands with accessible sand beaches. The effects of commercial activities and public uses (both wildlife-dependent and non-wildlife-dependent) have not been fully evaluated and visitor carrying capacities have not been quantified.

We have an active volunteer program to assist in all facets of refuge management. Partnerships for these purposes and for research are encouraged and maintained. Under this alternative, the existing level of administrative resources (*e.g.,* staffing, facilities and assets, funding, and partnerships) would be maintained. This means some positions may not be filled when vacated if funds need to be reallocated to meet rising costs or new priorities.

Alternative B—(Preferred Alternative)

This alternative assumes a slow-to-moderate growth of refuge resources over the 15-year implementation period of the CCP. It proposes a proactive and adaptive ecosystem-management approach for the enhancement of wildlife populations. It will promote a natural diversity and abundance of habitats for native plants and animals, especially Keys' endemic, trust, and keystone imperiled species. Many of the objectives and strategies are designed to maintain and restore native communities. Active management strategies will be applied particularly within the globally imperiled pine rockland, salt marsh transition, and freshwater wetland habitats, and island beach berm communities. We will initiate research and long-term monitoring to expand the collection of baseline data and measure variables of ecosystem health. We will promote

cooperative studies to monitor and model the immediate and/or long-term effects of natural catastrophic events (*e.g.,* hurricanes, wildfire) and global climate change, particularly sea level rise.

Current ongoing and proposed programs and efforts focus on threatened, endangered, and candidate species of plants and animals. The need for more comprehensive inventorying and long-term monitoring is addressed in this alternative, particularly for priority imperiled species and their habitats within the refuges. The feasibility of managing the core population of Key deer to minimize the effects of over-browsing on native plants will be considered in accordance with the Endangered Species Act.

Habitat enhancement for critically imperiled species, such as the Lower Keys marsh rabbit and Key tree cactus, will occur to ensure the long-term sustainability of these species. Opportunities for land acquisition will focus more strategically on protecting environmentally sensitive habitat by contacting specific property owners to determine their willingness to sell, with a particular emphasis on enhancing habitat connectivity and protecting marsh rabbit habitat. Off-refuge nursery propagation of the Key tree cactus will be implemented for later translocation to suitable refuge habitats. Cooperative partnerships with nurseries and botanical gardens will be developed to secure seed and plant material of rare and endemic plant species to ensure genetically viable sources for future restoration needs. Research will be initiated to identify causal reasons for the marked, long-term decline in the great white heron nesting population and to evaluate the potential impacts of sea level rise on the ecology of wading birds.

Since a primary purpose of the refuges is to provide sanctuary for nesting and migratory birds, we will provide greater protection from human disturbance, particularly at colonial nesting bird rookeries and at beach habitats in the backcountry islands. Additional limitations to public use may be implemented in sensitive beach areas important for shorebirds, terns, sea turtles, and butterflies.

Strategies are proposed to enhance the biological diversity and resiliency of the fire-dependent pine rocklands and also to enhance fire-adapted habitat features in salt marsh transition and freshwater wetlands that benefit priority species in the National Key Deer Refuge. Prescribed fire and mechanical or manual vegetation treatments will be used as habitat management tools to reduce wildland fuels and restore desirable habitat features where appropriate. Predictive modeling and fire effects monitoring will be used on all prescribed-fire treatments in an adaptive management approach to develop site-specific burn prescriptions and to determine whether objectives were met. We will conduct research on fire behavior, fuel response, and fire history. The fire management step-down plan will be revised and implemented accordingly in conjunction with the development of a habitat management step-down plan.

We will continue exotic plant control as an ongoing operation within the refuges to maintain native habitats and prevent new infestations. Cooperative efforts will be sought with private property owners and homeowners associations to control seed sources from private lands. Existing partnerships will be reinforced to increase coordinated mapping and monitoring of treated areas with known infestations and ongoing control needs. Management of non-native exotic predators will be implemented as directed by the South Florida Multi-Species Recovery Plan for the benefit of threatened and endangered species. An early detection and rapid response program will be implemented in cooperation with Federal, State, and local authorities to address the increasing invasion by and potential establishment of exotic snakes, lizards, and other non-native animals in the Florida Keys.

A primary focus of the visitor services program, as proposed, is to enhance environmental education and outreach efforts substantially to reach larger numbers of residents, students, educators, and visitors. This alternative also focuses on increasing public awareness, understanding, and support for the refuges' conservation mission. It places priority on wildlife-dependent uses, such as photography and wildlife observation. A new visitor center on U.S. Highway 1 on Big Pine Key and enhanced visitor facilities at existing sites (*e.g.,* Blue Hole and Watson-Mannillo Nature Trails) are proposed. Non-wildlife-dependent forms of recreation will be limited or restricted in sensitive areas and awareness efforts will be stepped-up to inform visitors about protecting wilderness areas. A Visitor Services step-down plan will specify program details consistent with the Service's visitor service program standards.

The basic administrative and operational needs of the refuges have been addressed. Essential new staffing is proposed through the addition and funding of five permanent, full-time employees. Daily operation of the refuges will be guided by the CCP and the development and implementation of 19 projects and 11 step-down management plans. Wilderness and cultural resource protection objectives and strategies will be incorporated within the appropriate step-down management plans. The modest growth in administrative resources will be used for wildlife monitoring and habitat enhancement to better serve the refuges' purposes and the CCP's vision. With the exception of a new Visitor Center that is proposed, the existing number of facilities will be maintained. Energy efficiency standards will be applied wherever feasible during facility maintenance, repair, or renovation projects. Existing vehicles will be replaced with alternative fuel vehicles to increase fuel efficiency and reduce carbon emissions.

Alternative C

This alternative assumes a moderate-to-substantial growth of refuge resources from internal or external sources. It would more fully realize the refuges' missions and address the large number of threatened, endangered, and candidate species along with other imperiled species and habitat types. While Alternative C contains many of the provisions to protect and restore habitats similar to Alternative B, it emphasizes a broader suite of priority species, assuming the addition of several new staff positions and increased funding. The long-term inventorying and monitoring plan would be expanded to cover more species and species suites. Additional studies on some species would be undertaken and additional biological staffing would be required. The use of captive, off-refuge sources of some species facing potential extirpation (*e.g.,* Lower Keys marsh rabbit) would be explored for reintroduction after a natural catastrophe, such as a major hurricane. In certain habitats, some alternative habitat management techniques would be studied and applied. Fire management efforts would emphasize fire suppression and the reduction of hazardous fuels by mechanical or manual means to protect private properties, and the use of prescribed fire would be reduced or eliminated. Under this alternative, the CCP anticipates shifts in the Visitor Services program in order to increase visitation and public use. A refuge ranger position is proposed to coordinate and enhance volunteerism, to foster expanded relationships with the Friends and Volunteers of Refuges

(FAVOR), and to establish new partnerships for environmental education and outreach programs.

Resource protection and visitor safety would be greatly enhanced through this alternative, with the addition of two law enforcement officers. This would allow for more patrol and enforcement of closures and sensitive areas protection, especially of wilderness areas or cultural resource sites. New areas of the backcountry would be closed to public access to protect wildlife resources. We would seek expanded management authority to regulate public and commercial activities in nearshore waters and submerged lands under the Management Agreement. A cultural resources field investigation and inventory would be conducted.

Implementation of Alternative C would also occur through the development of 11 step-down management plans. New staffing would be proposed through the addition of 6 permanent, full-time employees. The positions would be in addition to the 5 full-time positions proposed in Alternative B, for a total of 11 full-time positions in Alternative C. New maintenance and government housing facilities would be proposed along with new vehicles and boats to accommodate the staff increases. While Alternative C would promote our vision for these refuges, the resources available to implement it would not likely be forthcoming in the current economic environment as compared to when first proposed.

Background

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation. We will review and update the CCP at least every15 years in accordance with the Administration Act.

Comments

Notices of availability of the Draft Comprehensive Conservation Plan and Environmental Assessment (Draft CCP/EA) were sent to 200 persons on the mailing list and copies were made available for a 30-day public review period as announced in the **Federal Register** on May 23, 2008 (73 FR 30139). At least 47 persons attended two public meetings held on the Draft CCP/EA during the open comment period. We received 25 comment letters by mail or e-mail from 16 persons and 11 non-governmental organizations. Comments were received from 4 government agencies and 1 Tribal government. The Draft CCP/EA was circulated through the Florida State Clearinghouse to 8 State, regional, and local governments.

Selected Alternative

After considering the comments we received, and based on the professional judgment of the planning team, we selected Alternative B to implement the CCP. It promotes the enhancement of wildlife populations by maintaining and enhancing a diversity and abundance of habitats for native plants and animals, especially imperiled species that are only found in the Florida Keys. Many of the objectives and strategies are designed to maintain and restore native plant communities and ensure the biological integrity across the landscape. Strategies are designed to restore and maintain the fire-dependent pine rocklands and to enhance habitat features of selected salt marsh transition and freshwater wetland communities that benefit priority species in the National Key Deer Refuge. Research and monitoring will provide essential information for implementing an adaptive management approach to strategic landscape conservation, providing flexibility in management strategies in order to incorporate new information and changing environmental conditions. The CCP also provides for obtaining baseline data and monitoring indicator species to detect changes in ecosystem diversity and integrity related to climate change.

Since a primary purpose of the refuges is to provide sanctuary for nesting and migratory birds, protection from human disturbance will be enhanced, particularly at colonial nesting bird rookeries and at beach habitats in the backcountry islands of the Key West and Great White Heron NWRs. Ongoing research to identify causal reasons for the marked, long-term decline in the great white heron nesting population, as well as studies on the impacts of sea level rise on wading birds, will be expanded.

A primary focus of the visitor services program is to enhance environmental education and outreach efforts through existing venues and expanded partnerships to reach a diversity of local residents, businesses, students, educators, and visitors. This plan focuses on increasing public awareness, understanding, and support for the refuges' conservation mission. It places priority on wildlife-dependent recreational uses, such as wildlife observation and photography. Non-wildlife dependent forms of recreation, such as beach picnicking and sunbathing, will be limited or restricted in sensitive areas. Awareness efforts will be expanded to inform visitors about protecting wilderness values.

The compatibility determinations for (1) Environmental education and interpretation; (2) hiking/daypacking, jogging, and walking (National Key Deer Refuge only); (3) bicycling (National Key Deer Refuge only); (4) wildlife observation and photography; (5) fishing; (6) beach use (National Key Deer Refuge only); (7) public use on wilderness and backcountry islands; (8) research and monitoring; (9) mosquito management (National Key Deer Refuge and Great White Heron NWR only); and (10) horseback riding (National Key Deer Refuge only) are available in Appendix F of the CCP.

Authority

This notice is published under the authority of the National Wildlife Refuge System Improvement Act of 1997, Public Law 105–57.

Dated: August 24, 2009.

Patrick Leonard,

Acting Regional Director.

[FR Doc. 2010–447 Filed 1–12–10; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

National Park Service

Draft General Management Plan and Environmental Impact Statement, New River Gorge National River, WV

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of availability of the Draft General Management Plan and Environmental Impact Statement for New River Gorge National River.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service announces the availability of the

Draft General Management Plan and Environmental Impact Statement (Draft GMP/EIS) for New River Gorge National River, West Virginia. Consistent with National Park Service laws, regulations, and policies, and the purpose of the National River, the Draft GMP/EIS describes and analyzes five alternatives, including the no action alternative, to guide the management of the National River over the next 15 to 20 years. The alternatives incorporate various management prescriptions to ensure protection, access and enjoyment of the park's resources.

Alternative 1 is the no action alternative, which would continue current management and trends, with no major changes in direction.

Alternative 2 emphasizes the substantial differences among subareas of the gorge, improving them to reflect their differing character, resources, and visitor experiences. Management actions would build upon the cultural resource, interpretive, and recreational opportunities of the north and south ends of the park, while retaining a primitive and remote feeling in the middle of the park.

Alternative 3 would unify the park by providing a north-south through park hike and bike trail, enhancing existing scenic roads, and building new access and facilities in the middle of the park to balance opportunities for visitors throughout the park.

Alternative 4 recognizes river gateways and the rim to river experiences that take visitors to them as the primary access points and orientation venues in the park. River gateways would be enhanced to tell gorge stories while providing improved river, trail, and recreational access. The NPS and gateway communities would work cooperatively to enhance rim to river experiences.

Alternative 5 is the National Park Service's preferred alternative. Alternative 5 would preserve areas for primitive recreational experiences from end to end of the park. Interspersed with these primitive areas would be cultural and interpretive resource focal areas where visitors could explore communities and other places that once populated the gorge, experience the river, and enjoy a variety of recreational experiences. A north-south through park connector composed of improved scenic roads and trails would enable visitors to travel the length of the park, visit these areas, and access the backcountry. Partnerships with gateway communities and improved rim to river experiences would foster links to the park as a whole and to specific cultural and interpretive resource areas within the park.

The Draft GMP/EIS evaluates potential environmental consequences of implementing the five alternatives. It describes the affected natural, cultural, scenic, and socioeconomic environments within and near the park and analyzes potential impacts on park resources and values. Seventeen resource topics are addressed, including physiography, geology, and soils; floodplains; water quality; vegetation; aquatic wildlife; terrestrial wildlife; rare, threatened, and endangered species; scenic resources; archeological resources; cultural landscapes; historic structures; ethnographic resources; regional and local economy; communities; visitor use and visitor experience; park access; and park operations.

DATES: The National Park Service will accept comments on the Draft GMP/EIS from the public for 60 days from the date the Environmental Protection Agency publishes their Notice of Availability in the **Federal Register.** Public meetings will be held in Hinton, Beckley, and Fayetteville, West Virginia to solicit comments on the Draft GMP/EIS during the public review period. The dates, times, and locations will be announced on the park's Web site at *http://www.nps.gov/neri;* on the NPS Planning, Environment, and Public Comment (PEPC) Web site at *http://parkplanning.nps.gov/neri;* in local papers; and can also be obtained by contacting the park at (304) 465–0508.

ADDRESSES: The Draft GMP/EIS will be available for public review and comment online at the NPS PEPC Web site *(http://parkplanning.nps.gov/neri),* and at the park's Web site *(http://www.nps.gov/neri).* Printed copies (in limited quantity) and CDs can be requested by calling (304) 465–0508. Printed hardcopies can be viewed at the following locations:

New River Gorge National River—Headquarters, 104 Main Street, Glen Jean, WV 25846.

New River Gorge National River—Canyon Rim Visitor Center, 162 Visitor Center Road (off US 19, north of the New River Gorge Bridge), Lansing, WV 25862.

New River Gorge National River—Sandstone Visitor Center, Meadow Creek Road, Sandstone, WV 25958.

Raleigh County Public Library, 221 N. Kanawha Street, Beckley, WV 25801.

Summers County Public Library, 201 Temple Street, Hinton, WV 25951.

Oak Hill Public Library, 611 Main Street. Oak Hill, WV 25901.

The preferred method to comment is to submit comments electronically through the NPS PEPC Web site at *http://parkplanning.nps.gov/neri.* You may also send written comments to Superintendent Don Striker, New River Gorge National River, 104 Main St., Glen Jean, WV 25846. Before including your address, phone number, e-mail 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.

FOR FURTHER INFORMATION CONTACT: Don Striker, Superintendent, New River Gorge National River, 104 Main Street, Glen Jean, WV 25846, (304) 465–0508.

SUPPLEMENTARY INFORMATION: Through the Draft GMP/EIS planning process, the NPS was able to develop a unified approach to managing the major changes in and adjacent to the park since the 1982 General Management Plan was prepared, to focus on protecting park natural, cultural, and scenic resources, and to identify opportunities to facilitate appropriate forms of visitor education, interpretation and use. Twelve related legislative mandates have been added since the enabling legislation was signed into law in 1978, including several boundary changes. The most recent legislation mandates the continuation of hunting within the park. The Draft GMP/EIS includes a recommendation for additional boundary changes as well as a wilderness eligibility assessment for all National Park Service lands and waters within the current park boundary.

Mary Pearson-Cooper,

Acting Regional Director, Northeast Region, National Park Service.

[FR Doc. 2010–444 Filed 1–12–10; 8:45 am]

BILLING CODE 4310–YP–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Notice of Intent To Prepare an Environmental Impact Statement for the Restoration Design Energy Project and Possible Land Use Plan Amendment

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent.

SUMMARY: In compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, and the

Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Arizona State Office intends to prepare an Environmental Impact Statement (EIS) to support possible amendments to several BLM-Arizona Resource Management Plans (RMP) to identify sites and/or areas managed by the BLM that may be suitable for the development of renewable energy and to establish appropriate design criteria for such projects. By this notice, BLM-Arizona State Office is announcing the beginning of the scoping process to solicit public comments and identify issues.

DATES: This notice initiates the public scoping process for the EIS and possible plan amendments. Comments on issues may be submitted in writing until March 1, 2010. The dates and locations of any scoping meetings will be announced at least 15 days in advance through local media, newspapers and the BLM Web site at: *http://www.blm.gov/az/st/en.html*. In order to be included in the Draft EIS, all comments must be received prior to the close of the scoping period or 15 days after the last public meeting, whichever is later. We will provide additional opportunities for public participation upon publication of the Draft EIS.

ADDRESSES: You may submit comments on issues and planning criteria related to the Restoration Design Energy Project by any of the following methods:

- *Web site: http://www.blm.gov/az/st/en/prog/energy/arra_solar.htm;*
- *E-mail:* Include your name, any organization you represent, and return address in the e-mail message to: *az_arra_rdep@blm.gov;*
- *Fax:* Attn: Teri Raml, (602) 417–9454; and
- *Mail or other delivery service:* Please be sure to include your name, any organization you represent, and a return address to: Restoration Design Energy Project, Attention: Teri Raml, BLM-Arizona State Office, One North Central Avenue, Suite 800, Phoenix, Arizona 85004–4427.

Documents pertinent to this proposal may be examined at the BLM-Arizona State Office, One North Central Avenue, Suite 800, Phoenix, Arizona 85004.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to our mailing list, contact Teri Raml, Project Manager, telephone (602) 417–9388; address One North Central Avenue, Suite 800, Phoenix, Arizona 85004; or by e-mail *teri_raml@blm.gov*.

SUPPLEMENTARY INFORMATION: The purpose of the Restoration Design Energy Project is to foster environmentally responsible production of renewable energy by amending plans, as necessary, to identify sites or areas that are already disturbed or that may be in need of some level of remediation or restoration, and which may be suitable for siting of renewable energy projects, as well as allocate such sites or areas for this purpose. Possible plan amendments may also include decisions about acquisition, disposal, or retention of sites or areas. The BLM will establish management direction for lands acquired for the purposes of this Project or will extend the applicable land use plan decisions to these lands, provided there are no unresolved management issues associated with the newly acquired lands. The environmental analysis will address, at each site or area, both existing remediation needs and any potential for renewable energy generation, and may also identify project design criteria to address environmental issues particular to the site or area identified. Implementation of the Project will help meet community energy needs, create economic opportunities, and provide good value to the taxpayer for the use of public lands. To accomplish this, some or all of the BLM's RMPs throughout Arizona may need to be amended. Plans that may be amended include the following: the Yuma Field Office RMP—2010; the Agua Fria and Bradshaw-Harquahala RMP—2010; the Arizona Strip Field Office RMP—2008; the Lake Havasu Field Office RMP—2007; the Kingman Resource Area RMP—1995; the Safford District RMP—1991; the Phoenix RMP—1988; the Lower Gila South RMP—1988 as amended 2005; and the Lower Gila North Management Framework Plan—1983 as amended 2005.

The Energy Policy Act of 2005 (Title II, Sec. 211) establishes a goal that at least 10,000 megawatts of renewable energy production capacity be approved on public lands by 2015. Additionally, Secretarial Order 3285 directs agencies within the Department of the Interior to encourage the development of environmentally responsible renewable energy generation. The Project is consistent with the Congressional direction, Department of the Interior policies, and is unique in that it offers an alternative process for site selection that includes the identification of lands in need of remediation that have renewable energy generation potential. At the initiation of the Project, the BLM-Arizona State Office requested individual field offices and members of the public to identify previously utilized sites that might be suitable for development of renewable energy for consideration for inclusion in the Project. Examples of submitted sites include gravel pits, mine sites, landfills, isolated parcels that have been disturbed, and abandoned unauthorized airstrips. Sites and/or areas proposed for the Project will be analyzed according to the BLM's planning regulations at 43 CFR part 1600, and proposed planning amendments will analyzed in the EIS. This analysis will take into consideration: (1) 42 proposed sites covering approximately 26,000 acres; (2) knowledge of existing and proposed energy transmission options; (3) concentrations of existing and proposed energy generation; (4) technical factors; and (5) environmental factors. The sites submitted so far include BLM-administered, State, municipal, and private lands. While the BLM planning process will primarily address management of those lands and interests in lands administered by the BLM, the analysis in the EIS may be broader in scope. Additional restoration design concepts, which may be incorporated into the possible design criteria applicable to particular sites or areas, are expected to be developed through scoping. Suitable sites for application of this approach to reuse of land may also continue to be identified over time, and may be considered in this or subsequent planning initiatives, depending on when they are identified.

The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the process for developing the EIS. At present, the BLM has identified the following preliminary issues: (1) Site or area suitability for renewable energy generation and scale of possible generation; (2) site or area proximity to the existing electrical transmission grid and the feasibility of integrating new electric generation projects with the grid; (3) site or area proximity to population and electric use (load) centers; (4) determining the appropriate renewable energy generation technologies for implementation on a site-by-site and/or area-by-area basis; and (5) the possible need for environmental remediation of project sites or areas based on previous uses and levels of disturbance and possible contamination of the sites or areas, as well as how addressing the possible need for remediation may be incorporated into design criteria that may be applicable to projects proposed for a particular site or area.

The EIS will use existing data for the analysis to support the planning decisions (*e.g.*, allocation, disposal, or

retention decisions) that may be made as a result of this initiative. When individual project proposals for renewable development are received, any site-specific analysis could be tiered to the EIS for this Project to avoid unnecessary duplication of analysis.

Authorization of the project may require amendment of some or all of the BLM RMPs throughout Arizona, as listed above. By this notice, the BLM is complying with requirements in 43 CFR 1610.2(c) to notify the public of potential amendments to land use plans, predicated on the findings of the EIS. If land use plan amendments are necessary, the BLM will integrate the land use planning process with the NEPA process for this project.

The BLM will utilize and coordinate the NEPA commenting process to satisfy the public involvement process for Section 106 of the National Historic Preservation Act (16 U.S.C. 470f) as provided for in 36 CFR 800.2(d)(3). Native American Tribal consultations will be conducted and Tribal concerns, including impacts on Indian trust assets, will be given due consideration. Federal, State, and local agencies, along with other stakeholders that may be interested or affected by the BLM's decision on this project are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate as a cooperating agency. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1501.7 and 43 CFR 1610.2.

Helen Hankins,

BLM Associate State Director.

[FR Doc. 2010–404 Filed 1–12–10; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

National Park Service

2010 Meetings of the Big Cypress National Preserve Off-Road Vehicle (ORV) Advisory Committee

AGENCY: Department of the Interior, National Park Service, ORV Advisory Committee.

ACTION: Notice of meetings.

SUMMARY: In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App 1, 10), notice is hereby given of the meetings of the Big Cypress National Preserve ORV Advisory Committee for 2010.

DATES: The Committee will meet on the following dates:

Tuesday, February 2, 2010, 3:30–8 p.m.

Tuesday, April 20, 2010, 3:30–8 p.m.

Tuesday, June 22, 2010, 3:30–8 p.m.

Tuesday, August 17, 2010, 3:30–8 p.m.

Tuesday, October 26, 2010, 3:30–8 p.m.

Tuesday, December 7, 2010, 3:30–8 p.m.

ADDRESSES: All meetings will be held at the Big Cypress Swamp Welcome Center, 33000 Tamiami Trail East, Ochopee, Florida. Written comments and requests for agenda items may be submitted electronically on the Web site *http://www.nps.gov/bicy/parkmgmt/orv-advisory-committee.htm.* Alternatively, comments and requests may be sent to: Superintendent, Big Cypress National Preserve, 33100 Tamiami Trail East, Ochopee, FL 34141–1000, Attn: ORV Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Pedro Ramos, Superintendent, Big Cypress National Preserve, 33100 Tamiami Trail East, Ochopee, Florida 34141–1000; 239–695–1103, or go to the Web site *http://parkplanning.nps.gov/projectHome.cfm?parkId=352&projectId=20437.*

SUPPLEMENTARY INFORMATION: The Committee was established (**Federal Register,** August 1, 2007, pp. 42108–42109) pursuant to the Preserve's 2000 *Recreational Off-road Vehicle Management Plan* and the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix) to examine issues and make recommendations regarding the management of off-road vehicles (ORVs) in the Preserve. The agendas for these meetings will be published by press release and on the *http://parkplanning.nps.gov/projectHome.cfm?parkId=352&projectId=20437* Web site. The meetings will be open to the public, and time will be reserved for public comment. Oral comments will be summarized for the record. If individuals wish to have their comments recorded verbatim, they must submit them in writing.

Pedro Ramos,

Superintendent, Big Cypress National Preserve.

[FR Doc. 2010–445 Filed 1–12–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before December 19, 2009. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St., NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St., NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by January 28, 2010.

Alexandra Lord,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

California

Monterey County

USS MACON (airship remains), Address Restricted, Big Sur, 09001274.

Colorado

Las Animas County

Latuda, Frank, House, 431 W. Colorado Ave., Trinidad, 09001275.

Montrose County

Denver & Rio Grande Western Railroad Stock Car No. 5620, 82800Q 83rd Rd., Cimarron Visitor Center, Curecanti National Recreation Area, Cimarron, 09001276.

Denver & Rio Grande Western Railroad Stock Car No. 5679D, 82800Q 83rd Rd., Cimarron Visitor Center, Curecanti National Recreation Area, Cimarron, 09001277.

Florida

Alachua County

Jones, A. Quinn, House, 1013 NW. 7th Ave., Gainesville, 09001278.

Idaho

Canyon County

Hat, The, 2112 Cleveland Blvd., Caldwell, 09001279.

Latah County

Bovill Opera House, (Motion Picture Theater Buildings in Idaho MPS) 412 2nd Ave., Bovill, 09001280.

Cox Barn, (Agricultural Properties of Latah County, Idaho) 1290 American Ridge Rd., Kendrick, 09001281.

Maryland

Allegany County

Klots Throwing Company Mill, 917 Gay St., Cumberland, 09001282.

New York

Columbia County

Hillsdale Hamlet Historic District, NY Rts. 22 & 23, Anthony, Cold Water & Maple Sts., Old Town & Pill Hill Rds., Hillsdale, 09001283.

Delaware County

Main Street Historic District, Main, N. & S. Center, John Sts. & Dutchess, Park, S. Maple & Elm Aves., Millerton, 09001284.

Monroe County

Sage, Simeon, House, 69 Main St., Scottsville, 09001285.

New York

Oneida County

First Methodist Episcopal Church of Rome, 400 N. George St., Rome, 09001286.

Rockland County

Brook Chapel, 6th St., Hillburn, 09001287.

Suffolk County

Fire Island Light Station Historic District, (Light Stations of the United States MPS) Burma Rd., Fire Island, 09001288.

Puerto Rico

Trujillo Alto Municipality

Puente de Trujillo Alto, (Historic Bridges of Puerto Rico MPS) PR 181, km. 5.6, Trujillo Alto, 09001289.

Rhode Island

Kent County

Hopkins Hollow Village, Hopkins Hollow Rd., Narrow Ln., Perry Hill Rd., Coventry and W. Greenwich, 09001290.

Utah

Salt Lake County

Altadena Apartments, (Salt Lake City MPS) 310 S. 300 E., Salt Lake City, 09001291.

Sampson Apartments, (Salt Lake City MPS) 276 E. 300 S., Salt Lake City, 09001292.

Utah County

Chipman, Henry & Elizabeth Parker, House, 846 E. 300 N., American Fork, 09001293.

Dunn-Binnall House & Farmstead, 352 N. 200 E., American Fork, 09001294.

Washington

Whatcom County

South Hill Historic District, Bounded by Knox, 11th, State, Cedar, 17th, and Highland, Bellingham, 09001296.

York Historic District, Bounded roughly by Ellis St., Meador Ave., 1–5, and Lakeway Dr., Bellingham, 09001297.

Wisconsin

Dodge County

St. Andrew's Church, W3081 Co. Hwy Y, LeRoy, 09001295.

[FR Doc. 2010–431 Filed 1–12–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2009–N271; 20124–1113–0000–F5]

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications; request for public comment.

SUMMARY: The following applicants have applied for scientific research permits, or the Fish and Wildlife Service is amending their existing permit, to conduct certain activities with endangered species under the Endangered Species Act of 1973, as amended (Act). The Act requires that we invite public comment on these permit applications.

DATES: To ensure consideration, written comments must be received on or before February 12, 2010.

ADDRESSES: Written comments should be submitted to the Chief, Endangered Species Division, Ecological Services, P.O. Box 1306, Room 6034, Albuquerque, NM 87103. Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act. Documents will be available for public inspection, by appointment only, during normal business hours at the U.S. Fish and Wildlife Service, 500 Gold Ave., SW., Room 6034, Albuquerque, NM. Please refer to the respective permit number for each application when submitting comments.

FOR FURTHER INFORMATION CONTACT: Susan Jacobsen, Chief, Endangered Species Division, P.O. Box 1306, Albuquerque, NM 87103; (505) 248–6920.

SUPPLEMENTARY INFORMATION:

Public Availability of Comments

Before including your address, phone number, e-mail 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.

Permit TE–233201

Applicant: Amistad National Recreation Area, Del Rio, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys for interior least tern (*Sterna antillarum*) within Texas.

Permit TE–227505

Applicant: Thomas D. Bonn, Lockhart, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys for golden-cheeked warbler (*Dendroica chrysoparia*) and black-capped vireo (*Vireo atricapilla*) within Texas.

Permit TE–841353

Applicant: Loomis Partners, Inc., Austin, Texas.

Applicant requests an amendment to a current permit for research and recovery purposes to conduct presence/absence surveys for northern aplomado falcon (*Falco femoralis septentrionalis*) within Texas.

Permit TE–045236

Applicant: SWCA Inc., Albuquerque, New Mexico.

Applicant requests an amendment to a current permit for research and recovery purposes to conduct presence/absence surveys for Virgin River chub (*Gila seminuda*) and woundfin (*Plagopterus argentissimus*) within Arizona.

Permit TE–232639

Applicant: Dixie Environmental Services Co., LP, Magnolia, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys for red-cockaded woodpecker (*Picoides borealis*) and white bladderpod (*Lesquerella pallid*) within Texas.

Permit TE–227505

Applicant: Kathleen O'Connor, Georgetown, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys for northern aplomado falcon (*Falco femoralis septentrionalis*) within Texas.

Permit TE–821577

Permittee: Arizona Game and Fish Department, Phoenix, Arizona.

The Service is amending Arizona Game and Fish Department's current permit for research and recovery purposes for the range of activities they undertake; including, but not limited to, presence/absence surveys, research, and reestablishment of the following species: Kanab ambersnail (*Oxyloma haydeni kanabensis*), lesser long-nosed bat (*Leptonycteris curasoae yerbabuenae*), Mexican long-nosed bat (*Leptonycteris nivalis*), masked bobwhite (*Colinus virginianus ridgwayi*), bonytail chub (*Gila elegans*), Gila chub (*Gila intermedia*), humpback chub (*Gila cypha*), Colorado pikeminnow (*Ptychocheilus lucius*), Quitobaquito pupfish (*Cyprinodon eremus*), Virgin River chub (*Gila seminuda*), woundfin (*Plagopterus argentissimus*),Yaqui chub (*Gila purpurea*), Yaqui topminnow (*Poeciliopsis occidentalis sonoriensis*), California condor (*Gymnogyps californianus*), northern aplomado falcon (*Falco femoralis septentrionalis*), thick-billed parrot (*Rhynchopsitta pachyrhyncha*), black-footed ferret (*Mustela nigripes*), southwestern willow flycatcher (*Empidonax traillii extimus*), California least tern (*Sterna antillarum browni*), jaguar (*Pathera onca*), jaguarundi (*Herpailurus yagouaroundi tolteca*), ocelot (*Leopardus pardalis*), Sonoran pronghorn (*Antilocapra americana sonoriensis*), desert pupfish (*Cyprinodon macularius*), Yuma clapper rail (*Rallus longirostris yumanensis*), Sonoran tiger salamander (*Ambystoma tigrinum stebbinsi*), Mount Graham red squirrel (*Tamiasciurus hudsonicus grahamensis*), razorback sucker (*Xyrauchen texanus*), Gila topminnow (*Poeciliopsis occidentalis*), Hualapai Mexican vole (*Microtus mexicanus hualpaiensis*), gray wolf (*Canis lupus*), Kearney's blue-star (*Amsonia kearneyana*), Arizona hedgehog cactus (*Echinocereus triglochidiatus var. arizonicus*), Brady pincushion cactus (*Pediocactus bradyi*), Nichol's Turk's head cactus (*Echinocactus horizonthalonius* var. *nicholii*), Peebles Navajo cactus (*Pediocactus peeblesianus* var. *peeblesianus*), Pima pineapple cactus (*Coryphantha scheeri* var. *robustispina*), Arizona cliff-rose (*Purshia subintegra*), Canelo Hills ladies'-tresses (*Spiranthes delitescens*), Holmgren milk-vetch (*Astragalus holmgreniorum*), sentry milk-vetch (*Astragalus cremnophylax* var. *cremnophylax*), and Huachuca water umbel (*Lilaeopsis schaffneriana* var. *recurva*).

Authority: 16 U.S.C. 1531 *et seq.*

Dated: January 6, 2010.

Benjamin N. Tuggle,

Regional Director, Southwest Region, Fish and Wildlife Service.

[FR Doc. 2010–451 Filed 1–12–10; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF JUSTICE

Office of Justice Programs; Bureau of Justice Assistance

[OMB Number 1121–0220]

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection Under Review; Extension of currently approved collection. Bureau of Justice Assistance Application Form: Public Safety Officers' Educational Assistance.

The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. This proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until March 15, 2010. If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact M. Berry at 1–866–859–2687, Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice, 810 7th Street, NW., Washington, DC 20531 or by e-mail at *M.A.Berry@ojp.usdoj.gov*.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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.

Overview of This Information Collection

(1) *Type of information collection:* Extension of currently approved collection.

(2) *The title of the form/collection: Public Safety Officers' Educational Assistance*

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. Bureau of Justice Assistance, Office of Justice Programs, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Dependent spouses and/or children of public safety officers who were killed or permanently and totally disabled in the line of duty.

Abstract: BJA's Public Safety Officers' Benefits (PSOB) Office will use the PSOEA application information to confirm the eligibility of applicants to receive PSOEA benefits. Eligibility is dependent on several factors, including the applicant having received or being eligible to receive a portion of the PSOB death benefit, or having a family member who received the PSOB disability benefit. Also considered are the applicant's age and the schools being attended. In addition, information to help BJA identify an individual is collected, such as Social Security number and contact numbers and e-mail addresses. The changes to the application form have been made in an effort to streamline the application process and eliminate requests for information that is either irrelevant or already being collected by other means.

Others: None.

(5) *An estimate of the total number of respondents and the amount of time needed for an average respondent to respond is as follows:* It is estimated that no more than 100 new respondents will apply a year. Each application takes approximately 20 minutes to complete.

(6) An estimate of the total public burden (in hours) associated with the collection is 33 hours. *Total Annual Reporting Burden:* 100 × 20 minutes per application = 2,000 minutes/by 60 minutes per hour = 33 hours.

If additional information is required, please contact, Clearance Officer,

United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: January 7, 2010.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. 2010–408 Filed 1–12–10; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number 1121–0235]

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Extension of a currently approved collection; Bulletproof Vest Partnership.

The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. This proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until March 15, 2010. If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact M. Berry at 202–353–8643 or 1–866–859–2687, by e-mail at *M.A.Berry@ojp.usdoj.gov* or by postal mail at the Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice, 810 7th Street, NW., Washington, DC 20531.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility.

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

(3) Enhance the quality, utility, and clarity of the information to be collected.

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *The title of the form/collection:* Bulletproof Vest Partnership.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form Number: None, Bureau of Justice Assistance, Office of Justice Programs, Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract. *Primary:* State, Local, or Tribal Governments. *Other:* None. Abstract: The Bureau of Justice Assistance (BJA) collects this information as part of the application for federal assistance process under the Bulletproof Vest Partnership (BVP) Program. The purpose of this program is to help protect the lives of law enforcement officers by helping states and units of local and tribal governments equip their officers with armor vests. An applicant may request funds to help purchase one vest per officer per fiscal year. Federal payment covers up to 50 percent of each jurisdiction's total costs. BJA uses the information collected to review, approve, and make awards to jurisdictions in accordance with programmatic and statutory requirements.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* There are approximately 4,500 respondents who will respond approximately once per year, for a total of 4,500 responses. Each response will require approximately 1 hour to complete.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual public burden hours for this information collection is estimated to be 5,000 hours: 5,000 × 60 minutes per application = 300,000 minutes/by 60 minutes per hour = 5,000 hours.

If additional information is required, please contact, Lynn Bryant, Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: January 7, 2010.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. 2010–409 Filed 1–12–10; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on November 6, 2009, Mallinckrodt Inc., 3600 North Second Street, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Phenylacetone (8501)	II
Coca Leaves (9040)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances for the manufacture of controlled substances in bulk for distribution to its customers.

No comments, objections, or requests for any hearings will be accepted on any application for registration or re-registration to import crude opium, poppy straw, concentrate of poppy straw or coca leaves. As explained in the Correction to Notice of Application pertaining to Rhodes Technologies, 72 FR 3417 (2007), comments and requests for hearings on applications to import narcotic raw material are not appropriate.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement

Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, VA 22152; and must be filed no later than February 12, 2010.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745), all applicants for registration to import a basic class of any controlled substances in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: January 6, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–504 Filed 1–12–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Notice of Registration

By Notice dated August 28, 2009, and published in the **Federal Register** on September 8, 2009, (74 FR 46231), Cody Laboratories, 601 Yellowstone Avenue, Cody, Wyoming 82414, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedules I and II:

Drug	Schedule
Dihydromorphine (9145)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Methadone (9250)	II
Morphine (9300)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans on manufacturing the listed controlled substances in bulk for sale to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cody Laboratories to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Cody Laboratories to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: January 6, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–511 Filed 1–12–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 28, 2009, and published in the **Federal Register** on September 8, 2009, (74 FR 46231), Chemic Laboratories, Inc., 480 Neponset Street, Building 7, Canton, Massachusetts 02021, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Cocaine (9041), a basic class of controlled substance listed in schedule II.

The company plans to manufacture small quantities of the above listed controlled substance for distribution to its customers for the purpose of research.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Chemic Laboratories to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Chemic Laboratories to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: January 6, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–515 Filed 1–12–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated September 14, 2009, and published in the **Federal Register** on September 18, 2009, (74 FR 47962), GE Healthcare, 3350 North Ridge Avenue, Arlington Heights, Illinois 60004–1412, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Cocaine (9041), a basic class of controlled substance listed in schedule II.

The company plans to manufacture a radioactive product used in diagnostic imaging in the diagnosis of Parkinson's Disease and for manufacture in bulk for investigational new drug (IND) submission and clinical trials.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of GE Healthcare to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated GE Healthcare to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33,

the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: January 6, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–509 Filed 1–12–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 28, 2009 and published in the **Federal Register** on September 8, 2009, (74 FR 46232), Noramco Inc., Division of Ortho McNeil, Inc., 500 Swedes Landing Road, Wilmington, Delaware 19801–4417, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Noroxymorphone (9668), a basic class of controlled substance listed in schedule II.

The company plans to bulk manufacture the listed controlled substance as a reference standard for distribution to its customers which are analytical laboratories.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Noramco Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Noramco Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: January 6, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–508 Filed 1–12–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 28, 2009, and published in the **Federal Register** on September 8, 2009, (74 FR 46233), National Center for Natural Products Research-NIDA MProject, University of Mississippi, 135 Coy Waller Lab Complex, University, Mississippi 38677, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule I:

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to cultivate marihuana for the National Institute on Drug Abuse for research approved by the Department of Health and Human Services.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of National Center for Natural Products Research-NIDA MProject to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated National Center for Natural Products Research-NIDA MProject to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: January 6, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2010–506 Filed 1–12–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—Curriculum Development: Training for Correctional Industries Directors

AGENCY: National Institute of Corrections, Department of Justice.

ACTION: Solicitation for a cooperative agreement.

SUMMARY: The National Institute of Corrections' (NIC) Transition and Offender Workforce Development (T/OWD) and Academy Divisions are seeking applications for the development of a competency based, blended modality training curriculum that will provide Correctional Industries Directors with the knowledge, skills and abilities needed to set organizational priorities, identify strategic objectives, create measurable goals, establish collaborative partnerships, utilize current labor market information, and provide specialized services and programming that support the offenders' long term attachment to the labor force.

DATES: Applications must be received by 4 p.m. EST on Friday, February 12, 2010.

ADDRESSES: Mailed applications must be sent to: Director, National Institute of Corrections, 320 First Street, NW., Room 5007, Washington, DC 20534. Applicants are encouraged to use Federal Express, UPS, or similar service to ensure delivery by the due date.

Hand delivered applications should be brought to 500 First Street, NW., Washington, DC 20534. At the front desk, dial 7–3106, extension 0 for pickup.

Faxed applications will not be accepted. Electronic applications can be submitted via *http://www.grants.gov.*

FOR FURTHER INFORMATION CONTACT: All technical or programmatic questions concerning this announcement should be directed to Michael Guevara, Correctional Program Specialist, National Institute of Corrections. He can be reached by calling 303–365–4415, or by e-mail at *mguevara@bop.gov.* Questions will be accepted until one week prior to the application due date. At this time responses to the questions will be posted on the NIC Web site.

SUPPLEMENTARY INFORMATION:

Overview: NIC is looking to develop a curriculum, which follows NIC's Instructional Theory Into Practice (ITIP) model, to be written based on occupational documentation that includes a completed DACUM (*D*eveloping *A C*urricul*um*) and a

DACUM validation for the position of Correctional Industries Director. It is anticipated that the curriculum will utilize blended learning formats to accommodate the possibility of distance learning. The curriculum will be piloted and changes made based upon evaluation of the pilot.

Background: NIC has been committed for years to improving offender transition, workforce development, and correctional industries. In an effort to expand on the resources NIC provides the field in these areas, a DACUM was completed for the job of Correctional Industries Director. This was followed by a DACUM validation. The next step is to create and pilot a training curriculum for this position.

Purpose: To create and pilot a complete training curriculum for Correctional Industries Directors.

Scope of Work: At the end of this Cooperative Agreement, a curriculum will have been developed using NIC's Instructional Theory Into Practice (ITIP) model. This model can be found on NIC's Web site via the following link: *http://www.nicic.org/pubs/1992/010714.pdf.* The curriculum will include a facilitator's manual, participant's manual, and all relevant supplemental material (such as PowerPoint slides, visual and/or audio aids, handouts, exercises, *etc.*). The use of blended learning tools such as a live web-based training environment (*e.g.* WebEx) or supplemental on-line training courses is encouraged. Clear learning objectives will be contained in each lesson, and delivery modality will be based on how to most efficiently and effectively achieve these objectives. The curriculum will have been piloted and changes incorporated as necessary. A pre-and post-test, as well as quizzes will have been developed as necessary. Consideration will be given to advance work for participants, such as reading assignments or taking an online course through NIC's Learning Center. An evaluation, to be distributed at the conclusion of the training, will also have been developed. This evaluation will examine the content, processes, and delivery of the program. The evaluation will be designed with the purpose in mind of helping to revise and improve the training and curriculum. After it is developed under this cooperative agreement, the proposed evaluation protocol must be submitted to NIC for review and approval before use.

Specific Requirements: The training curriculum will be based on a recently established needs assessment identified through the use of a DACUM for Correctional Industries Directors. Modules may address the following: Dynamic Leadership; Financial Self-Sufficiency; Offender Workforce Development; Marketing Strategies; Staff Workforce Competencies; Stakeholder Network; Internal and External Customer Satisfaction; Reentry Services; Organizational Performance; Engaging in Legislative Processes, and Balancing Internal/External Environments.

Document Requirements: The following are the expected document requirements. **Note:** Publications produced under this award must follow the "Guidelines for Preparing and Submitting Manuscripts for Publication" as found in the General Guidelines for Cooperative Agreements included in the award package. All final publications submitted for posting on the NIC Web site must meet the federal government's requirement for accessibility (508 PDF or HTML file). All documents developed under this cooperative agreement must be submitted in draft form to NIC for review before the final products are delivered.

Application Requirements: Applications should be concisely written, contain no more than 20 double spaced typed pages (exclusive of resumes and summaries of experience), and reference the project by the "NIC Opportunity Number" and Title in this announcement. The package must include: a cover letter that identifies the audit agency responsible for the applicant's financial accounts as well as the audit period or fiscal year that the applicant operates under (*e.g.,* July 1 through June 30); a program narrative in response to the statement of work and a budget narrative explaining projected costs. The following forms must also be included: OMB Standard Form 424, Application for Federal Assistance; OMB Standard Form 424A, Budget information—Non-Construction Programs; OMB Standard Form 424B, Assurances—Non-Construction Programs (these forms are available at *http://www.grants.gov*) and DOJ/NIC Certification Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and the Drug-Free Workplace Requirements (available at *http://www.nicic.gov/Downloads/PDF/certif-frm.pdf.*)

Applications may be submitted in hard copy, or electronically via *http://www.grants.gov.* If submitted in hard copy, there needs to be an original and three copies of the full proposal (program and budget narratives, application forms and assurances). The original should have the applicant's signature in blue ink.

Authority: Public Law 93–415.

Funds Available: NIC is seeking the applicant's best ideas regarding accomplishment of the scope of work and the related costs for achieving the goals of this solicitation. Funds may only be used for the activities that are linked to the desired outcome of the project.

This project will be a collaborative venture with NIC's Transition & Offender Workforce Development and Academy Divisions.

Eligibility of Applicants: An eligible applicant is any public or private agency, educational institution, organization, individual or team with expertise in the described areas.

Review Considerations: Applications received under this announcement will be subjected to a 3 to 5 person NIC Peer Review Process. The criteria for the evaluation of each application will be as follows:

Programmatic (60%)

Is there demonstrated knowledge of curriculum development? Is a specific model of curriculum development (*e.g.* ITIP) proposed? Is there demonstrated knowledge of training for leadership and executive positions? Is there demonstrated knowledge of techniques and/or interventions that successfully address acquisition and retention of new knowledge, skills and abilities? Does the proposal include blended and distance learning approaches? Are project goals/tasks adequately discussed? Is there a clear statement of how project goals will be accomplished, to include: major tasks that will lead to achieving the goal, the strategies to be employed, required staffing and other required resources? Are there any innovative approaches, techniques, or design aspects proposed that will enhance the project?

Organizational (20%)

Do the skills, knowledge, and expertise of the organization and the proposed project staff demonstrate a high level of competency to carry out the tasks? Does the applicant/organization have the necessary experience and organizational capacity to carry out all goals of the project? Are the proposed project management and staffing plans realistic and sufficient to complete the project within the 12-month time frame?

Project Management/Administration (20%)

Does the applicant identify reasonable objectives, milestones, and measures to track progress? If consultants and/or partnerships are proposed, is there a reasonable justification for their inclusion in the project and a clear

structure to ensure effective coordination? Is the proposed budget realistic, does it provide sufficient cost detail/narrative, and does it represent good value relative to the anticipated results?

Note: NIC will NOT award a cooperative agreement to an applicant who does not have a Dun and Bradstreet Database Universal Number (DUNS) and is not registered in the Central Contractor Registry (CCR).

A DUNS number can be received at no cost by calling the dedicated toll-free DUNS number request line at 1–800–333–0505 (if you are a sole proprietor, you would dial 1–866–705–5711 and select option 1).

Registration in the CRR can be done online at the CCR Web site: *http://www.ccr.gov.* A CCR Handbook and worksheet can also be reviewed at the Web site.

Number of Awards: One.

NIC Opportunity Number: 10A30. This number should appear as a reference line in the cover letter, where indicated on Standard Form 424, and outside of the envelope in which the application is sent.

(Catalog of Federal Domestic Assistance Number: 16.601. Executive Order 12372: This project is not subject to the provisions of Executive Order 12372)

Morris L. Thigpen,

Director, National Institute of Corrections.

[FR Doc. 2010–505 Filed 1–12–10; 8:45 am]

BILLING CODE 4410–36–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation (NSF).

ACTION: Submission for OMB Review; Comment Request and Final Notice of a Uniform Research Performance Progress Report (RPPR) format.

SUMMARY: Effective with publication of this Notice in the **Federal Register**, agencies will be able to utilize a new uniform format for reporting performance progress on Federally-funded research projects. The Research Performance Progress Report (RPPR) will directly benefit award recipients by making it easier for them to administer Federal grant and cooperative agreement programs through standardization of the types of information required in interim performance reports—thereby reducing their administrative effort and costs. The RPPR will also make it easier to compare the outputs, outcomes, etc. of research programs across the government.

The RPPR resulted from an initiative of the Research Business Models (RBM) Subcommittee of the Committee on Science (CoS), a committee of the National Science and Technology Council (NSTC). One of the RBM Subcommittee's priority areas is to create greater consistency in the administration of Federal research awards. Given the increasing complexity of interdisciplinary and interagency research, it is important for Federal agencies to manage awards in a similar fashion. Upon implementation, the RPPR will be used by agencies that support research and research-related activities for use in submission of interim progress reports. It is intended to replace other interim performance reporting formats currently in use by agencies. The RPPR does not change the performance reporting requirements specified in 2 CFR part 215 (OMB Circular A–110) and the Common Rule implementing OMB Circular A–102.

Each category in the RPPR is a separate reporting component. Agencies will direct recipients to report on the one mandatory component ("Accomplishments"), and also may direct them to report on optional components, as appropriate. Within a particular component, agencies may direct recipients to complete only specific questions, as not all questions within a given component may be relevant to all agencies. Agencies may develop an agency- or program-specific component, if necessary, to meet programmatic requirements, although agencies should minimize the degree to which they supplement the standard components. Such agency- or program-specific requirements will require review and clearance by OMB.

Agencies also may use other OMB-approved reporting formats, such as the Performance Progress Report (PPR), if those formats are better suited to the agency's reporting requirements, for example, for research centers/institutes, clinical trials, or fellowship/training awards or in connection to reporting on program performance, through mechanisms such as the Performance Assessment Rating Tool.

On behalf of the RBM Subcommittee, the National Science Foundation (NSF) has agreed to serve as sponsor of this new format. We anticipate this being the final notice before the format and instructions are finalized. The general public and Federal agencies, however, are invited to comment on the proposed final format during the 30 day public comment period. The Government-wide RPPR is posted on the NSF Web site at: *http://www.nsf.gov/bfa/dias/policy/rppr/index.jsp.*

Comments: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Science Foundation is publishing the following summary of a proposed collection 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.

DATES: Comments must be received by *February 12, 2010.*

ADDRESSES: Comments should be addressed to Suzanne H. Plimpton, Reports Clearance Officer, Division of Administrative Services, National Science Foundation, 4201 Wilson Blvd, Arlington, VA 22230, e-mail *splimpton@nsf.gov;* telephone: (703) 292–7556; fax: (703) 292–9188. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays.

We encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Please include "*Research Performance Progress Reporting*" in the subject line of the e-mail message; please also include the full body of your comments in the text of the message, and as an attachment. Include your name, title, organization, postal address, telephone number, and e-mail address in your message.

FOR FURTHER INFORMATION CONTACT: For information on the RPPR, contact Jean Feldman; Head, Policy Office, Division of Institution & Support; National Science Foundation; 4201 Wilson Blvd; Arlington, VA 22230; e-mail: *jfeldman@nsf.gov;* telephone: (703) 292–8243; fax: (703) 292–9171.

For further information on the NSTC RBM Subcommittee, contact Diane DiEuliis, at the Office of Science and Technology Policy, 725 17th Street, NW., Washington, DC 20503; e-mail: *ddieuliis@ostp.eop.gov;* telephone: 202–

456–6059; fax: 202–456–6027. See also the RBM Subcommittee's Web site: *http://rbm.nih.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Purpose of Today's Federal Register Notice

This project is an initiative of the Research Business Models (RBM) Subcommittee of the Committee on Science (COS), a committee of the National Science and Technology Council (NSTC). The RBM Subcommittee's objectives include:

- Facilitating a coordinated effort across Federal agencies to address policy implications arising from the changing nature of scientific research; and
- Examining the effects of these changes on business models for the conduct of scientific research sponsored by the Federal government.

The Subcommittee used public comments, agency perspectives, and input from a series of regional public meetings to identify priority areas on which it would focus its initial efforts. In each priority area, the Subcommittee is pursuing initiatives to promote, as appropriate, common policy, streamlining of current procedures, or the identification of agencies' and institutions' "best practices." As further information about initiatives becomes available, it will be posted at the Subcommittee's Web site at: *http://rbm.nih.gov.*

One of the RBM Subcommittee's priority areas is greater uniformity in the form and content of performance reports that are required by Federal grants and cooperative agreements awarded under research programs. Many Federal agencies have their own forms or formats that recipients must use to report progress on activities supported by research awards. While agencies use different formats and different language to request information on progress, they generally collect similar information. These variations increase the administrative effort and costs for recipients of Federal awards, and make it difficult to compare the outputs, outcomes, etc., of research programs across the government. The RPPR format will increase uniformity of content across Federal research agencies.

The RBM Subcommittee reviewed forms and formats currently in use by Federal agencies for reporting performance on research grants. The reporting categories used by the NSF were selected as a starting point for designing a standard format, as hundreds of NSF research programs have used these categories successfully. The RPPR does not change the performance reporting requirements specified in 2 CFR part 215 (OMB Circular A–110) and the Common Rule implementing OMB Circular A–102; it merely provides additional clarification, instructions, and a standard format for collecting the information.

The RPPR is intended for use in submission of interim progress reports, not for use in submission of final reports, and it is intended to replace other formats currently in use by agencies supporting research and research-related activities. The RBM Subcommittee plans to undertake development of a final Research Performance Progress Report format upon completion of the interim RPPR exercise. The RPPR addresses progress for the most recently completed period, at the frequency required or designated by the sponsoring agency. Information, once reported, may not have to be provided again on subsequent reports, if an agency has implemented an electronic solution for submission of progress reports. However, upon implementation, agencies may use this format in either paper copy or in electronic form.

The National Science Foundation (NSF), on behalf of the National Science and Technology Council's Research Business Models Subcommittee, proposed the draft RPPR for comment in the **Federal Register** [Volume 72, pages 63629–63631, November 9, 2007]. 347 public comments were received from a wide variety of respondents, including six institutions of higher education; three associations of academic and nonprofit institutions; components of six Federal agencies; and one individual. All comments were carefully considered in developing a final version of the RPPR. The majority of public comments strongly supported the overall proposal to create a government-wide standard RPPR, citing the advantages of increased consistency in Federal agencies' reporting requirements. A number of specific issues were raised, and those comments and responses are summarized in Section II.

Each category in the RPPR is a separate reporting component. Agencies will direct recipients to report on the one mandatory component ("Accomplishments"), and may also direct them to report optional components, as appropriate. Recipients will not be required or expected to report on each of the questions or items listed under a particular category. They will be advised to state "Nothing to Report" if they have nothing significant to report during the reporting period. Within a particular component, agencies also may direct recipients to complete only specific questions, as not all questions within a given component may be relevant to all agencies.

Agencies will utilize the standard instructions that have been developed for each category, but may provide additional program-specific instructions necessary to clarify a requirement for a particular program. For example, the Environmental Protection Agency (EPA) is required to collect information on environmental impacts; so EPA can direct recipients to report on the research's benefit to the environment or human health under the following reporting question: "How has the project contributed to society beyond science and technology?"

Agencies may develop additional agency- or program-specific reporting components and instructions (*e.g.,* the National Institutes of Health may need to collect information on clinical trials in certain types of awards); however, to maintain maximum uniformity, agencies will be instructed to minimize the degree to which they supplement the standard categories. Such agency- or program-specific requirements will require review and clearance by OMB.

Agencies also may use other OMB-approved reporting formats, such as the Performance Progress Report (PPR), if those formats are better suited to the agency's reporting requirements, for example, for research centers/institutes, clinical trials, or fellowship/training awards or in connection to reporting on program performance, through mechanisms such as the Performance Assessment Rating Tool.

II. Comments, Responses, and Changes to the Research Performance Progress Report Format

The following are the comments, and associated responses, resulting from the November 9, 2007 **Federal Register** Notice.

Comment: Four Federal and six university commenters questioned the process for development and implementation of the RPPR.

Response: When the RBM Working Group was initially formed in 2004, it examined existing research progress reports with the intent of standardizing the reporting requirements across agencies. Once a draft was developed, the RPPR Working Group requested comments and modified the format based on the comments. Once final, NSF (on behalf of the National Science and Technology Council's Research Business Models subcommittee) will send the RPPR to OMB for clearance as part of the Paperwork Reduction Act

(PRA) process. The RPPR Working Group will develop guidance and training as part of the implementation.

Comment: Nine Federal commenters requested additional data elements associated with project budgets.

Response: Agree. A new, optional "Budget" section of the format was created.

Comment: Six Federal commenters requested additional data elements to comply with agency special reporting requirements on things such as clinical trials.

Response: Agree. An optional "Special reporting requirements" section of the format was added.

Comment: One Federal commenter requested the addition of a data element capturing changes in project/performance site.

Response: Agree. A "Change of primary performance site location" data element was added.

Comment: Five Federal commenters requested the inclusion of contact information and signature for the authorized official submitting the report, as well as date of submission.

Response: Agree. Data elements to capture the electronic or hard copy signature and contact information of the authorized official and date of submission were added and are expected to be captured as part of the electronic implementation solution.

Comment: 60 Federal commenters requested additional data elements to meet agency-specific requirements.

Response: No change. The information is either already captured in the report, or the proposed data element would go beyond the scope of the report, potentially increasing grantee burden and confusing users. Agencies may pursue developing agency-specific requirements through OMB. However, every attempt was made to minimize the need for agency-specific requirements.

Comment: Seven Federal commenters expressed concern that the format would not be adequate for an agency's reporting requirements, especially in regards to reporting on PART.

Response: Agencies may consider using the Performance Progress Report (PPR) in lieu of the RPPR. The PPR has a specific section for reporting on the Program Assessment Rating Tool. Agencies also may pursue developing agency-specific requirements through OMB.

Comment: 29 Federal, nine university, and four association commenters noted the use of current agency data collection systems and the need to develop a new, electronic, web-based solution for research performance progress reporting.

Response: All electronic system implementation comments received in response to the **Federal Register** Notice will be forwarded to the Grants Executive Board and the Grants Management Line of Business for dissemination to appropriate agency contacts for further consideration However, upon implementation, agencies may use this format in either paper copy or in electronic form.

Comment: One Federal and five university commenters suggested that agencies be able to pre-populate the report with data from the grants.gov application.

Response: The information collected on Grants.gov and in grant applications would not be appropriate for the RPPR because the information often changes between application and award.

Comment: One Federal commenter requested the development of a standard taxonomy for types of projects.

Response: Keeping an updated list would be extremely time consuming and difficult. However, if an agency or group develops a standardized taxonomy, the RPPR Working Group will consider incorporating this taxonomy in a future update to the format.

Comment: Four Federal commenters suggested page and word limits for report responses.

Response: This is a format, not a form. Agencies can define page and word limits when appropriate.

Comment: 48 Federal and six university commenters requested clarifications regarding the type of data requested and the purpose of each section in the instructions.

Response: Agree. The instructions were amended to clarify the type of data requested and the purpose of each section, where necessary.

Comment: Ten Federal commenters questioned the broad applicability and order of the proposed format.

Response: The RPPR is intentionally broad to create maximum flexibility, allowing agencies to use it for all research and research-related programs. The standardized instructions were developed to ensure consistency across agencies wherever possible. There is no prescribed order to the format because the order will depend on which sections an agency determines to be mandatory.

Comment: Four Federal and five association commenters questioned the intent of and need for the demographic information in the "Participants" section.

Response: The demographics information being requested is based on government-wide standard categories currently in use on a variety of forms. The demographics being requested only pertain to the people who have directly worked on the award. This section is optional and if another institution has regulations preventing its reporting, the award recipient may choose not to provide such data. While demographic data will be used by agencies for data analysis and reporting, it will not be used by agencies as part of the progress report evaluation.

Comment: Six Federal and one association commenters requested a clearer indication of which paid persons an award recipient should report on and clarification of 'person months' in the "Participants" section.

Response: Agree. Language was added to the instructions.

Comment: Three Federal and one university commenters proposed the use of "None" or "Nothing to report" vs. allowing an award recipient to leave a box blank.

Response: Agree. "Nothing to report" is more accurate and was added. A blank field could represent "nothing to report" or a spot that the awardee forgot to fill in.

Comment: Eight Federal, four university, and two association commenters expressed concern about the potential burden the report might create.

Response: The burden was carefully considered during the development of the RPPR. Depending on how it is implemented by each agency, the RPPR may request more extensive data than are currently collected; but both agencies and award recipients will receive better information. As with any standardization effort, there may be a short term burden increase in order to produce a long-term gain. Finally, while there may be additional burden on the first report for the project, assuming an electronic solution, the next form could potentially be pre-populated with information that carries over, leading to a burden reduction.

Comment: Four Federal commenters noted apparent redundancy of data elements across different sections of the report.

Response: Each section captures different types of data. Any apparent redundancy is intentional to ensure agencies using only a select few of the optional sections capture the necessary data.

Comment: One Federal commenter questioned the need for invention, patent, and license information, since it is already captured elsewhere by many agencies.

Response: The purpose of this section is to provide the agency program officer with a record of all that has occurred

within the reporting period, including patents.

Comment: 26 Federal, four university, and two association commenters questioned the distinction between the mandatory and optional sections of the form.

Response: Only the "Accomplishments" component of the RPPR format is mandatory, while the other components are for optional use at the discretion of the agencies. The Federal awarding agency determines which categories are mandatory or optional for the award recipient to complete. This should be determined as early as possible, preferably at the time the funding opportunity is issued. As information required can vary between agencies and programs, the combination of mandatory and optional sections provides agencies the maximum flexibility to collect only the information they specifically require.

Comment: One Federal commenter asked whether the RPPR would be required in addition to the PHS 2590.

Response: The RPPR would replace the PHS 2590. Information not collected as part of the RPPR could be requested through the optional agency-specific categories.

Comment: Three Federal commenters asked for a clear definition of research—which programs are considered research or research-related programs?

Response: It is up to the agencies to determine which programs are research or research-related programs.

Comment: Four Federal and one university commenters requested language stating that the RPPR should not be used as the vehicle for seeking prior approvals and/or fulfilling invention reporting requirements.

Response: Agree. Appropriate language was added to the RPPR.

Comment: 25 Federal, five university, and one association commenters offered suggestions regarding the development of a Final Report format.

Response: These comments will be considered after the development and implementation of the RPPR has been completed.

III. Paperwork Reduction Act

In furtherance of the goals of the National Science and Technology Council's Research Business Models Subcommittee, this proposed format aims to reduce the burden on recipients currently expending time and effort on a variety of agency-specific forms. Under the PRA, OMB assigns a control number to each "collection of information" that it reviews and approves for use by an agency. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB Control Number. The PRA also requires agencies to estimate the burden for each collection of information. It should be noted that burden estimates associated with forms currently in use range from a minimum of 2 hours to a maximum of 16 hours, depending on the type of research project being supported.

The following table provides the estimated numbers of annual progress reports, hours per report, and total annual burden hours by agency:

Department/agency name	Number of annual progress reports	Number of annual burden hours	Total annual burden hours
DHHS (including NIH)	37,900	14.862	563,275
DHS	411	12	4,932
DoC/NIST	100	4	400
DoC/NOAA	1,105	2	2,210
DoD	11,000	6	66,000
DoE	16,000	5	80,000
DoEd/IES	500	16	8,000
EPA	150	4	600
NASA	4,000	4	16,000
NEH	55	2	1,100
NSF	28,030	5	140,150
USDA/NIFA	12,658	2.7	34,177
Totals	116,404	6.6	916,844

IV. Final Administrative Requirements and Future Steps

The final version of the uniform Research Performance Progress Report format that incorporates the changes discussed in the preceding Sections I and II of Supplementary Information, may be viewed at: *http://www.nsf.gov/bfa/dias/policy/rppr/index.jsp.*

Each Federal research agency that supports research and research-related activities must post their policy or an implementation plan on the NSF and RBM Web sites within nine months after issuance of OSTP/OMB policy direction. Each implementation plan will address whether the agency plans to implement the RPPR in paper or electronic format, and include an anticipated implementation date.

Dated: January 8, 2010.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2010–469 Filed 1–12–10; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–7016; CLI–10–04]

GE-Hitachi Global Laser Enrichment LLC; (GLE Commercial Facility); Notice of Receipt of Application for License; Notice of Consideration of Issuance of License; Notice of Hearing and Commission Order; and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information for Contention Preparation

Commissioners: Gregory B. Jaczko, Chairman; Dale E. Klein; Kristine L. Svinicki.

I. Receipt of Application and Availability of Documents

Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC or the Commission) received on June 26, 2009, an application from GE-Hitachi Global Laser Enrichment LLC (GLE), for a license to possess and use source, byproduct, and special nuclear material and to enrich natural uranium to a maximum of 8 percent U–235 by a laser-based enrichment process. The plant, to be known as the GLE Commercial Facility (GLE–CF), would be located approximately six miles north of the City of Wilmington in New Hanover County, North Carolina and would have a nominal capacity of six million separative work units (SWU) per year.

GLE is a Delaware limited liability company and is a subsidiary of majority owner and Delaware limited liability company GE-Hitachi Nuclear Energy Americas LLC (GEH), which is a wholly owned subsidiary of GE-Hitachi Nuclear Energy Holdings LLC (GEH-Holdings). GEH-Holdings is a subsidiary of majority owner GENE Holding LLC (GENE) and minority owner Hitachi America, Ltd. GENE, also a Delaware limited liability company, is wholly owned by General Electric Company (GE), a United States corporation incorporated in New York. Hitachi America is a wholly owned subsidiary of Hitachi Ltd., a Japanese corporation. GLE also has two minority owners, GENE and Cameco Enrichment Holdings, LLC, a Delaware limited liability company wholly owned by Cameco US Holdings, Inc., a Nevada corporation, which is in turn wholly owned by Cameco Corporation, a Canadian corporation. GE, through its wholly owned and majority owned subsidiaries, has a 51% indirect interest in GLE. GLE's minority owners Hitachi and Cameco have indirect interests of 25% and 24%, respectively.

On January 13, 2009, GLE was granted an exemption to file its environmental report in advance of its license application. GLE submitted its environmental report on January 30, 2009; and on July 13, 2009, GLE submitted a supplement to its environment report, GLE Environmental Report Supplement 1—Early Construction. On April 9, 2009, the NRC published notice of its intent to prepare an Environmental Impact Statement (EIS) on the proposed action and the opportunity for public comment on the appropriate scope of issues to be considered in the EIS. See 74 FR 16237 (April 9, 2009). By notice published in the **Federal Register** on July 24, 2009, the NRC extended the public comment period to allow members of the public to review the publicly available portions of the license application filed after June 26, 2009. See 74 FR 36781 (July 24, 2009). On August 6, 2009, the NRC staff notified GLE by letter that staff had completed its acceptance review and had determined that the application was acceptable for formal review.

Copies of GLE's application, safety analysis report, environmental report and supplement to its environmental report (except for portions subject to withholding from public inspection in accordance with 10 CFR 2.390, Availability of Public Records) are available for public inspection at the Commission's Public Document Room (PDR) at One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. These documents are also available for review and copying using any of the following methods: (1) Enter the NRC's GE Laser Enrichment Facility Licensing Web site at *http://www.nrc.gov/materials/fuel-cycle-fac/laser.html#2a;* (2) enter the NRC's Agencywide Document Access and Management System (ADAMS) at *http://www.nrc.gov/reading-rm/adams.html,* where the accession number for GLE's Environmental Report is ML090910573; accession number for the license application is ML091871003, and the accession number for Supplement 1 to the Environmental Report is ML092100577; (3) contact the PDR by calling (800) 397–4209, faxing a request to (301) 415–3548, or sending a request by electronic mail to *pdr@nrc.gov.* Hard copies of the documents are available from the PDR for a fee.

As indicated above, GLE's initial application has been accepted for docketing and formal review (ADAMS accession number ML091960561) and, accordingly, the Commission is providing this notice of hearing and notice of opportunity to intervene in GLE's application for a license to construct and operate a laser enrichment facility. Pursuant to the Atomic Energy Act of 1954, as amended (AEA), the NRC staff will prepare a safety evaluation report (SER) after reviewing the application and make findings concerning the public health and safety and common defense and security. In addition, pursuant to the National Environmental Policy Act of 1969 (NEPA) and the Commission's regulations in 10 CFR part 51, the NRC staff will complete an environmental evaluation and prepare an EIS before the hearing on the issuance of a license is completed. See Notice of Intent to Prepare an Environmental Impact Statement for the Proposed General Electric-Hitachi Global Laser Enrichment Uranium Enrichment Facility, 74 FR 16237 (April 9, 2009); and Extension of Public Scoping Period for the Environmental Impact Statement for the Proposed General Electric-Hitachi Global Laser Enrichment Facility, 74 FR 36781 (July 24, 2009).

When available, the NRC staff's SER and EIS (except for portions subject to withholding from public inspection in accordance with 10 CFR 2.390) will also be placed in the PDR and in ADAMS. Copies of correspondence between the NRC and GLE, and transcripts of prehearing conferences and hearings (except for portions subject to withholding from public inspection in accordance with 10 CFR 2.390) similarly will be made available to the public.

If, following the hearing, the Commission is satisfied that GLE has complied with the Commission's regulations and the requirements of this Notice and Commission Order and the Commission finds that the application satisfies the applicable standards set forth in 10 CFR Parts 30, 40, and 70, a single license will be issued authorizing: (1) The construction and operation of the GLE–CF; and (2) the receipt, possession, use, delivery, and transfer of byproduct (*e.g.*, calibration sources), source and special nuclear material at the GLE–CF. If the GLE–CF is licensed, prior to commencement of operations the NRC will verify through an inspection conducted in accordance with section 193(c) of the AEA and 10 CFR 70.32(k) that the facility meets the construction and operation requirements of the license. The inspection findings will be published in the **Federal Register.**

II. Notice of Hearing

A. Pursuant to 10 CFR 70.23a and Section 193 of the AEA, as amended by the Solar, Wind, Waste, and Geothermal Power Production Incentives Act of 1990 Public Law 101–575, § 5, 104 Stat. 2834, 2835–36 (codified as amended at 42 U.S.C. 2243), a hearing will be conducted according to the rules of practice in 10 CFR part 2, subparts A, C, G, and to the extent that classified information becomes involved, Subpart I. The hearing will be held under the authority of sections 53, 63, 189, 191, and 193 of the AEA. The applicant and the NRC staff shall be parties to the proceeding.

B. Pursuant to 10 CFR part 2, Subparts C and G, a contested hearing shall be conducted by an Atomic Safety and Licensing Board (Licensing Board) appointed by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel. Notice as to the

membership of the Licensing Board will be published in the **Federal Register** at a later date.

C. The matters of fact and law to be considered are whether the application satisfies the standards set forth in this Notice and Commission Order and the applicable standards in 10 CFR parts 30, 40, and 70, and whether the requirements of NEPA and the NRC's implementing regulations in 10 CFR part 51 have been met.

D. If this proceeding is not a contested proceeding, as defined by 10 CFR 2.4, the Licensing Board will determine the following without conducting a de novo evaluation of the application: (1) Whether the application and record of the proceeding contain sufficient information to support license issuance and whether the NRC staff's review of the application has been adequate to support findings to be made by the Director of the Office of Nuclear Materials Safety and Safeguards with respect to the matters set forth in paragraph C of this section; and (2) whether the review conducted by the NRC staff pursuant to 10 CFR part 51 has been adequate.

E. Regardless of whether the proceeding is contested or uncontested, the Licensing Board will, in the initial decision, in accordance with Subpart A of 10 CFR part 51: Determine whether the requirements of sections 102(2)(A), (C), and (E) of NEPA and subpart A of 10 CFR part 51 have been complied with in the proceeding; independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; and determine, after weighing the environmental, economic, technical, and other benefits against the environmental and other costs, and considering reasonable alternatives, whether a license should be issued, denied, or appropriately conditioned to protect environmental values.

F. If the proceeding becomes a contested proceeding, the Licensing Board shall make findings of fact and conclusions of law on admitted contentions. With respect to matters set forth in paragraph C of this section, but not covered by admitted contentions, the Licensing Board will make the determinations set forth in paragraph D without conducting a *de novo* evaluation of the application.

III. Intervention

A. By March 15, 2010, any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Petitions for leave to intervene shall be filed in accordance with the provisions of 10 CFR 2.309. Interested persons should consult 10 CFR part 2, section 2.309, which is available at the NRC's PDR, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, MD (or call the PDR at (800) 397–4209 or (301) 415–4737). NRC regulations are also accessible electronically from the NRC's Electronic Reading Room on the NRC Web site at *http://www.nrc.gov.*

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 must provide the name, address, and telephone number of the petitioner and specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the AEA to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order that may be entered in the proceeding on the petitioner's interest.

A petition for leave to intervene must also include a specification of the contentions that the petitioner seeks to have litigated in the hearing. For each contention, the petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings the NRC must make to support the granting of a license in response to GLE's application. The petition must also include a concise statement of the alleged facts or expert opinions which support the position of the petitioner and on which the petitioner intends to rely at hearing, together with references to the specific sources and documents on which the petitioner intends to rely. Finally, the petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the application that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's belief. Each contention must be one that, if proven, would entitle the petitioner to relief.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies, and procedures. The Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Non-timely petitions for leave to intervene and contentions, amended petitions, and supplemental petitions will not be entertained absent a determination by the Commission, the Licensing Board or a Presiding Officer that the petition should be granted and/or the contentions should be admitted based upon a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii).

B. A State, county, municipality, Federally-recognized Indian Tribe, or agencies thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(d)(2). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by March 15, 2010. The petition must be filed in accordance with the filing instructions in section IV, and should meet the requirements for petitions for leave to intervene set forth in section III.A, except that State and Federally-recognized Indian Tribes do not need to address the standing requirements in 10 CFR 2.309(d)(1) if the facility is located within its boundaries. The entities listed above could also seek to participate in a hearing as a nonparty pursuant to 10 CFR 2.315(c).

C. Any person who does not wish, or is not qualified, to become a party to this proceeding may request permission to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to such limits and conditions as may be imposed by the Licensing Board. Persons desiring to make a limited appearance are requested to inform the

Secretary of the Commission by March 15, 2010.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a petition for leave to intervene and proffered contentions, any motion or other document filed in the proceeding prior to the submission of a 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. 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 a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the petitioner must contact the Office of the Secretary by e-mail at *Hearing.Docket@nrc.gov*, or by calling (301) 415–1677, to request: (1) A digital 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/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner (or its counsel or representative) already holds an NRC issued digital ID certificate). Each petitioner will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/sitehelp/e-submittals/install-viewer.html.* 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.*

Once a petitioner has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a petition for leave to intervene including proffered contentions. 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 filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE 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 e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC 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 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 through the "Contact Us" link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html* or by calling the NRC electronic filing Help Desk, which is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays. The toll-free help line number is (866) 672–7640. A person filing electronically may also seek assistance by sending an e-mail to the NRC electronic filing Help Desk at *MSHD.Resource@nrc.gov.*

Participants who believe that they have a good cause for not submitting documents electronically must, in accordance with 10 CFR 2.302(g), file an exemption request 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.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/EHD_Proceeding/home.asp*, unless excluded pursuant to an order of the Commission, the Licensing Board, or a 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.

V. Commission Guidance

A. Licensing Board Determination of Contentions

The Licensing Board shall issue a decision on the admissibility of contentions no later than June 14, 2010.

B. Novel Legal Issues

If rulings on petitions, contention admissibility, or admitted contentions, raise novel legal or policy questions, the Commission will provide early guidance and direction on the treatment and resolution of such issues. Accordingly, the Commission directs the Licensing Board to promptly certify to the Commission in accordance with 10 CFR 2.319(l) and 2.323(f) all novel legal or policy issues that would benefit from early Commission consideration should such issues arise in this proceeding.

C. Discovery Management

(1) All parties, except the NRC staff, shall make the mandatory disclosures required by 10 CFR 2.704(a) and (b) within forty-five (45) days of the issuance of the Licensing Board order admitting contentions.

(2) The Licensing Board, consistent with fairness to all parties, should narrow the issues requiring discovery and limit discovery to no more than one round for admitted contentions.

(3) All discovery against the NRC staff shall be governed by 10 CFR 2.336(b) and 2.709. The NRC staff shall comply with 10 CFR 2.336(b) no later than 30 days after the Licensing Board order admitting contentions and shall update the information at the same time as the issuance of the SER or the Final Environmental Impact Statement (FEIS), and, subsequent to the publication of the SER and FEIS, as otherwise required by the Commission's regulations. Discovery under 10 CFR 2.709 shall not commence until the issuance of the particular document, *i.e.*, SER or EIS, unless the Licensing Board, in its discretion, finds that commencing discovery against the NRC staff on safety

issues before the SER is issued, or on environmental issues before the FEIS is issued will expedite the hearing without adversely affecting the Staff's ability to complete its evaluation in a timely manner.

(4) No later than 30 days before the commencement of the hearing at which an issue is to be presented, all parties other than the NRC staff shall make the pretrial disclosures required by 10 CFR 2.704(c).

D. Hearing Schedule

In the interest of providing a fair hearing, avoiding unnecessary delays in NRC's review and hearing process, and producing an informed adjudicatory record that supports the licensing determination to be made in this proceeding, the Commission expects that both the Licensing Board and NRC staff, as well as the applicant and other parties to this proceeding, will follow the applicable requirements contained in 10 CFR part 2 and guidance in the *Commission's Statement of Policy on Conduct of Adjudicatory Proceedings,* CLI–98–12, 48 NRC 18 (1998) (63 FR 41872 (August 5, 1998)) to the extent that such guidance is not inconsistent with specific guidance in this Order. The guidance in the Statement of Policy on Conduct of Adjudicatory Proceedings is intended to improve the management and the timely completion of the proceeding and addresses hearing schedules, parties' obligations, contentions and discovery management. In addition, the Commission is providing the following direction for this proceeding:

(1) The Commission directs the Licensing Board to set a schedule for the hearing in this proceeding consistent with this Order that establishes, as a goal, the issuance of a final Commission decision on the pending application within two-and-one-half years (30 months) from the date of this Order. Accordingly, the Licensing Board should issue its decision on either the contested or mandatory hearing, or both, held in this matter no later than 28½ months (855 days) from the date of this Order. Formal discovery against the Staff shall be suspended until after the Staff completes its final SER and EIS in accordance with the direction provided in paragraph C(3) above.

(2) The evidentiary hearing with respect to issues should commence promptly after completion of the final Staff documents (SER or EIS) unless the Licensing Board, in its discretion, finds that starting the hearing with respect to one or more safety issues prior to issuance of the final SER [1] (or one or more environmental contentions directed to the applicant's Environmental Report) will expedite the proceeding without adversely impacting the Staff's ability to complete its evaluations in a timely manner.

(3) The Commission also believes that issuing a decision on the pending application within about two-and-one-half years may be reasonably achieved under the rules of practice contained in 10 CFR part 2 and the enhancements directed by this Order. We do not expect the Licensing Board to sacrifice fairness and sound decision-making to expedite any hearing granted on this application. We do expect the Licensing Board to use the applicable techniques specified in: this Order; 10 CFR 2.332, 2.333 and 2.334; and the Commission's policy statement on the conduct of adjudicatory proceedings (CLI–98–12, *supra*) to ensure prompt and efficient resolution of contested issues. *See also Statement of Policy on Conduct of Licensing Proceedings,* CLI–81–8, 13 NRC 452 (1981).

(4) If this is a contested proceeding, the Licensing Board should adopt the following milestones, in developing a schedule, for conclusion of significant steps in the adjudicatory proceeding.[2]

Within *March 15, 2010*	Deadline for Requests for Hearing; Petitions to Intervene and Contentions; and Requests for Limited Participation.
Within *April 13, 2010*	Answers to Requests for Hearing; Petitions to Intervene and Request for Limited Participation.
Within *April 23, 2010*	Replies to Answers regarding Requests for Hearing; Petitions to Intervene and Request for Limited Participation.
Within *May 13, 2010*	Licensing Board holds Pre-hearing Conference to hear arguments on petitions to intervene and contention admissibility.
Within *30 days* of pre-hearing conference	Licensing Board issues order determining intervention.
Within *10 days* of the Licensing Board order determining intervention:	Discovery commences, except against the Staff.
Within *20 days* of the Licensing Board order determining intervention:	Persons admitted or entities participating under 10 CFR 2.309(d) may submit a motion for reconsideration (*see* below, at Section VI.B).*
Within *30 days* of the Licensing Board decision determining intervention:	Persons admitted or entities participating under 10 CFR 2.309(d) may respond to any motion for reconsideration.
Date of issuance of final SER/EIS	Staff prepares hearing file.
Within *20 days* of the issuance of the final SER/EIS:	Staff updates hearing file.
Within *40 days* of the issuance of final SER/EIS:	Discovery commences against the Staff.
	Motions to amend contentions; motions for late-filed contentions.
Within *50 days* of the issuance of the final SER/EIS:	Completion of answers and replies to motions for amended and late-filed contentions.
	Completion of discovery on original contentions.
	Deadline for summary disposition motions on original contentions.**
	Licensing Board decision on admissibility of late-filed contentions.**

[1] The Commission believes that, in the appropriate circumstances, allowing discovery or an evidentiary hearing with respect to safety-related issues to proceed before the final SER is issued will serve to further the Commission's objective, as reflected in the Statement of Policy on Conduct of Adjudicatory Proceedings, CLI–98–12, *supra,* to ensure a fair, prompt, and efficient resolution of contested issues. For example, it may be appropriate for the Board to permit discovery against the staff and/or the commencement of an evidentiary hearing with respect to safety issues prior to the issuance of the final SER in cases where the applicant has responded to the Staff's "open items" and there is an appreciable lag time until the issuance of the final SER, or in cases where the initial SER identifies only a few open items.

[2] This schedule assumes that the SER and FEIS are issued essentially at the same time. If these documents are not to be issued very close in time, the Board should adopt separate schedules but concurrently running for the safety and environmental reviews consistent with the timeframes herein for each document.

Within *55 days* of the issuance of the final SER/EIS:	Licensing Board determination as to whether resolution of any motion for summary disposition will serve to expedite the proceedings.
Within *65 days* of the issuance of the final SER/EIS:	Answers to motions for summary disposition identified by Licensing Board.
Within *75 days* of the issuance of the final SER/EIS:	Replies to answers to motions for summary disposition.
Within *80 days* of the issuance of final SER/EIS:	Completion of discovery on late-filed contentions.
Within *105 days* of the issuance of the final SER/EIS:	Licensing Board decision on summary disposition motions on original contentions.
Within *115 days* of the issuance of final SER/EIS:	Direct testimony filed on original contentions and any amended or admitted late-filed contentions.
Within *125 days* of the issuance of final SER/EIS:	Cross-examination plans filed on original contentions and any amended or admitted late-filed contentions.
Within *135 days* of the issuance of final SER/EIS:	Evidentiary hearing begins on original contentions and any amended or admitted late-filed contentions.
Within *160 days* of the issuance of final SER/EIS:	Completion of evidentiary hearing on remaining contentions and any amended or admitted late-filed contentions.
Within *205 days* of the issuance of final SER/EIS:	Completion of findings and replies.
Within *245 days* of the issuance of final SER/EIS:	Licensing Board's initial decision.***

* Motions for reconsideration do not stay this schedule.
** No summary disposition motions on late-filed contentions are contemplated.
*** The Licensing Board's initial decision with respect to either a contested adjudicatory hearing or an uncontested, mandatory hearing should be issued no later than 28½ months from the date of this Order.

To avoid unnecessary delays in the proceeding, the Licensing Board should not routinely grant requests for extensions of time and should manage the schedule such that the overall hearing process is completed within 28½ months. Although summary disposition motions are included in the schedule above, the Licensing Board shall not entertain motions for summary disposition under 10 CFR 2.710, unless the Licensing Board finds that such motions, if granted, are likely to expedite the proceeding. Unless otherwise justified, the Licensing Board shall provide for the simultaneous filing of answers to proposed contentions, responsive pleadings, proposed findings of fact, and other similar submittals.

(5) Parties are obligated to comply with applicable requirements in 10 CFR part 2, unless directed otherwise by this Order or the Licensing Board. They are also obligated in their filings before the Licensing Board and the Commission to ensure that their arguments and assertions are supported by appropriate and accurate references to legal authority and factual basis, including, as appropriate, citation to the record. Failure to do so may result in material being stricken from the record or, in extreme circumstances, a party being dismissed from the proceeding.

(6) The Commission directs the Licensing Board to inform the Commission promptly, in writing, if the Licensing Board determines that any single milestone could be missed by more than 30 days. The Licensing Board must include an explanation of why the milestone cannot be met and the measures the Licensing Board will take to mitigate the failure to achieve the milestone and restore the proceeding to the overall schedule.

E. Commission Oversight

As in any proceeding, the Commission retains its inherent supervisory authority over the proceeding to provide additional guidance to the Licensing Board and participants and to resolve any matter in controversy itself.

VI. Applicable Requirements

A. Licensing

The Commission will license and regulate byproduct, source, and special nuclear material at the GLE–CF in accordance with the Atomic Energy Act of 1954, as amended. Section 274c.(1) of the AEA was amended by Public Law 102–486 (October 24, 1992) to require the Commission to retain authority and responsibility for the regulation of uranium enrichment facilities. Therefore, in compliance with law, the Commission will be the sole licensing and regulatory authority with respect to byproduct, source, and special nuclear material for the GLE–CF and with respect to the control and use of any equipment or device in connection therewith.

Many rules and regulations in 10 CFR Chapter I are applicable to the licensing of a person to receive, possess, use, transfer, deliver, or process byproduct, source or special nuclear material in the quantities that would be possessed at the GLE–CF. These include 10 CFR parts 19, 20, 21, 25, 30, 40, 51, 70, 71, 73, 74, 95, 140, 170, and 171 for the licensing and regulation of byproduct, source, and special nuclear material, including requirements for notices to workers, reporting of defects, radiation protection, waste disposal, decommissioning funding, and insurance.

With respect to these regulations, the Commission notes that this is the fifth proceeding involving the licensing of an enrichment facility. The Commission issued a number of decisions in earlier proceedings regarding proposed sites in Homer, Louisiana (*Claiborne* Enrichment Center); Eunice, New Mexico (National Enrichment Facility); and Piketon, Ohio (American Centrifuge Plant). These final decisions—*Louisiana Energy Services* (*Claiborne Enrichment Center*), CLI–92–7, 35 NRC 93 (1992); *Louisiana Energy Services* (*Claiborne Enrichment Center*), CLI–97–15, 46 NRC 294 (1997); *Louisiana Energy Services* (*Claiborne Enrichment Center*), CLI–98–3, 47 NRC 77 (1998); *Louisiana Energy Services* (*National Enrichment Facility*), CLI–05–05, 61 NRC 22, 36 (2005); *Louisiana Energy Services* (*National Enrichment Facility*), *et al.,* CLI–05–17, 62 NRC 5 (2005); *USEC, Inc.* (*American Centrifuge Plant*), CLI–07–05, 65 NRC 109 (2007)—resolve a number of issues concerning uranium enrichment licensing and may be relied upon as precedent.

Consistent with the AEA, and the Commission's regulations, the Commission is providing the following direction for licensing uranium enrichment facilities:

1. Environmental Issues

(a) *General:* 10 CFR part 51 governs the preparation of an environmental report and an EIS for a materials license. GLE's environmental report and the NRC staff's associated EIS are to include a statement on the alternatives to the proposed action, including a discussion of the no-action alternative.

(b) *Treatment of depleted uranium hexafluoride tails:* As to the treatment of the disposition of depleted uranium hexafluoride tails (depleted tails) in

these environmental documents, unless GLE demonstrates a use for uranium in the depleted tails as a potential resource, the depleted tails will be considered waste. The Commission has previously concluded that depleted uranium from an enrichment facility is appropriately classified as low-level radioactive waste. *See Louisiana Energy Services* (National Enrichment Facility), CLI–05–05, 61 NRC 22, 36 (2005). An approach for disposition of tails that is consistent with the USEC Privatization Act, such as transfer to DOE for disposal, constitutes a "plausible strategy" for disposition of the GLE depleted tails. *Id.* The NRC staff may consider the Department of Energy's *Final Programmatic Environmental Impact Statement for Alternative Strategies for the Long-Term Management and Use of Depleted Uranium Hexaflouride* (DOE/EIS–0269), 64 FR 43358 (Aug. 10, 1999), in preparing the staff's EIS. Alternatives for the disposition of depleted uranium tails will need to be addressed in these documents. As part of the licensing process, GLE must also address the health, safety, and security issues associated with the on-site storage of depleted uranium tails pending removal of the tails from the site for disposal or DOE disposition.

2. Financial Qualifications

Review of financial qualifications for enrichment facility license applications is governed by 10 CFR part 70. In *Louisiana Energy Services* (*Claiborne Enrichment Center*), CLI–97–15, 46 NRC 294, 309 (1997), the Commission held that the 10 CFR part 70 financial criteria, 10 CFR 70.22(a)(8) and 70.23(a)(5), could be met by conditioning the LES license to require funding commitments to be in place prior to construction and operation. The specific license condition imposed—providing one way to satisfy the requirements of 10 CFR part 70—required LES to have in place prior to commencement of construction or operation: a minimum equity contribution of 30% of project costs from the parents and affiliates of LES partners prior to construction of the associated capacity; firm funding commitments for the remaining project costs; and long term enrichment contracts with prices sufficient to cover both construction and operating costs, including a return on investment, for the entire term of the contracts.

3. Antitrust Review

Section 105 of the AEA conferred on the NRC certain antitrust responsibilities with respect to applications for section 103 or 104b. licenses to construct or operate utilization or production facilities filed prior to August 8, 2005. The GLE enrichment facility, the application for which was filed after August 8, 2005, is subject to sections 53 and 63 of the AEA and is not a production or utilization facility within the meaning of section 105. Consequently, the NRC does not have antitrust responsibilities for GLE. The NRC will not entertain or consider antitrust issues in connection with the GLE application in this proceeding.

4. Foreign Ownership

The GLE application is governed by sections 53 and 63 of the AEA, and, consequently, issues of foreign involvement shall be determined pursuant to sections 57 and 69, not sections 103, 104 or 193(f). Sections 57 and 69 of the AEA require, among other things, an affirmative finding by the Commission that issuance of a license for the GLE–CF will not be "inimical to the common defense and security." The requirements of sections 57 and 69 are incorporated in 10 CFR 70.31 and 10 CFR 40.32, respectively.

5. Creditor Requirements

Pursuant to section 184 of the AEA, the creditor regulations in 10 CFR 50.81 shall apply to the creation of creditor interests in equipment, devices, or important parts thereof, capable of separating the isotopes of uranium or enriching uranium in the isotope U–235. In addition, the creditor regulations in 10 CFR 70.44 shall apply to the creation of creditor interests in special nuclear material. These creditor regulations may be augmented by license conditions as necessary to allow ownership arrangements (such as sale and leaseback) not covered by 10 CFR 50.81, provided it can be found that such arrangements are not inimical to the common defense and security of the United States.

6. Classified Information

All matters of classification of information related to the design, construction, operation, and safeguarding of the GLE–CF shall be governed by classification guidance in "DOE Classification Guide for Isotope Separation by the Gas Centrifuge Process," (June 2002); Change 1 (Sept. 2005); Change 2 (May 2007) (CG–ICG–1); "Joint NRC/DOE Classification Guide for Louisiana Energy Services Gas Centrifuge Plant (U)," Confidential RD (Jan 2008) (CG–LCP–3A); and "Joint NRC/DOE Class. Guide for Louisiana Energy Services Gas Centrifuge Plant Safeguards & Security (U)," OUO (Jan 2008) (CG–LCP–3B), and any later versions thereof. Any person producing such information must adhere to the criteria in CG–IGC–1, CG–LCP–3A and CG–LCP–3B. All decisions on questions of classification or declassification of information shall be made by appropriate classification officials in the NRC and are not subject to *de novo* review in this proceeding.

7. Access to Classified Information

Portions of GLE's application for a license are classified Restricted Data or National Security Information. Persons needing access to those portions of the application will be required to have the appropriate security clearance for the level of classified information to which access is required. Access requirements apply equally to intervenors, their witnesses and counsel, employees of the applicant, its witnesses and counsel, NRC personnel, and others. Any person who believes that he or she will have a need for access to classified information for the purpose of this licensing proceeding, including the hearing, should immediately contact the NRC, Division of Fuel Cycle Safety and Safeguards, Washington, DC 20555, for information on the clearance process. Telephone calls may be made to Timothy C. Johnson, Senior Project Manager, Uranium Enrichment Branch, Fuel Facility Licensing Directorate, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards. Telephone: (301) 492–3121.

8. Obtaining NRC Security Facility Approval for Safeguarding Classified Information Received or Developed Pursuant to 10 CFR Part 95

Any person who requires possession of classified information in connection with the licensing proceeding may process, store, reproduce, transmit, or handle classified information only in a location for which facility security approval has been obtained from the NRC's Division of Security Operations (NSIR), Washington, DC 20555. Telephone calls may be made to A. Lynn Silvious, Chief, Information Security Branch. Telephone: (301) 415–2214.

B. Reconsideration

The above guidance does not foreclose the applicant, any person admitted as a party to the hearing, or an entity participating under 10 CFR 2.315(c) from litigating material factual issues necessary for resolution of contentions in this proceeding. Persons permitted to intervene and entities participating under 10 CFR 2.315(c) as

of the date of the order on intervention may also move the Commission to reconsider any portion of section VI of this Notice and Commission Order where there is no clear Commission precedent or unambiguously governing statutes or regulations. Any motion to reconsider must be filed within 10 days after the order on intervention. The motion must contain all technical or other arguments to support the motion. Other persons granted intervention and entities participating under 10 CFR 2.315(c), including the applicant and the NRC staff, may respond to motions for reconsideration within 20 days of the order on intervention. Motions will be ruled upon by the Commission. A motion for reconsideration does not stay the schedule set out above in section V.D.(4). However, if the Commission grants a motion for reconsideration, it will, as necessary, provide direction on adjusting the hearing schedule.

VII. Notice of Intent Regarding Classified Information

As noted above, a hearing on this application will be governed by 10 CFR part 2, Subparts A, C, G, and to the extent classified material becomes involved, subpart I. Subpart I requires in accordance with 10 CFR 2.907 that the NRC staff file a notice of intent if, at the time of publication of Notice of Hearing, it appears that it will be impracticable for the staff to avoid the introduction of Restricted Data or National Security Information into a proceeding. The applicant has submitted portions of its application that are classified. The Commission notes that, since the entire application may become part of the record of the proceeding, the NRC staff has found it impracticable for it to avoid the introduction of Restricted Data or National Security Information into the proceeding.

VIII. Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing sensitive unclassified information (including Sensitive Unclassified Non-Safeguards Information (SUNSI) and Safeguards Information (SGI)). Requirements for access to SGI are primarily set forth in 10 CFR Parts 2 and 73. Nothing in this Order is intended to conflict with the SGI regulations.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI or SGI is necessary to respond to this notice may request access to SUNSI or SGI. A "potential party" is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI or SGI submitted later than 10 days after publication will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI, SGI, or both to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The e-mail address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[3] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1);

(3) If the request is for SUNSI, the identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention;

(4) If the request is for SGI, the identity of each individual who would have access to SGI if the request is granted, including the identity of any expert, consultant, or assistant who will aid the requester in evaluating the SGI. In addition, the request must contain the following information:

(a) A statement that explains each individual's "need to know" the SGI, as required by 10 CFR 73.2 and 10 CFR 73.22(b)(1). Consistent with the definition of "need to know" as stated in 10 CFR 73.2, the statement must explain:

(i) Specifically why the requester believes that the information is necessary to enable the requester to proffer and/or adjudicate a specific contention in this proceeding;[4] and

(ii) The technical competence (demonstrable knowledge, skill, training or education) of the requester to effectively utilize the requested SGI to provide the basis and specificity for a proffered contention. The technical competence of a potential party or its counsel may be shown by reliance on a qualified expert, consultant, or assistant who satisfies these criteria.

(b) A completed Form SF–85, "Questionnaire for Non-Sensitive Positions" for each individual who would have access to SGI. The completed Form SF–85 will be used by the Office of Administration to conduct the background check required for access to SGI, as required by 10 CFR part 2, subpart G and 10 CFR 73.22(b)(2), to determine the requester's trustworthiness and reliability. For security reasons, Form SF–85 can only be submitted electronically through the electronic questionnaire for investigations processing (e-QIP) Web site, a secure Web site that is owned and operated by the Office of Personnel Management. To obtain online access to the form, the requester should contact the NRC's Office of Administration at (301) 492–3524.[5]

(c) A completed Form FD–258 (fingerprint card), signed in original ink, and submitted in accordance with 10 CFR 73.57(d). Copies of Form FD–258 may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by calling (301) 415–7232 or (301) 492–7311, or by e-mail to *Forms.Resource@nrc.gov*. The fingerprint card will be used to satisfy the requirements of 10 CFR part 2, 10

[3] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's "E-Filing Rule," the initial request to access SUNSI and/or SGI under these procedures should be submitted as described in this paragraph.

[4] Broad SGI requests under these procedures are unlikely to meet the standard for need to know; furthermore, staff redaction of information from requested documents before their release may be appropriate to comport with this requirement. These procedures do not authorize unrestricted disclosure or less scrutiny of a requester's need to know than ordinarily would be applied in connection with an already-admitted contention or non-adjudicatory access to SGI.

[5] The requester will be asked to provide his or her full name, Social Security number, date and place of birth, telephone number, and e-mail address. After providing this information, the requester usually should be able to obtain access to the online form within one business day.

CFR 73.22(b)(1), and Section 149 of the Atomic Energy Act of 1954, as amended, which mandates that all persons with access to SGI must be fingerprinted for an FBI identification and criminal history records check;

(d) A check or money order payable in the amount of $ 200.00[6] to the U.S. Nuclear Regulatory Commission for each individual for whom the request for access has been submitted, and

(e) If the requester or any individual who will have access to SGI believes they belong to one or more of the categories of individuals that are exempt from the criminal history records check and background check requirements in 10 CFR 73.59, the requester should also provide a statement identifying which exemption the requester is invoking and explaining the requester's basis for believing that the exemption applies. While processing the request, the Office of Administration, Personnel Security Branch, will make a final determination whether the claimed exemption applies. Alternatively, the requester may contact the Office of Administration for an evaluation of their exemption status prior to submitting their request. Persons who are exempt from the background check are not required to complete the SF–85 or Form FD–258; however, all other requirements for access to SGI, including the need to know, are still applicable.

Note: Copies of documents and materials required by paragraphs C.(4)(b), (c), and (d) of this Order must be sent to the following address: Office of Administration, U.S. Nuclear Regulatory Commission, Personnel Security Branch, Mail Stop TWB–05–B32M, Washington, DC 20555–0001.

These documents and materials should not be included with the request letter to the Office of the Secretary, but the request letter should state that the forms and fees have been submitted as required above.

D. To avoid delays in processing requests for access to SGI, the requester should review all submitted materials for completeness and accuracy (including legibility) before submitting them to the NRC. The NRC will return incomplete packages to the sender without processing.

E. Based on an evaluation of the information submitted under paragraphs C.(3) or C.(4) above, as applicable, the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requester has established a legitimate need for access to SUNSI or need to know the SGI requested.

F. For requests for access to SUNSI, if the NRC staff determines that the requester satisfies both E.(1) and E.(2) above, the NRC staff will notify the requester in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requester may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[7] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

G. For requests for access to SGI, if the NRC staff determines that the requester has satisfied both E.(1) and E.(2) above, the Office of Administration will then determine, based upon completion of the background check, whether the proposed recipient is trustworthy and reliable, as required for access to SGI by 10 CFR 73.22(b). If the Office of Administration determines that the individual or individuals are trustworthy and reliable, the NRC will promptly notify the requester in writing. The notification will provide the names of approved individuals as well as the conditions under which the SGI will be provided. Those conditions may include, but not be limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[8] by each individual who will be granted access to SGI.

H. *Release and Storage of SGI.* Prior to providing SGI to the requester, the NRC staff will conduct (as necessary) an inspection to confirm that the recipient's information protection system is sufficient to satisfy the requirements of 10 CFR 73.22. Alternatively, recipients may opt to view SGI at an approved SGI storage location rather than establish their own SGI protection program to meet SGI protection requirements.

I. *Filing of Contentions.* Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI or SGI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI or SGI contentions by that later deadline.

J. *Review of Denials of Access.*

(1) If the request for access to SUNSI or SGI is denied by the NRC staff either after a determination on standing and requisite need, or after a determination on trustworthiness and reliability, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) Before the Office of Administration makes an adverse determination regarding the proposed recipient(s) trustworthiness and reliability for access to SGI, the Office of Administration, in accordance with 10 CFR 2.705(c)(3)(iii), must provide the proposed recipient(s) any records that were considered in the trustworthiness and reliability determination, including those required to be provided under 10 CFR 73.57(e)(1), so that the proposed recipient(s) have an opportunity to correct or explain the record.

(3) The requester may challenge the NRC staff's adverse determination with respect to access to SUNSI by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(4) The requester may challenge the NRC staff's or Office of Administration's adverse determination with respect to access to SGI by filing a request for review in accordance with 10 CFR 2.705(c)(3)(iv). Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

K. *Review of Grants of Access.* A party other than the requester may challenge an NRC staff determination granting access to SUNSI or SGI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief

[6] This fee is subject to change pursuant to the Office of Personnel Management's adjustable billing rates.

[7] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[8] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SGI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 180 days of the deadline for the receipt of the written access request.

Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[9]

L. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI or SGI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 7th day of January 2010.

For the Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

Chairman Gregory B. Jaczko, Offering a Separate Statement

I support issuance of this notice and order in part. As I explained in my separate statement for the Areva notice, I welcome the opportunity for interested members of the public to participate in our hearing process and to have their concerns about the proposed facility heard. I have, however, the same concerns with this hearing notice as I expressed with regard to the Areva notice.

First, I am troubled by establishing a tight schedule that depends on superior applicant performance and therefore may turn out to be unrealistic. For example, the schedule reduces the time normally allowed for applicant responses to staff requests for additional information despite the fact that the agency has no control over the timeliness or quality of applicant submittals. Establishing timelines which may not be met, even through no fault of the staff, may result in unfounded claims that the agency's process is inefficient and decrease confidence in our licensing process.

I also believe that the numerous milestones set forth in the order are unnecessary and overly prescriptive. With the milestones and deadlines already provided in our regulations, the agency has the structure in place to ensure an efficient and effective hearing process. Importantly, those regulations allow the Boards flexibility in adapting the hearing schedule to accommodate the complexity of the issues and the circumstances unique to each adjudicatory proceeding. I believe this flexibility is important and should be retained for enrichment applications.

Recent developments highlight my concerns. Staff has informed the Commission that issuance of the final Environmental Impact Statements (EISs) will be delayed at least seven months in light of information only recently submitted by Areva concerning the need to construct additional transmission lines. Staff explained that its aggressive review schedule is predicated upon the submittal of complete information by Areva. Therefore, any deficiency in Areva's submittals, like this one, can delay the staff's review and, consequently, the hearing schedule. Events which can impact schedule are inevitable and unpredictable given the complexity and length of these adjudications. The schedule adjustments necessitated by these events are best handled by the Boards responsible for the hearings without rigid Commission deadlines which may compromise the fairness or thoroughness of the hearing process.

In addition, as I stated in regard to the Areva notice, I believe the order should state that the Commission, rather than the licensing board, should preside over the mandatory hearing. Gaining experience in this mandatory proceeding will aid the Commission in handling mandatory hearings on new reactor applications.

Unlike the Areva notice, this notice is silent on the question of whether the NEPA review should address terrorism. I believe that the Commission should direct the staff to consider terrorism in its environmental review, as we did in the Areva notice. I believe that the Commission should have a consistent, nationwide approach to NEPA and should discontinue the practice of addressing terrorism only for facilities within the jurisdiction of the Ninth Circuit. This practice creates a disparity in the public information we provide concerning the potential impacts of a terrorist attack on our nuclear facilities based on the arbitrary criteria of geographic location. This disparity is highlighted when, as here, the agency simultaneously conducts NEPA reviews for similar facilities within and outside the geographical boundaries of the Ninth Circuit. I believe the public is disserved when they are selectively and arbitrarily denied information on a matter of this importance to health and safety. As a policy matter, I believe that the Commission's commitment to transparency should no longer be compromised, particularly now that we know that the environmental impacts of terrorism can be analyzed and disclosed meaningfully to the public, while appropriately protecting classified information.

Lastly, I am troubled by a matter which is related to both the Areva and GE–Hitachi applications—the prospect of allowing applicants to conduct construction activities prohibited by our regulations through issuance of exemptions. In my view, the appropriate process for allowing construction activities before licensing is the one we used for reactor licensees—our rulemaking process. This process, which allows stakeholder input and, therefore, offers transparency in our decision-making process, should not be circumvented by the use of exemptions which I believe should be reserved for circumstances unique to a specific facility.

Commissioners Dale E. Klein and Kristine L. Svinicki, Offering a Further Statement

We support issuance of this order, in its entirety, as we did the AREVA notice of hearing. *Areva Enrichment Services, LLC* (Eagle Rock Enrichment Facility), CLI–09–15 (July 23, 2009). The U.S. NRC Strategic Plan recognizes that initiatives such as the Government Performance and Results Act challenge Federal agencies to become more effective and efficient and to justify their budget requests with demonstrated program results. The NRC must strive to become more effective and efficient in light of the increasing licensing workload and the drive to improve performance in government. With this in mind, the NRC has formally adopted strategic goals in the area of organizational excellence, including the following: "NRC actions are high quality, efficient, timely, and realistic, to enable the safe and beneficial use of radioactive materials."

The NRC has recognized, in setting its strategic goals and through its performance and accountability reporting, that the efficiency of the agency's regulatory processes is important to the regulated community and other stakeholders, including

[9] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI/SGI request submitted to the NRC staff under these procedures.

Federal, State, local, and Tribal authorities and the public. The NRC has committed itself to improving the timeliness of its application reviews without compromising safety and security, and acknowledges that this is possible provided industry submits complete, high-quality applications. Quoting again from the NRC Strategic Plan: "While the NRC will never compromise safety and security for increased efficiency, the agency works to improve the efficiency of its regulatory processes wherever possible."

High quality—on both the agency's and the applicant's parts—should be, and is, the NRC's goal. The proceeding at issue here is no exception. We believe that the schedule laid out in the order—while demanding the requisite quality in licensee submittals—has been demonstrated for similar applications, is achievable with no compromise to the agency's safety and security missions, and is representative of the performance expectations the NRC should set for itself. Our judgment is not altered by the Chairman's reliance on the recently-announced events in an entirely separate proceeding—the AREVA Eagle Rock enrichment facility application. There, NRC Staff announced a delay in issuing the final EIS as a result of AREVA's recent submission on the need to construct additional transmission lines. This is thin support at best for the Chairman's unwarranted conclusion that the Commission's deadlines "may compromise the fairness or thoroughness of the hearing process." A later date for the scheduled issuance of the final EIS may delay completion of the hearing, but it does not necessitate any change in the milestones since the milestones that follow the issuance of the final EIS are measured from the date of its issuance.

Further, we are not persuaded by the Chairman's argument regarding consideration of terrorism under NEPA. We have considered this issue in many proceedings,[1] and are not prepared to abandon our carefully-considered decisions without sufficient justification. Fundamentally, we cannot agree with the Chairman's assertion that our approach is at odds with the agency's commitment to transparency. At bottom, this ruling reflects our consistent position on the requirements of NEPA and their application.[2] Moreover, there is no dispute that the agency has devoted enormous resources and effort to ensure the adequate protection of public health and safety from the risks of terrorism after the events of September 11, 2001. Our differences with Chairman Jaczko on this issue should not obscure this fact.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION AND SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) and/or Safeguards Information (SGI) with information: supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding; demonstrating that access should be granted (e.g., showing technical competence for access to SGI); and, for SGI, including application fee for fingerprint/background check.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI and/or SGI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows (1) need for SUNSI or (2) need to know for SGI. (For SUNSI, NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents). If NRC staff makes the finding of need to know for SGI and likelihood of standing, NRC staff begins background check (including fingerprinting for a criminal history records check), information processing (preparation of redactions or review of redacted documents), and readiness inspections.
25	If NRC staff finds no "need," no "need to know," or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
190	(Receipt +180) If NRC staff finds standing, need to know for SGI, and trustworthiness and reliability, deadline for NRC staff to file motion for Protective Order and draft Non-disclosure Affidavit (or to make a determination that the proposed recipient of SGI is not trustworthy or reliable). Note: Before the Office of Administration makes an adverse determination regarding access to SGI, the proposed recipient must be provided an opportunity to correct or explain information.
205	Deadline for petitioner to seek reversal of a final adverse NRC staff trustworthiness or reliability determination either before the presiding officer or another designated officer under 10 CFR 2.705(c)(3)(iv).
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI and/or SGI consistent with decision issuing the protective order.

[1] *See, e.g., AmerGen Energy Co., LLC* (Oyster Creek Nuclear Generating Station, CLI–07–8, 65 NRC 124 (2007), *aff'd N.J. Dep't of Envtl. Prot.* v. *NRC,* 561 F.3d 132 (3d Cir. 2009).

[2] We have complied with the Ninth Circuit's ruling for facilities within the Ninth Circuit, as we are required to do. That experience, however, is very limited, and does not demonstrate that conducting environmental analyses of terrorist scenarios for the licensing of all major facilities would be practicable or lead to meaningful additional information.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION AND SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

Day	Event/activity
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI and/or SGI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI or SGI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI and/or SGI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2010–485 Filed 1–12–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2010–0009]

Final Regulatory Guide: Issuance, Availability

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Issuance and Availability of Regulatory Guide (RG) 5.71, "Cyber Security Programs for Nuclear Facilities."

FOR FURTHER INFORMATION CONTACT: Karl J. Sturzebecher, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: (301) 251–7494 or e-mail *Karl.Sturzebecher@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC or Commission) is issuing a new guide in the agency's "Regulatory Guide" series. This series was developed to describe and make available to the public information such as methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

RG 5.71, "Cyber Security Programs for Nuclear Facilities," was issued with a temporary identification as Draft Regulatory Guide, DG–5022. This regulatory guide provides guidance to applicants and licensees on satisfying the requirements of 10 CFR 73.54. The information contained within this guide represents the results of research conducted by the NRC Office of Nuclear Regulatory Research concerning cyber security program development and the collective body of knowledge and experience that has been developed through all of the actions identified above. In addition, this guide embodies the findings by standards organizations and agencies, such as the International Society of Automation, the Institute of Electrical and Electronic Engineers, and the National Institute of Standard and Technology, as well as guidance from the U.S. Department of Homeland Security.

RG 5.71 provides a framework to aid in the identification of those digital assets that must be protected from cyber attacks. These identified digital assets are referred to as critical digital assets (CDAs). Licensees should address the potential cyber security risks of CDAs by applying the defensive architecture and the collection of security controls identified in this regulatory guide.

The RG 5.71 framework offers licensees and applicants the ability to address the specific needs of an existing or new system. The goal of this regulatory guide is to harmonize the well-known and well-understood set of security controls (based on NIST cyber security standards) that address potential cyber risks to CDAs to provide a flexible programmatic approach in which the licensee or applicant can establish, maintain, and successfully integrate these security controls into a site-specific cyber security program.

II. Further Information

The Agency released DG–5022, which contained safeguards information, directly to stakeholders, who provided comments on July 18, 2008, December 12, 2008, and January 14, 2009. The responses to stakeholder's comments are located in the NRC's Agencywide Documents Access and Management System under Accession Number ML090340185. Electronic copies of RG 5.71 are available through the NRC's public Web site under "Regulatory Guides" at *http://www.nrc.gov/reading-rm/doc-collections/.*

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR) located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555–0001. The PDR can also be reached by telephone at (301) 415–4737 or (800) 397–4205, by fax at (301) 415–3548, and by e-mail to *pdr.resource@nrc.gov.*

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 6th day of January, 2010.

For the Nuclear Regulatory Commission.

Andrea D. Valentin,

Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2010–488 Filed 1–12–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS), Planning and Procedures Subcommittee Meeting; Notice of Meeting

The ACRS Planning and Procedures Subcommittee will hold a meeting on February 3, 2010, Room T2–B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b (c)(2) and (6) to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, February 3, 2010, 12 p.m.–1 p.m.

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated

Federal Officer (DFO), Mr. Peter Wen, (Telephone: 301–415–2832, E-mail: *Peter.Wen@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 14, 2009, (74 FR 52829–52830).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained by contacting the DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the DFO if such rescheduling would result in major inconvenience.

Dated: *January 7, 2010.*

Antonio Dias,

Chief, Reactor Safety Branch B, Advisory Committee on Reactor Safeguards.

[FR Doc. 2010–500 Filed 1–12–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on AP1000; Notice of Meeting

The ACRS Subcommittee on the AP1000 will hold a meeting on February 2–3, 2010, 11545 Rockville Pike, Room T2–B1, Rockville, Maryland.

The meeting will be open to public attendance.

The proposed agenda for the subject meeting is as follows:

Tuesday, February 2, 2010—8:30 a.m.–5 p.m.

Wednesday, February 3, 2010—8:30 a.m.–5 p.m.

The Subcommittee will review selected chapters of the Draft Safety Evaluation Report associated with the amendment to the Westinghouse AP1000 Design Certification Document and the combined license (COL) application. The Subcommittee will hear presentations by and hold discussions with Westinghouse, Southern Nuclear Operating Company (SNC), and NRC staff representatives regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Mr. Peter Wen, (Telephone 301–415–2832, *E-mail: Peter.Wen@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a compact disk containing each presentation at least 30 minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 14, 2009 (74 FR 58268–58269).

Detailed ACRS meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs/.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in major inconvenience.

Dated: January 7, 2010.

Antonio F. Dias,

Chief, Reactor Safety Branch B Advisory Committee on Reactor Safeguards.

[FR Doc. 2010–498 Filed 1–12–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Seeks Qualified Candidates for the Advisory Committee on Reactor Safeguards

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Request for resumes.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) seeks qualified candidates for the Advisory Committee on Reactor Safeguards (ACRS). Submit resumes to Ms. Kendra Freeland, Analyst, ACRS, Mail Stop T2E–26, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or e-mail *Kendra.Freeland@NRC.GOV.*

SUPPLEMENTARY INFORMATION: The ACRS is a part-time advisory group, which is statutorily mandated by the Atomic Energy Act of 1954, as amended. ACRS provides independent expert advice on matters related to the safety of existing and proposed nuclear power plants and on the adequacy of proposed reactor safety standards. Of primary importance are the safety issues associated with the operation of 104 commercial nuclear power plants in the United States and regulatory initiatives, including risk-informed and performance-based regulations, license renewal, power uprates, and the use of mixed oxide and high burnup fuels. An increased emphasis is being given to safety issues associated with new reactor designs and technologies, including passive system reliability and thermal hydraulic phenomena, use of digital instrumentation and control, international codes and standards used in multinational design certifications, material and structural engineering, nuclear analysis and reactor core performance, and nuclear materials and radiation protection. The ACRS also has some involvement in security matters related to the integration of safety and security of commercial reactors.

See NRC Web site at *http://www.nrc.gov/aboutnrc/regulatory/advisory/acrs.html* for additional information about ACRS. Criteria used to evaluate candidates include education and experience, demonstrated skills in nuclear reactor safety matters, the ability to solve complex technical problems, and the ability to work collegially on a board, panel, or committee. The Commission, in selecting its Committee members, considers the need for a specific expertise to accomplish the work expected to be before the ACRS. ACRS Committee members are appointed for four-year terms and normally serve no more than three terms. The Commission looks to fill potential multiple vacancies as a result of this request. For these positions, a candidate must have at least 10 years of broad experience in nuclear engineering coupled with operational exposure to issues relative to new reactor designs pertaining to digital instrumentation and control, civil/

structural engineering, or radiation protection. Candidates with pertinent graduate level experience will be given additional consideration. Consistent with the requirements of the Federal Advisory Committee Act, the Commission seeks candidates with diverse backgrounds, so that the membership on the Committee is fairly balanced in terms of the points of view represented and functions to be performed by the Committee. Candidates will undergo a thorough security background check to obtain the security clearance that is mandatory for all ACRS members. The security background check will involve the completion and submission of paperwork to NRC.

Candidates for ACRS appointments may be involved in or have financial interests related to NRC-regulated aspects of the nuclear industry. However, because conflict-of-interest considerations may restrict the participation of a candidate in ACRS activities, the degree and nature of any such restriction on an individual's activities as a member will be considered in the selection process. Each qualified candidate's financial interests must be reconciled with applicable Federal and NRC rules and regulations prior to final appointment. This might require divestiture of securities or discontinuance of certain contracts or grants. Information regarding these restrictions will be provided upon request. A résumé describing the educational and professional background of the candidate, including any special accomplishments, publications, and professional references should be provided. Candidates should provide their current address, telephone number, and e-mail address. All candidates will receive careful consideration. Appointment will be made without regard to factors such as race, color, religion, national origin, sex, age, or disabilities. Candidates must be citizens of the United States and be able to devote approximately 100 days per year to Committee business. Resumes will be accepted until April 13, 2010.

Dated: January 7, 2010.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2010–494 Filed 1–12–10; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Monday, January 11, 2010 at 10:30 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(10) and 17 CFR 200.402(a)(10), 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 a closed session, and determined that no earlier notice thereof was possible.

The subject matter of the Closed Meeting scheduled for Monday, January 11, 2010 will be: post argument discussion.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551–5400.

Dated: January 11, 2010.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–592 Filed 1–11–10; 4:15 pm]

BILLING CODE 8011–01–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Assistance to Small Shipyards Grant Program

AGENCY: Maritime Administration, Department of Transportation, Office of Shipyards and Marine Technology.

ACTION: Notice of Small Shipyard Grant Program.

Catalog of Federal Domestic Assistance Number: 20.814.

FOR FURTHER INFORMATION CONTACT: Carl Setterstrom, Director, Office of Shipyards and Marine Engineering, Maritime Administration, Room W21–318, 1200 New Jersey Ave., SE., Washington, DC 20590; phone: (202) 366–5737; or fax: (202) 366–6988.

Key Dates: The period for submitting grant applications, as mandated by statute, commenced on December 16, 2009 and will terminate on February 16, 2010. The applications must be received by the Maritime Administration by 5 p.m. EST on February 16, 2010. Applications received later than this time will not be considered. The Maritime Administration intends to award grants no later than April 15, 2010.

Funding Opportunity: Section 54101 of Title 46, United States Code, and the section entitled "Assistance to Small Shipyards" in the Consolidated Appropriations Act, 2010 (Pub. L. 111–117), provide that the Maritime Administration shall establish an assistance program for small shipyards. Under this program, there is currently $14,700,000 available for grants for capital and related improvements for qualified shipyard facilities that will be effective in fostering efficiency, competitive operations, and quality ship construction, repair, and reconfiguration. ($300,000 of the $15,000,000 appropriated for the program is reserved for program administration.) Such grants may not be used to construct buildings or other physical facilities or to acquire land unless such use is specifically approved by the Maritime Administration as being consistent with and supplemental to capital and related infrastructure improvements. Grant funds may also be used for maritime training programs to foster technical skills and operational productivity in communities whose economies are related to or dependent upon the maritime industry. Grants for such training programs may only be awarded to "Eligible Applicants" as described below but training programs can be established through vendors to such applicants.

Award Information: The Maritime Administration intends to award the full amount of the available funding through grants to the extent that there are worthy applications. No more than 25 percent of the funds available will be awarded to shipyard facilities in one geographic location that have more than 600 production employees. The Maritime Administration will seek to obtain the maximum benefit from the available funding by awarding grants for as many of the most worthy projects as possible. The Maritime Administration may partially fund applications by selecting parts of the total project. The start date and period of performance for each

award will depend on the specific project and must be agreed to by the Maritime Administration.

Eligibility Information: 1. Eligible Applicants—the statutes referenced in "Funding Opportunity" above provide that shipyards can apply for grants. The shipyard facility for which a grant is sought must be in a single geographical location, located in or near a maritime community, and may not have more than 1,200 production employees. The applicant must be the operating company of the shipyard facility. The shipyard facility must construct, repair, or reconfigure vessels 40 ft. in length or greater, for commercial or government use. 2. Eligible Projects—capital and related improvement projects that will be effective in fostering efficiency, competitive operations, and quality ship construction, repair, and reconfiguration; and training projects that will be effective in fostering employee skills and enhancing productivity. For capital improvement projects all items proposed for funding must be new and to be owned by the applicant. For both capital improvement and training projects all project costs, including the recipients share, must be incurred after the date of the grant agreement.

Matching Requirements: The Federal funds for any eligible project will not exceed 75 percent of the total cost of such project. However, for good cause shown, the Maritime Administrator may waive the matching requirement in whole or in part. The remaining portion of the cost shall be paid in funds from or on behalf of the recipient. The applicant is required to submit detailed financial statements and supporting documentation demonstrating how and when such matching requirement is proposed to be funded as described below. The recipient's entire matching requirement must be paid prior to payment of any federal funds for the project.

Application: An application should be filed on standard Form SF–424 which can be found on the Internet at *http://www.Marad.dot.gov.* Although the form is available electronically, the application must be filed in hard copy as indicated below due to the amount of information requested. A shipyard facility in a single geographic location applying for multiple projects must do so in a single application. The application for a grant must include all of the following information as an addendum to Form SF–424. The information should be organized in sections as described below:

Section 1: A description of the shipyard including (a) location of the shipyard; (b) a description of the shipyard facilities; (c) years in operation; (d) ownership; (e) customer base; (f) current order book including type of work; (g) vessels delivered (or major projects) over last 5 years; and (h) Web site address, if any.

Section 2: For each project proposed for funding the following:

(a) A comprehensive detailed description of the project including a statement of whether the project will replace existing equipment, and if so the disposition of the replaced equipment.

(b) A description of the need for the project in relation to shipyard operations and business plan and an explanation of how the project will fulfill this need.

(c) A quantitative analysis demonstrating how the project will be effective in fostering efficiency, competitive operations, and quality ship construction, repair, or reconfiguration (for capital improvement projects) or how the project will be effective in fostering employee skills and enhancing productivity (for training projects). The analysis should quantify the benefits of the projects in terms of man-hours saved, dollars saved, percentages, or other meaningful metrics. The methodology of the analysis should be explained with assumptions used identified and justified.

(d) A detailed methodology and timeline for implementing the project.

(e) A detailed itemization of the cost of the project together with supporting documentation, including current vendor quotes and estimates of installation costs.

(f) A statement explaining if any elements of the project require action under the National Environmental Policy Act (42 U.S.C. sec. 4321, *et seq.*) or require any licenses or permits. Items 2(a) thru 2(f) should be repeated, in order, for each separate project included in the application.

Section 3: A table with a prioritized list of projects and total cost and Government portion (in dollars) for each.

Section 4: A description of any existing programs or arrangements, if any, which will be used to supplement or leverage the federal grant assistance.

Section 5: Special economic circumstances and conditions, if any, of the maritime community in which the shipyard is located (beyond that which is reflected in the unemployment rate of the county in which the shipyard is located and whether that county is in an economically distressed area, as defined by 42 U.S.C. 3161).

Section 6: Shipyard company officer's certification of each of the following requirements:

(a) That the shipyard facility for which a grant is sought is located in a single geographical location in or near a maritime community and (i) the shipyard facility has no more than 600 production employees, or (ii) the shipyard facility has more than 600 production employees, but less than 1,200 production employees (the shipyard officer must certify to one or the other of (i) or (ii));

(b) That the applicant has the authority to carry out the proposed project; and

(c) Certification in accordance with the Department of Transportation's regulation restricting lobbying, 49 CFR part 20, that the applicant has not, and will not, make any prohibited payments out of the requested grant.

Certifications are not required to be notarized.

Section 7: Unique identifier of shipyard's parent company (when applicable): Data Universal Numbering System (DUNS + 4 number) (when applicable).

Section 8: 2008 or 2009 (if available) year-end audited, reviewed or compiled financial statements, prepared by a certified public accountant, according to U.S. generally accepted accounting principles, not on an income tax basis. September 30, 2009 financial statements prepared by the company if December 31, 2009 CPA-prepared statements are not available. Do not provide tax returns.

Section 9: Statement regarding the relationship between applicants and any parents, subsidiaries or affiliates, if any such entity is going to provide a portion of the match.

Section 10: Evidence documenting applicant's ability to make proposed matching requirement (loan agreement, commitment from investors, cash on balance sheet, *etc.*) and in the times outlined in 2(d) above.

Section 11: Pro-forma financial statements reflecting (a) September 30, or December 31, 2009 financial condition; (b) effect on balance sheet of grant and matching funds (*i.e.,* a decrease in cash or increase in debt, additional equity and an increase in fixed assets); and (c) impact on company's projected financial condition (balance sheet) of completion of project, showing that company will have sufficient financial resources to remain in business.

Section 12: Statement whether during the past five years, the applicant or any predecessor or related company has been in bankruptcy or in reorganization

under Chapter 11 of the Bankruptcy Code, or in any insolvency or reorganization proceedings, and whether any substantial property of the applicant or any predecessor or related company has been acquired in any such proceeding or has been subject to foreclosure or receivership during such period. If so, give details.

Additional information may be requested as deemed necessary by the Maritime Administration in order to facilitate and complete its review of the application. If such information is not provided, the Maritime Administration may deem the application incomplete and cease processing it.

Where to File Application: Submit an original copy and one additional paper copy of the application and two CDs each containing an electronic copy only, no additional information of the application in PDF format to: Associate Administrator for Business and Workforce Development, Room W21–318, Maritime Administration, 1200 New Jersey Ave., SE., Washington, DC 20590.

Evaluation of Applications: The Maritime Administration will evaluate the applications on the basis of how well the project for which a grant is requested would be effective in fostering efficiency, competitive operations, and quality ship construction, repair, and reconfiguration (for capital improvement projects) or how well the project for which a grant is requested would be effective in fostering employee skills and enhancing productivity (for training projects) and the economic circumstances and conditions of the surrounding community. The economic circumstances and conditions will be based upon the unemployment rate of the county in which the shipyard is located and whether that county is an economically distressed area, supplemented by any special economic circumstances and conditions identified by the applicant. The Maritime Administration will award grants in its sole discretion in such amounts and under such conditions it determines will best further the statutory purposes of the small shipyard grant program. Projects that may require additional environmental assessments such as those including waterside improvements (dredging, bulk heading, pier work, pilings, *etc.*) will not be considered for funding. Preference will be given to funding applications: (1) From companies that have not previously been awarded a small shipyard grant; (2) that propose matching funds greater than a 25% share of the project; (3) that impact existing operations and/or product lines rather than expand the capabilities of the shipyard into new product lines or capabilities; and (4) that result in a geographic diversity of grant recipients.

Potential applicants are advised that it is expected, based on past experience, that applications will far exceed the funds available and that only a small percentage of applications will be funded. It is anticipated that between 10 and 15 applications will be selected for funding with an average grant amount of $1 to $1.5 million.

Conditions Attached to Awards: The grant agreement will set out the records to be maintained by the recipient that must be available for review and audit by the Maritime Administration, as well as any other conditions and requirements.

Dated: January 7, 2010.

By Order of the Acting Maritime Administrator.

Murray Bloom,

Acting Secretary, Maritime Administration.

[FR Doc. 2010–475 Filed 1–12–10; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Membership Availability in the National Parks Overflights Advisory Group Aviation; Rulemaking Committee To Represent Commercial Air Tour Concerns

ACTION: Notice.

SUMMARY: The National Park Service (NPS) and the Federal Aviation Administration (FAA), as required by the National Parks Air Tour Management Act of 2000, established the National Parks Overflights Advisory Group (NPOAG) in March 2001. The NPOAG was formed to provide continuing advice and counsel with respect to commercial air tour operations over and near national parks. This notice informs the public of one vacancy (due to completion of membership on May 19, 2010) on the NPOAG (now the NPOAG Aviation Rulemaking Committee (ARC)) for a member representing commercial air tour operator concerns and invites interested persons to apply to fill the vacancy.

DATES: Persons interested in serving on the NPOAG ARC should contact Mr. Barry Brayer at the mailing or e-mail address below in writing on or before February 19, 2010.

FOR FURTHER INFORMATION CONTACT: Barry Brayer, AWP–1SP, Special Programs Staff, Federal Aviation Administration, Western-Pacific Region Headquarters, P.O. Box 92007, Los Angeles, CA 90009–2007, telephone: (310) 725–3800, e-mail: *Barry.Brayer@faa.gov,* or Karen Trevino, National Park Service, Natural Sounds Program, 1201 Oakridge Dr., Suite 100, Fort Collins, CO 80525, telephone (970) 225–3563, e-mail: *Karen_Trevino@nps.gov.*

SUPPLEMENTARY INFORMATION:

Background

The National Parks Air Tour Management Act of 2000 (the Act) was enacted on April 5, 2000, as Public Law 106–181. The Act required the establishment of the advisory group within 1 year after its enactment. The advisory group was established in March 2001, and is comprised of a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating 1-year terms as chairman of the advisory group.

The advisory group provides "advice, information, and recommendations to the Administrator and the Director—

(1) On the implementation of this title [the Act] and the amendments made by this title;

(2) On commonly accepted quiet aircraft technology for use in commercial air tour operations over a national park or tribal lands, which will receive preferential treatment in a given air tour management plan;

(3) On other measures that might be taken to accommodate the interests of visitors to national parks; and

(4) On safety, environmental, and other issues related to commercial air tour operations over a national park or tribal lands."

Members of the advisory group may be allowed certain travel expenses as authorized by section 5703 of Title 5, United States Code, for intermittent Government service.

By FAA Order No. 1110–138, signed by the FAA Administrator on October 10, 2003, the NPOAG became an Aviation Rulemaking Committee (ARC). FAA Order No. 1110–138, was amended and became effective as FAA Order No. 1110–138A, on January 20, 2006.

The current NPOAG ARC is made up of one member representing general aviation, three members representing the commercial air tour industry, four

members representing environmental concerns, and two members representing Native American tribal concerns. Current members of the NPOAG ARC are: Robert Hackman, Aircraft Owners and Pilots Association; Alan Stephen, fixed-winged air tour operator representative; Elling Halvorson, Papillon Airways, Inc.; Matthew Zuccaro, Helicopter Association International; Chip Dennerlein, Siskiyou Project; Gregory Miller, American Hiking Society; Kristen Brengel, National Parks Conservation Association; Bryan Faehner, National Parks Conservation Association; Rory Majenty, Hualapai Nation; and Ray Russell, Navajo Parks and Recreation.

Public Participation in the NPOAG ARC

In order to retain balance within the NPOAG ARC, the FAA and NPS invite persons interested in serving on the ARC to represent commercial air tour operator concerns, to contact Mr. Barry Brayer (contact information is written above in **FOR FURTHER INFORMATION CONTACT**).

Requests to serve on the ARC must be made to Mr. Brayer in writing and postmarked or e mailed on or before February 19, 2010. The request should indicate whether or not you are a member of an association or group representing commercial air tours, or have another affiliation with issues relating to aircraft flights over national parks. The request should also state what expertise you would bring to the NPOAG ARC as related to the vacancy you are seeking to fill (*e.g.,* commercial air tour concerns). The term of service for NPOAG ARC members is 3 years.

Issued in Hawthorne, CA on January 6, 2010.

Barry Brayer,

NPOAG Chairman, Manager, Special Programs Staff, Western-Pacific Region.

[FR Doc. 2010–386 Filed 1–12–10; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket ID. FMCSA–2009–0321]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 33 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce without meeting the Federal vision standard.

DATES: Comments must be received on or before February 12, 2010.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2009–0321 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket ID for this Notice. Note that DOT posts all comments received without change to *http://www.regulations.gov*, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19476). This information is also available at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Director, Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption." FMCSA can renew exemptions at the end of each 2-year period. The 33 individuals listed in this notice have each requested an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Qualifications of Applicants

Bradley T. Alspach

Mr. Alspach, age 50, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/200. Following an examination in 2009, his ophthalmologist noted, "In my opinion, he has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Alspach reported that he has driven straight trucks for 16 years, accumulating 332,800 miles, and buses for 7 months, accumulating 2,625 miles. He holds a Class B Commercial Driver's License (CDL) from Illinois. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

William M. Arbogast

Mr. Arbogast, 58, has a macular scar in his left eye due to a traumatic injury sustained in 1968. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/1600. Following an examination in 2009, his optometrist noted, "It is my opinion that Mr. Arbogast has sufficient vision to safely drive and operate a commercial vehicle." Mr. Arbogast reported that he has driven straight trucks for 40 years,

accumulating 900,000 miles, and tractor-trailer combinations for 30 years, accumulating 675,000 miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

John E. Cain

Mr. Cain, 59, has a retinal detachment in his left eye due to a traumatic injury sustained as a child. The best corrected visual acuity in his right eye is 20/20 and in his left eye, light perception only. Following an examination in 2009, his optometrist noted, "In my medical opinion, Mr. Cain has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Cain reported that he has driven straight trucks for 28 years, accumulating 350,000 miles. He holds a Class B CDL from New Mexico. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Terry A. Crites

Mr. Crites, 41, has had refractive amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20 and in his left eye, 20/200. Following an examination in 2009, his optometrist noted, "Mr. Terry Crites in my medical opinion has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Crites reported that he has driven tractor-trailer trucks for 18 years, accumulating 1.4 million miles. He holds a Class A CDL from West Virginia. His driving record for the last 3 years shows no crashes and two convictions for moving violations in a CMV. In one instance, he exceeded the speed limit by 4 mph and in the other, by 16 mph.

Daniel M. Cannon

Mr. Cannon, 35, has had glaucoma in his right eye since birth. The visual acuity in his right eye is light perception only and in his left eye, 20/15. Following an examination in 2009, his optometrist noted, "It is my opinion that Daniel has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Cannon reported that he has driven straight trucks for 11 years, accumulating 16,500 miles. He holds a Class B CDL from Oregon. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Eugene Contreras

Mr. Contreras, 68, has corneal scarring in his left eye due to trauma sustained as a child. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/400. Following an examination in 2009, his ophthalmologist noted, "It is my opinion that Mr. Contreras does have sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Contreras reported that he has driven buses for 8 years, accumulating 16,000 miles. He holds a Class B CDL from New Mexico. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Curtis J. Crowston

Mr. Crowston, 44, has a prosthetic left eye due to a traumatic injury sustained in 1996. The visual acuity in his left eye is 20/50. Following an examination in 2009, his optometrist noted, "In my opinion, based on his monocular standing of visual acuity, color vision, and visual field testing, that Curtis has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Crowston reported that he has driven straight trucks for 6 years, accumulating 180 miles, and tractor-trailer combinations for 5 years, accumulating 100,000 miles. He holds a Class A CDL from North Dakota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Jim L. Davis

Mr. Davis, 54, has complete loss of vision in his right eye due to a traumatic injury sustained during childhood. The best corrected visual acuity in his left eye is 20/20. Following an examination in 2009, his optometrist noted, "It was my opinion that Mr. Davis had sufficient vision to perform the tasks required to drive a commercial vehicle." Mr. Davis reported that he has driven straight trucks for 5 years, accumulating 650,000 miles, and tractor-trailer combinations for 2 years, accumulating 100,000 miles. He holds a Class B CDL from New Mexico. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Clifford W. Doran, Jr.

Mr. Doran, 49, has a macular scar in his left eye due to ocular histoplasmosis syndrome. The best corrected visual acuity in his right eye is 20/15 and in his left eye, 20/300. Following an examination in 2009, his ophthalmologist noted, "His vision is best corrected and he is doing fine and I think he is okay to be able to drive a commercial vehicle because of his good peripheral vision in both eyes." Mr. Doran reported that he has driven straight trucks for 8 months, accumulating 40,000 miles, and tractor-trailer combinations for 20 years, accumulating 1 million miles. He holds a Class A CDL from North Carolina. His driving record for the last 3 years shows no crashes and two convictions for speeding in a CMV. In both instances, he exceeded the speed limit by 9 miles per hour (mph).

Daniel W. Doshier

Mr. Doshier, 61, has aphakia in his right eye due to a traumatic injury sustained at age 17. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/400. Following an examination in 2009, his optometrist noted, "I feel Mr. Doshier is visually able to perform any commercial driving tasks that he may be asked to do." Mr. Doshier reported that he has driven straight trucks for 4 years, accumulating 36,000 miles. He holds a Class B CDL from Arkansas. His driving record for the last 3 years shows no crashes and one conviction for speeding in a CMV. He exceeded the speed limit by 15 mph.

Charles L. Dunn

Mr. Dunn, 43, has had retinal detachment in his right eye since 1999. The best corrected visual acuity in his right eye is hand-motion vision and in his left eye, 20/15. Following an examination in 2009, his optometrist noted, "In my opinion, Mr. Dunn has sufficient vision to perform the driving tasks required to operate a commercial vehicle at this time." Mr. Dunn reported that he has driven straight trucks for 8½ years, accumulating 743,750 miles, and tractor-trailer combinations for 20 years, accumulating 1.7 million miles. He holds a Class A CDL from Oklahoma. His driving record for the last 3 years shows no crashes and two convictions for speeding in a CMV. In one instance, he exceeded the speed limit by 10 mph and in the other by 12 mph.

Andrew G. Fornsel

Mr. Fornsel, 46, has complete loss of vision in his right eye due to phtitesis bulbi caused by a traumatic injury sustained 39 years ago. The visual acuity in his left eye is 20/20. Following an examination in 2009, his optometrist noted, "It is my professional opinion that Mr. Andrew Fornsel has sufficient vision to perform any and all the driving tasks required to operate a commercial vehicle." Mr. Fornsel reported that he has driven straight trucks for 25 years, accumulating 750,000 miles, and tractor-trailer combinations for 20 years, accumulating 1 million miles. He holds a Class A CDL from New York. His driving record for the last 3 years shows

no crashes and no convictions for moving violations in a CMV.

Jamie L. French

Mr. French, 45, has a macular scar in his right eye due to toxoplasmosis which occurred in 1999. The visual acuity in his right eye is 20/200, and in his left eye, 20/20 . Following an examination in 2009, his ophthalmologist noted, "In my opinion, Mr. French has vision that is sufficient to perform the driving tasks required to operate a commercial vehicle." Mr. French reported that he has driven straight trucks for 2½ years, accumulating 77,500 miles, and tractor-trailer combinations for 13 years, accumulating 540,800 miles. He holds a Class A CDL from North Carolina. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Archie C. Hillsman

Mr. Hillsman, 56, has complete loss of vision in his left eye due to a traumatic injury sustained during childhood. The best corrected visual acuity in his right eye is 20/20. Following an examination in 2009, his optometrist noted, "Archie's vision is sufficient to perform the driving tasks required to operate a commercial vehicle." Mr. Hillsman reported that he has driven straight trucks for 4 years, accumulating 40,000 miles, and tractor-trailer combinations for 5½ years, accumulating 343,750 miles. He holds a Class A CDL from Oregon. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Amos W. Hulsey

Mr. Hulsey, 42, has complete loss of vision in his right eye since birth. The visual acuity in his left eye is 20/20. Following an examination in 2009, his optometrist noted, "It is my opinion that if Mr. Hulsey meets the standard requirements for the U.S. Department of Transportation Safety Administration, he does have sufficient vision in the left eye to perform the driving tasks required to operate a commercial vehicle." Mr. Hulsey reported that he has driven straight trucks for 5 years, accumulating 250,000 miles, and tractor-trailer combinations for 6 years, accumulating 420,000 miles. He holds a Class D operator's license from Alabama. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Guy A. Lanham

Mr. Lanham, 47, has had complete loss of vision in his right eye due to a corneal ulcer diagnosed in 2003 and two failed corneal transplants. The visual acuity in his left eye is 20/20. Following an examination in 2009, his optometrist noted, "It is my professional opinion that Mr. Lanham has sufficient vision to perform driving tasks required to operate a commercial vehicle." Mr. Lanham reported that he has driven straight trucks for 3 years, accumulating 72,000 miles, and tractor-trailer combinations for 12 years, accumulating 1.5 million miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes and one conviction for speeding in a CMV. He exceeded the speed limit by 20 mph.

Glenn Lewis

Mr. Lewis, 41, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/70 and in his left eye, 20/20. Following an examination in 2009, his optometrist noted, "In my opinion, from past performance and the current vision situation, Glenn should still be able to operate a commercial vehicle effectively for his employment, just as he has done for the past 12 years." Mr. Lewis reported that he has driven straight trucks for 15 years, accumulating 3 million miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV

James M. McCormick

Mr. McCormick, 42, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/60 and in his left eye, 20/15. Following an examination in 2009, his ophthalmologist noted, "I do believe he is capable of safely operating a commercial motor vehicle in interstate commerce with his current vision." Mr. McCormick reported that he has driven straight trucks for 15 years, accumulating 75,000 miles. He holds a Class A CDL from Idaho. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Shane W. Mincey

Mr. Mincey, 38, has corneal scarring in his right eye due to a traumatic injury sustained as a child. The best corrected visual acuity in his right eye is 20/200 and in his left eye, 20/20. Following an examination in 2009, his optometrist noted, "In my medical opinion, I feel Shane has sufficient vision to operate a commercial vehicle safely." Mr. Mincey reported that he has driven straight trucks for 4 years, accumulating 120,000 miles. He holds a Class D operator's license from Alabama. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Millard F. Neace, II

Mr. Neace, 36, has a retinal detachment in his left eye which occurred in 1996. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/60. Following an examination in 2009, his optometrist noted, "Due to the stable chronic condition of his left eye, he has sufficient vision to operate a commercial vehicle." Mr. Neace reported that he has driven straight trucks for 3 years, accumulating 216,000 miles, and tractor-trailer combinations for 4 years, accumulating 280,000 miles. He holds a Class A CDL from West Virginia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Frank L. Ortolani

Mr. Ortolani, 56, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/200 and in his left eye, 20/20. Following an examination in 2009, his optometrist noted, "Although he may not have good central snellen visual acuity in the right eye, he does maintain normal peripheral visual fields which is sufficient to perform the driving test required to operate a commercial vehicle." Mr. Ortolani reported that he has driven straight trucks for 15 years, accumulating 375,000 miles. He holds a Class B CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Paul D. Prillaman

Mr. Prillaman, 47, has a prosthetic left eye due to corneal dystrophy which began as a child. The visual acuity in his right eye is 20/20. Following an examination in 2009, his ophthalmologist noted, "It is my professional medical opinion that Mr. Prillaman does have sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Prillaman reported that he has driven straight trucks for 31 years, accumulating 1.7 million miles. He holds a Class B CDL from Virginia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Scott A. Randol

Mr. Randol, 50, has had a cataract in his right eye since birth. The visual acuity in his right eye is 20/70, and in his left eye, 20/20. Following an examination in 2009, his optometrist noted, "In my medical opinion, Mr. Randol has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Randol reported that he has driven straight trucks for 30 years, accumulating 300,000 miles, and tractor-trailer combinations for 30 years, accumulating 300,000 miles. He holds a Class A CDL from Missouri. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Samuel E. Rees

Mr. Rees, 43, has a corneal scar in his right eye which occurred in 2004. The best corrected visual acuity in his right eye is 20/60 and in his left eye, 20/20. Following an examination in 2009, his optometrist noted, "Mr. Rees should have no visual problem operating a commercial vehicle." Mr. Rees reported that he has driven straight trucks for 10 years, accumulating 400,000 miles. He holds a Class A CDL from Arizona. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Danny L. Rolfe

Mr. Rolfe, 43, has retinal detachment in his right eye due to a traumatic injury sustained at age 18. The best corrected visual acuity in his left eye is 20/20. Following an examination in 2009, his optometrist noted, "From a vision perspective, I don't see any limitation to Dan's demonstrated ability to safely drive and operate commercial vehicles, it is my opinion that he is seeing adequately to continue driving." Mr. Rolfe reported that he has driven straight trucks for 25 years, accumulating 125,000 miles, and tractor-trailer combinations for 23 years, accumulating 1.2 million miles. He holds a Class A CDL from Maine. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Miguel A. Sanchez

Mr. Sanchez, 33, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is 20/100 and in his left eye, 20/20. Following an examination in 2009, his optometrist noted, "In my medical opinion Miguel has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Sanchez reported that he has driven straight trucks for 8 years, accumulating 28,800 miles, and tractor-trailer combinations for 7 years, accumulating 25,200 miles. He holds a Class B CDL from New Mexico. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Dennis R. Schneider

Mr. Schneider, 70, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/200 and in his left eye, 20/20. Following an examination in 2009, his optometrist noted, "In my opinion, Dennis has the visual ability to perform the driving tasks of a commercial vehicle." Mr. Schneider reported that he has driven straight trucks for 53 years, accumulating 31,800 miles, and buses for 46 years, accumulating 253,000 miles. He holds a Class A CDL from New Mexico. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Michael D. Stevens

Mr. Stevens, 47, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/70, and in his left eye, 20/20. Following an examination in 2009, his ophthalmologist noted, "In my medical opinion, the patient has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Stevens reported that he has driven tractor-trailer combinations for 9 years, accumulating 144,000 miles. He holds a Class A CDL from Michigan. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Thomas G. Tomasiewicz

Mr. Tomasiewicz, 63, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/200 and in his left eye, 20/20. Following an examination in 2009, his optometrist noted, "I do certify that this patient, Thomas Tomasiewicz, has sufficient visual abilities, in regard to acuity and visual field, to perform the task of driving and operating a commercial vehicle." Mr. Tomasiewicz reported that he has driven straight trucks for 3 years, accumulating 150,000 miles. He holds a Class C operator's license from Illinois. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

James E. Vickery

Mr. Vickery, 39, has had amblyopia in his left eye since birth. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/50. Following an examination in 2009, his optometrist noted, "In my medical opinion, Mr. Vickery has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Vickery reported that he has driven tractor-trailer combinations for 4 years, accumulating 208,000 miles. He holds a Class A CDL from Kentucky. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Billy R. Wilkey

Mr. Wilkey, 63, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/200 and in his left eye, 20/20. Following an examination in 2009, his ophthalmologist noted, "Mr. Wilkey's vision is sufficient to continue operating a commercial motor vehicle, in my opinion." Mr. Wilkey reported that he has driven straight trucks for 21 years, accumulating 168,000 miles, and tractor-trailer combinations for 21 years, accumulating 168,000 miles. He holds a Class A CDL from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

James H. Williams, Jr.

Mr. Williams, 62, has had retinal detachment in his left eye due to a traumatic injury sustained in 1985. The best corrected visual acuity in his right eye is 20/25 and in his left eye, 20/200. Following an examination in 2009, his optometrist noted, "I do believe that Mr. Williams has sufficient visual field in his left eye that will not hinder his capability for driving. His right eye has been trained to compensate for the blur straight ahead. I do recommend yearly testing to follow his condition and capabilities." Mr. Williams reported that he has driven straight trucks for 5 years, accumulating 150,000 miles, and tractor-trailer combinations for 35 years, accumulating 2.6 million miles. He holds a Class A CDL from Wisconsin. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Reginald J. Wuethrich

Mr. Wuethrich, 46, has a prosthetic right eye due to a traumatic injury sustained in 1982. The best corrected visual acuity in his left eye is 20/15. Following an examination in 2009, his ophthalmologist noted, "In my opinion, given the long standing and stable nature of his visual condition, there is no reason for him to be unable to perform the duties associated with

operating a commercial vehicle." Mr. Wuethrich reported that he has driven straight trucks for 26 years, accumulating 78,000 miles, and tractor-trailer combinations for 26 years, accumulating 520,000 miles. He holds a Class A CDL from Illinois. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business February 12, 2010. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable.

In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: January 6, 2010.

Larry W. Minor,

Associate Administrator for Policy and Program Development.

[FR Doc. 2010–412 Filed 1–12–10; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Opportunity for Public Comment on Surplus Property Release at Moore County Airport, Pinehurst/Southern Pines, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: Under the provisions of Title 49, U.S.C. Section 47153(d), notice is being given that the FAA is considering a request from the Moore County Airport Authority to waive the requirement that a 27.7 acre parcel of surplus property, located at the Moore County Airport, be used for aeronautical purposes.

DATES: Comments must be received on or before *February 12, 2010.*

ADDRESSES: Comments on this notice may be mailed or delivered in triplicate to the FAA at the following address: Atlanta Airports District Office, 1701 Columbia Ave., Campus Building, Suite 2–260, College Park, GA 30337.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Ms. Carol Thomas, Interim Airport Director at the following address: Airport Road, P.O. Drawer 5809, Pinehurst, NC 28374.

FOR FURTHER INFORMATION CONTACT: Rusty Nealis, Program Manager, Atlanta Airports District Office, 1701 Columbus Ave, Campus Bldg., Suite 2–260, College Park, GA 30337, (404) 305–7142. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA is reviewing a request by the Moore County Airport Authority to release 27.7 acres of surplus property at the Moore County Airport. The surplus property will be used as right-of-way for the newly constructed roadway associated with recent airport development.

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

In addition, any person may, upon request, inspect the request, notice and other documents germane to the request in person at the Moore County Airport, 7825 Aviation Drive, Carthage, NC 28327.

Issued in Atlanta, Georgia on January 4, 2010.

Scott L. Seritt,

Manager, Atlanta Airports District Office, Southern Region.

[FR Doc. 2010–397 Filed 1–12–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Departmental Offices; Debt Management Advisory Committee Meeting

Notice is hereby given, pursuant to 5 U.S.C. App. 2, § 10(a)(2), that a meeting will be held at the Hay-Adams Hotel, 16th Street and Pennsylvania Avenue, NW., Washington, DC, on February 2, 2010 at 8:30 a.m. of the following debt management advisory committee: Treasury Borrowing Advisory Committee of The Securities Industry and Financial Markets Association.

The agenda for the meeting provides for a charge by the Secretary of the Treasury or his designate that the Committee discuss particular issues and conduct a working session. Following the working session, the Committee will present a written report of its recommendations. The meeting will be closed to the public, pursuant to 5 U.S.C. App. 2, § 10(d) and Public Law 103–202, § 202(c)(1)(B) (31 U.S.C. 3 121 note).

This notice shall constitute my determination, pursuant to the authority placed in heads of agencies by 5 U.S.C. App. 2, § 10(d) and vested in me by Treasury Department Order No. 101–05, that the meeting will consist of discussions and debates of the issues presented to the Committee by the Secretary of the Treasury and the making of recommendations of the Committee to the Secretary, pursuant to Public Law 103–202, § 202(c)(1)(B). Thus, this information is exempt from disclosure under that provision and 5 U.S.C. 552b(c)(3)(B). In addition, the meeting is concerned with information that is exempt from disclosure under 5 U.S.C. 552b(c)(9)(A). The public interest requires that such meetings be closed to the public because the Treasury Department requires frank and full advice from representatives of the financial community prior to making its final decisions on major financing operations. Historically, this advice has been offered by debt management advisory committees established by the several major segments of the financial community. When so utilized, such a committee is recognized to be an advisory committee under 5 U.S.C. App. 2, § 3.

Although the Treasury's final announcement of financing plans may not reflect the recommendations provided in reports of the Committee, premature disclosure of the Committee's deliberations and reports would be likely to lead to significant financial speculation in the securities market. Thus, this meeting falls within the exemption covered by 5 U.S.C. 552b(c)(9)(A).

Treasury staff will provide a technical briefing to the press on the day before the Committee meeting, following the release of a statement of economic conditions, financing estimates and technical charts. This briefing will give the press an opportunity to ask questions about financing projections and technical charts. The day after the Committee meeting, Treasury will release the minutes of the meeting, any charts that were discussed at the meeting, and the Committee's report to the Secretary.

The Office of Debt Management is responsible for maintaining records of debt management advisory committee meetings and for providing annual reports setting forth a summary of Committee activities and such other matters as may be informative to the public consistent with the policy of 5 U.S.C. 552(b). The Designated Federal Officer or other responsible agency

official who may be contacted for additional information is Fred Pietrangeli, Deputy Director for Office of Debt Management (202) 622–1876

Dated: January 6, 2010.

Fred Pietrangeli,

Deputy Director, Office of Debt Management.

[FR Doc. 2010–271 Filed 1–12–10; 8:45 am]

BILLING CODE 4810–25–M

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 a continuing information collection, as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning its information collection titled, "Privacy of Consumer Financial Information (12 CFR part 40)." The OCC is also giving notice that it has sent the collection to OMB for review.

DATES: You should submit written comments by February 12, 2010.

ADDRESSES: Communications Division, Office of the Comptroller of the Currency, Mailstop 2–3, Attention: 1557–0216, 250 E Street, SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874–5274, or by electronic mail to *regs.comments@occ.treas.gov.* You may personally inspect and photocopy the comments at the OCC, 250 E Street, SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–4700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, you should send a copy of your comments by mail to OCC Desk Officer, 1557–0216, U.S. Office of Management and Budget, 725, 17th Street, NW., #10235, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: You can request additional information or a copy of the collection from Mary H. Gottlieb, OCC Clearance Officer, (202) 874–5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend OMB approval of the following information collection:

Title: Privacy of Consumer Financial Information (12 CFR part 40).

OMB Control No.: 1557–0216.

Description: This submission covers an existing regulation and involves no change to the regulation or to the information collection requirements. The OCC requests only that OMB approve its revised estimates.

The information collection requirements in part 40 are as follows:

§ 40.4(a)—Disclosure (institution)—Initial privacy notice to consumers requirement—A bank must provide a clear and conspicuous notice that accurately reflects its privacy policies and practices to customers and consumers.

§ 40.5(a)—Disclosure (institution)—Annual privacy notice to customers requirement—A bank must provide a clear and conspicuous notice to customers that accurately reflects its privacy policies and practices not less than annually during the continuation of the customer relationship.

§ 40.8—Disclosure (institution)—Revised privacy notices—If a bank wishes to disclose information in a way that is inconsistent with the notices previously given to a consumer, the bank must provide consumers with a clear and conspicuous revised notice of the bank's policies and procedures and a new opt out notice.

§ 40.7(a)—Disclosure (institution)—Form of opt out notice to consumers; opt out methods—Form of opt out notice—If a bank is required to provide an opt-out notice under § 40.10(a), it must provide a clear and conspicuous notice to each of its consumers that accurately explains the right to opt out under that section. The notice must state:

- That the bank discloses or reserves the right to disclose nonpublic personal information about its consumer to a nonaffiliated third party;
- That the consumer has the right to opt out of that disclosure; and
- A reasonable means by which the consumer may exercise the opt out right.

A bank provides a reasonable means to exercise an opt out right if it:

- Designates check-off boxes on the relevant forms with the opt out notice;
- Includes a reply form with the opt out notice;
- Provides electronic means to opt out; or
- Provides a toll-free number to opt out.

§§ 40.10(a)(2) and 40.10(c)—Consumers must take affirmative actions to exercise their rights to prevent financial institutions from sharing their information with nonaffiliated parties—

- Opt out—Consumers may direct that the bank not disclose nonpublic personal information about them to a nonaffiliated third party, other than permitted by §§ 40.13–40.15
- Partial opt out—Consumer may also exercise partial opt out rights by selecting certain nonpublic personal information or certain nonaffiliated third parties with respect to which the consumer wishes to opt out.

§§ 40.7(f) and (g)—Reporting (consumer)—Consumers may exercise continuing right to opt out—Consumer may opt out at any time—A consumer may exercise the right to opt out at any time. A consumer's direction to opt out is effective until the consumer revokes it in writing or, if the consumer agrees, electronically. When a customer relationship terminates, the customer's opt out direction continues to apply.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit; individuals.

Estimated Annual Number of Institution Respondents: Initial Notice, 11; Annual Notice and Change in Terms, 1,625; Opt-out Notice, 813.

Estimated Average Time per Response Per Institution: Initial Notice, 80 hours; Annual Notice and Change in Terms, 8 hours; Opt-out Notice, 8 hours.

Estimated Subtotal Annual Burden Hours for Institutions: 20,384 hours.

Estimated Annual Number of Consumer Respondents: 15,028,802.

Estimated Average Time per Consumer Response: 0.25 hours.

Estimated Subtotal Annual Burden Hours for Consumers: 3,757,200.5 hours.

Estimated Total Annual Burden Hours: 3,777,584.5 hours.

The OCC issued a 60-day **Federal Register** notice on November 3, 2009. 74 FR 56923. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility; (b) The accuracy of the OCC's estimate of the information collection burden; (c) Ways to enhance

the quality, utility, and clarity of the information to be collected; (d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: January 7, 2010.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. 2010–414 Filed 1–12–10; 8:45 am]

BILLING CODE 4810–33–P

Federal Register

Wednesday,
January 13, 2010

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, et al.

Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 422, and 495

[CMS–0033–P]

RIN 0938–AP78

Medicare and Medicaid Programs; Electronic Health Record Incentive Program

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology. The proposed rule would specify the—initial criteria an EP and eligible hospital must meet in order to qualify for the incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs and eligible hospitals failing to meaningfully use certified EHR technology; and other program participation requirements. Also, as required by ARRA the Office of the National Coordinator for Health Information Technology (ONC) will be issuing a closely related interim final rule that specifies the Secretary's adoption of an initial set of standards, implementation, specifications, and certification criteria for electronic health records. ONC will also be issuing a notice of proposed rulemaking on the process for organizations to conduct the certification of EHR technology.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 15, 2010.

ADDRESSES: In commenting, please refer to file code CMS–0033–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions on the home page.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0033–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0033–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

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

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

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

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

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

In the event that CMS must limit the number of employees reporting for duty during an emergency or for other reasons, submitting comments on CMS regulations and Paperwork Reduction Act (PRA) notices via *www.regulations.gov* will ensure that CMS considers the comments promptly. Comments mailed or delivered to the CMS headquarters may not be readily accessible for review if CMS employees are not able to report to work at the CMS headquarters. CMS wishes to ensure that public comments on its regulations and PRA notices are promptly displayed on the regulations.gov Web site for the public to review. To ensure that comments are displayed as quickly as possible, we request that the public use only one public comment submission option. These efforts are intended to ensure that CMS operations continue even during an emergency and that consideration of public comments and access to those comments occur timely.

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

FOR FURTHER INFORMATION CONTACT: Elizabeth Holland, (410) 786–1309, EHR incentive program issues. Edward Gendron, (410) 786–1064, Medicaid incentive payment issues. Jim Hart, (410) 786–9520, Medicare fee for service payment issues. Terry Kay, (410) 786–4493, Medicare fee for service payment issues.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code (CMS–0033–P) and the specific "issue identifier" that precedes the section on which you choose to comment.

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

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

Acronyms

ARRA American Recovery and Reinvestment Act of 2009
CAH Critical Access Hospital
CAHPS Consumer Assessment of Healthcare Providers and Systems
CCN CMS Certification Numbers
CHIP Children's Health Insurance Program
CHIPRA Children's Health Insurance Program Reauthorization Act of 2009
CMS Centers for Medicare & Medicaid Services
CY Calendar Year
EHR Electronic Health Record
EP Eligible Professionals
EPO Exclusive Provider Organization
FACA Federal Advisory Committee Act
FFP Federal Financial Participation
FFS Fee-For-Service
FQHC Federally Qualified Health Center
FTE Full-Time Equivalent
FY Fiscal Year
FFY Federal Fiscal Year
HEDIS Healthcare Effectiveness Data and Information Set
HHS Department of Health and Human Services
HIE Health Information Exchanges
HIT Health Information Technology
HIPPA 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 Services Administration
IAPD Implementation Advanced Planning Document
IPA Independent Practice Association
IHS Indian Health Services
IT Information Technology
MA Medicare Advantage
MAC Medicare Administrative Contractor
MCO Medicaid Managed Care Organization
MITA Medicaid Information Technology Architecture
MMIS Medicaid Management Information Systems
MSA Medical Savings Account
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NPI National Provider Identifier
ONC Office of the National Coordinator for Health Information Technology
PAHP Prepaid Ambulatory Health Plan
PAPD Planning Advanced Planning Document
PIHP Prepaid Inpatient Health Plan
PFFS Private Fee-For-Service
PHO Physician Hospital Organization
PHS Public Health Service
POS Place of Service
PPO Preferred Provider Organization
PSO Provider Sponsored Organization
RHC Rural Health Clinic
RPPO Regional Preferred Provider Organization
SMHP State Medicaid Health Information Technology Plan
TIN Tax Identification Number

Table of Contents

I. Background
A. Overview of the HITECH Programs Created by the American Recovery and Reinvestment Act of 2009
B. Statutory Basis for the Medicare & Medicaid EHR Incentive Programs
II. Provisions of the Proposed Regulations
A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs
1. Definitions
a. Certified Electronic Health Record (EHR) Technology
b. Qualified Electronic Health Record
c. Payment Year
d. First, Second, Third, Fourth, Fifth and Sixth Payment Year
e. EHR Reporting Period
f. Meaningful EHR User
2. Definition of Meaningful Use
a. Background
b. Common Definition of Meaningful Use Under Medicare and Medicaid
c. Considerations in Defining Meaningful Use
d. Stage 1 Criteria for Meaningful Use
3. Sections 4101(a) and 4102(a)(1) of HITECH Act: Reporting on Clinical Quality Measures Using EHR by EPs and All Eligible Hospitals
a. General
b. Requirements for the Submission of Clinical Quality Measures by EPs and Eligible Hospitals
c. Statutory Requirements and Other Considerations for the Proposed Selection of Clinical Quality Measures Proposed for Electronic Submission by EPs or Eligible Hospitals
(1) Statutory Requirements for the Selection of Clinical Quality Measures Proposed for Electronic Submission by EPs and Eligible Hospitals
(2) Other Considerations for the Proposed Selection of Clinical Quality Measures for Electronic Submission by EPs and Eligible Hospitals
d. Proposed Clinical Quality Measures for Electronic Submission Using Certified EHR Technology by Eligible Professionals
e. Clinical Quality Measures Reporting Criteria for Eligible Professionals
f. Proposed Clinical Quality Measures for Electronic Submission by Eligible Hospitals
g. Request for Public Comment on Potential Measures for Eligible Professionals and Eligible Hospitals in 2013 Payment Year and Subsequent Years
h. Proposed Reporting Method for Clinical Quality Measures
(1) Reporting Method for 2011 Payment Year
(2) Reporting Method for 2012
i. Alternative Reporting Methods for Clinical Quality Measures
j. Proposed Reporting Criteria for Eligible Professionals and Eligible Hospitals
k. Addressing Dually-Eligible Medicare/Medicaid Beneficiaries Under HITECH
4. Demonstration of Meaningful Use
a. Common Methods of Demonstration in Medicare and Medicaid
b. Methods for Demonstration of the Stage 1 Criteria of Meaningful Use
5. Data Collection for Online Posting, Program Coordination and Accurate Payments
a. Online Posting
b. Program Election Between Medicare FFS/MA and Medicaid for EPs
c. Data To Be Collected
6. Hospital-Based Eligible Professionals
7. Interaction With Other Programs
B. Medicare Fee-for-Service Incentives
1. Incentive Payments for Eligible Professionals
a. Definitions
b. Incentive Payment Limits
c. Increase in Incentive Payment for EPs who Predominantly Furnish Services in a Geographic Health Professional Shortage Area
d. Form and Timing of Payment
e. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs Who Are Not Meaningful Users of Certified EHR Technology
2. Incentive Payments for Hospitals
a. Definition of Eligible Hospital for Medicare
b. Incentive Payment Calculation for Eligible Hospitals
c. Medicare Share
d. Charity Care
e. Transition Factor
f. Duration and Timing of Incentive Payments
g. Incentive Payment Adjustment Effective in Federal FY 2015 and Subsequent Years for Eligible Hospitals Who Are Not Meaningful EHR Users
3. Incentive Payments for Critical Access Hospitals
a. Definition of CAHs for Medicare
b. Current Medicare Payment of Reasonable Cost for CAHs
c. Changes made by the HITECH Act
d. Incentive Payment Calculation for CAHs
e. Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users
4. Process for Making Incentive Payments Under the Medicare FFS Program
a. Incentive Payments to EPs
b. Incentive Payments to Eligible Hospitals
c. Incentive Payments to CAHs
d. Payment Accounting under Medicare
C. Medicare Advantage Organization Incentive Payments
1. Definitions
a. Qualifying MA Organization
b. Qualifying MA Eligible Professional
c. Qualifying MA-Affiliated Eligible Hospital
2. Identification of Qualifying MA Organizations, MA EPs, and MA-Affiliated Eligible Hospitals
3. Computation of Incentives to Qualifying MA Organizations for MA EPs and Hospitals
4. Timeframe for Payment
5. Avoiding Duplicate Payment
6. Meaningful User Attestation
7. Posting on Web site and Limitation on Review
8. Limitation on Review
9. Conforming Changes

10. Payment Adjustment and Future Rulemaking
D. Medicaid Incentives
1. Overview of Health Information Technology in Medicaid
2. General Medicaid Provisions
3. Identification of Qualifying Medicaid EPs and Eligible Hospitals
a. Overview
b. Program Participation
1. Acute Care Hospitals
2. Children's Hospitals
c. Medicaid Professionals Program Eligibility
d. Calculating Patient Volume Requirements
e. Entities Promoting the Adoption of Certified EHR Technology
4. Computation of Amount Payable to Qualifying Medicaid EPs and Eligible Hospitals
(1) General Overview
(2) Average Allowable Costs
(3) Net Average Allowable Costs
(4) Payments for Medicaid Eligible Professionals
(5) Basis for Medicaid EHR Incentive Program First Payment Year and Subsequent Payment Years
(i) Medicaid EP Who Begins Adopting, Implementing or Upgrading Certified EHR Technology in the First Year
(ii) Medicaid EP who has Already Adopted, Implemented or Upgraded Certified EHR Technology and Meaningfully Uses EHR Technology
b. Payment Methodology for Eligible Hospitals
c. Alternative and Optional Early State Implementation to Make Incentive Payments for Adopting, Implementing or Upgrading Certified EHR Technology
d. Process for Making and Receiving Medicaid Incentive Payments
e. Avoiding Duplicate Payment
f. Flexibility to Alternate Between Medicare and Medicaid Incentive Payment Program One Time
g. One State Selection
5. National Level Repository and State Data Collection
6. Collection of Information Related to the Eligible Professional's National Provider Identifier and the Tax Identification Number (TIN)
7. Activities Required to Receive Incentive Payments
a. General Overview
b. Definitions Related to Certified EHR Technology and Adopting, Implementing or Upgrading Such Technology
(1) Certified EHR Technology
(2) Adopting, Implementing or Upgrading
c. Other General Terminology
III. Collection of Information Requirements
A. ICRs Regarding Demonstration of Meaningful Use Criteria (§ 495.8)
B. ICRs Regarding Participation Requirements for EPs, Eligible Hospitals, and Qualifying CAHs (§ 495.10)
C. ICRs Regarding Identification of Qualifying MA Organizations, MA–EPs and MA-Affiliated Eligible Hospitals (§ 495.202)
D. ICRs Regarding Incentive Payments to Qualifying MA Organizations for MA–EPs and Hospitals (§ 495.204)
E. ICRs Regarding Meaningful User Attestation (§ 495.210)
F. ICRs Regarding Incentive Payments to Qualifying MA Organizations for MA-Eligible Professionals and Hospitals (§ 495.220)
G. ICRs Regarding Process for Payments (§ 495.312)
H. ICRs Regarding Activities Required to Receive an Incentive Payment (§ 495.314)
I. ICRs Regarding State Monitoring and Reporting Regarding Activities Required To Receive an Incentive Payment (§ 495.316)
J. ICRs Regarding State Responsibilities for Receiving FFP (§ 495.318)
K. ICRs Regarding Prior Approval Conditions (§ 495.324)
L. ICRs Regarding Termination of Federal Financial Participation (FFP) for Failure To Provide Access to Information (§ 495.330)
M. ICRs Regarding State Medicaid Agency and Medicaid EP and Hospital Activities (§ 495.332 Through § 495.338)
N. ICRs Regarding Access to Systems and Records (§ 495.342)
O. ICRs Regarding Procurement Standards (§ 495.344)
P. ICRs Regarding State Medicaid Agency Attestations (§ 495.346)
Q. ICRs Regarding Reporting Requirements (§ 495.348)
R. ICRs Regarding Retroactive Approval of FFP With an Effective Date of February 18, 2009 (§ 495.358)
S. ICRs Regarding Financial Oversight and Monitoring Expenditures (§ 495.362)
T. ICRs Regarding Appeals Process for a Medicaid Provider Receiving Electronic Health Record Incentive Payments (§ 495.366)
IV. Response to Comments
V. Regulatory Impact Analysis
A. Overall Impact
B. Regulatory Flexibility Analysis
C. Small Rural Hospitals
D. Unfunded Mandates Reform Act
E. Federalism
F. Anticipated Effects
G. HITECH Impact Analysis
H. Accounting Statement

I. Background

A. 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) was enacted on February 17, 2009. ARRA includes many measures to modernize our nation's infrastructure, enhance energy independence, expand educational opportunities, provide tax relief, and preserve and improve affordable health care. Title IV of Division B of ARRA amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs) and eligible hospitals to promote the adoption and meaningful use of interoperable health information technology and qualified EHRs. Expanded use of health information technology (HIT) and EHRs will improve the quality and value of American health care. These provisions, together with Title XIII of Division A of ARRA, may be cited as the Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act." The incentive payments for adoption and meaningful use of HIT and qualified EHRs are part of a broader effort under the HITECH Act to accelerate the adoption of HIT and utilization of qualified EHRs. We are developing the incentive programs which are outlined in Division B, Title IV of the HITECH Act and these programs are the keys to inducing providers to actively utilize HIT.

EPs and eligible hospitals qualify for the EHR incentive payments if, among other requirements, they meaningfully use certified EHR technology. This proposed rule sets forth a proposed definition of "meaningful use of certified EHR technology." Section 13101 of the HITECH Act adds a new section 3000 to the Public Health Service Act (PHSA), which defines "certified EHR technology" as a qualified EHR that has been properly certified as meeting standards adopted under section 3004 of the PHSA. CMS and ONC have been working closely to ensure that the definition of meaningful use of certified EHR technology and the standards for certified EHR technology are coordinated. "Meaningful use" is a term defined by CMS and describes the use of HIT that furthers the goals of information exchange among health care professionals. In an upcoming interim final rule, ONC will identify the initial set of standards and implementation specifications that EHR technology must implement, as well as the certification criteria that will be used to certify EHR technology, and will further define the term "certified EHR technology." In a related proposed rule, the Department will propose the development of a certification program for health IT. Specifically, we have sought to ensure that the definition of meaningful use of certified EHR technology does not require EPs and eligible hospitals to perform functionalities for which standards have not been recognized or established. Similarly, the functionality of certified EHR technology should enable and advance the definition of meaningful use.

We urge those interested in this proposed rule to also review the ONC interim final rule with comment and the related proposed rule when they are published later this year and to visit *http://healthit.hhs.gov* and *http://*

www.cms.hhs.gov/Recovery/11_HealthIT.asp#TopOfPage for more information on the efforts at the Department of Health and Human Services (HHS) to advance HIT initiatives.

B. Statutory Basis for the Medicare & Medicaid EHR Incentive Programs

Section 4101(a) of the HITECH Act adds a new subsection (o) to section 1848 of the Act. Section 1848(o) of the Act establishes incentive payments for the meaningful use of certified EHR technology by EPs participating in the original Medicare program or hereinafter referred to as Medicare Fee-for-Service (FFS) program beginning in calendar year (CY) 2011. Section 4101(b) of the HITECH Act also adds a new paragraph (7) to section 1848(a) of the Act. Section 1848(a)(7) of the Act provides that beginning in CY 2015, EPs who are not meaningful users of certified EHR technology will receive less than 100 percent of the fee schedule for their professional services. Section 4101(c) of the HITECH Act adds a new subsection (l) to section 1853 of the Act to provide incentive payments to Medicare Advantage (MA) organizations for their affiliated EPs who meaningfully use certified EHR technology and meet certain other requirements, and a requirement to make a downward adjustment to Medicare payments to MA organizations for professional services provided by any of their affiliated EPs who are not meaningful users of certified EHR technology, beginning in 2015, and avoids duplicate of payments from the MA EHR incentive program under this section and the FFS EHR incentive program under section 1848(o)(1)(A).

Section 4102(a) of the HITECH Act adds a new subsection (n) to section 1886 of the Act. Section 1886(n) of the Act establishes incentive payments for the meaningful use of certified EHR technology by subsection (d) hospitals, as defined under section 1886(d)(1)(B) of the Act, participating in Medicare FFS program beginning in Federal fiscal year (FY) 2011. Section 4102(b)(1) of the HITECH Act amends section 1886(b)(3)(B) of the Act to provide that, beginning in FY 2015, subsection (d) hospitals that are not meaningful users of certified EHR technology will receive a reduced annual payment update. Section 4102(b)(2) of the HITECH Act amends section 1814(l) of the Act to provide an incentive payment to critical access hospitals (CAHs) who meaningfully use certified EHR technology based on the hospitals' reasonable cost beginning in FY 2011. In addition, section 4102(a)(2) of the HITECH Act amends section 1814(l) of the Act to provide for a downward payment adjustment for hospital services provided by CAHs that are not meaningful users of certified EHR technology for cost reporting periods beginning in FY 2015. Section 4102(c) of the HITECH Act adds a new subsection (m) to section 1853 of the Act to provide incentive payments to MA organizations for certain affiliated hospitals that meaningfully use certified EHR technology to address avoidance of duplicate payments, and to make a downward adjustment to payments to MA organizations for inpatient hospital services provided by its affiliated hospitals that are not meaningful users of certified EHR technology beginning in FY 2015.

Section 4103 of the HITECH Act provides for implementation funding for the EHR incentives program under Medicare.

Section 4201 of the HITECH Act amends section 1903 of the Act to provide 100 percent Federal financial participation (FFP) to States for incentive payments to certain eligible providers participating in the Medicaid program to purchase, implement, and operate (including support services and training for staff) certified EHR technology and 90 percent FFP for State administrative expenses related to the program outlined in 1903(t) of the Act. Section 4201(a)(2) of the HITECH Act adds a new subsection (t) to section 1903 of the Act to establish a program with input from the States to provide incentives for the adoption and subsequent meaningful use of certified EHR technology for providers participating in the Medicaid program.

II. Provisions of the Proposed Regulations

We propose to add a new part 495 to title 42 of the Code of Federal Regulations to implement the provisions discussed in this section of the proposed rule related to certified EHR technology for providers participating in either the Medicare program or the Medicaid program.

The HITECH Act creates incentives in the Medicare Fee-for-Service (FFS), Medicare Advantage (MA), and Medicaid programs for demonstrating meaning EHR use and payment adjustments in the Medicare FFS and MA programs for not demonstrating meaningful EHR use. The three incentive programs contain many common elements and certain provisions of the HITECH Act encourage avoiding duplication of payments, reporting, and other requirements, particularly in the area of demonstrating meaningful use of certified EHR technology. Eligible hospitals may participate in either one of the Medicare (FFS or MA) programs and the Medicaid program, assuming they meet each program's eligibility requirements, which vary across programs. In certain cases, the HITECH Act has used nearly identical or identical language in defining terms that are used in the Medicare FFS, MA, and Medicaid programs, including such terms as "hospital-based EPs" and "certified EHR technology." In these cases, we seek to create as much commonality between the three programs as possible and have structured this proposed rule based on that premise by beginning with those provisions that cut across the three programs before moving on to discuss the provisions specific to Medicare FFS, MA and Medicaid.

A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs

Title IV, Division B of the HITECH Act establishes incentive payments under the Medicare and Medicaid programs for certain professionals and hospitals that meaningfully use certified EHR technology. Under Medicare, these incentive payments may be made to qualifying professionals, hospitals, and Medicare Advantage (MA) organizations on behalf of certain MA affiliated physicians and hospitals. We refer to the incentive payments made under the original Medicare program as the Medicare FFS EHR incentive program. We refer to the incentive payments made to qualifying MA organizations as the MA EHR incentive program, and the incentive payments made under Medicaid as the Medicaid EHR incentive program. When referring to Medicare EHR incentive program, we are referring to both the Medicare FFS EHR and the MA EHR incentive programs.

1. Definitions

Sections 4101, 4102, and 4202 of the HITECH Act use many identical or similar terms. In this section of the preamble, we discuss terms for which we are proposing uniform definitions for the Medicare FFS, Medicare Advantage, and Medicaid EHR incentive programs. These definitions would be included in part 495 subpart A of the regulations. For definitions specific to an individual program, the definition is set forth and discussed in the applicable EHR incentive program section.

a. Certified Electronic Health Record (EHR) Technology

The incentive payments are available to EPs (non-hospital-based physicians, as defined in section 1861(r) of the Act, who either receive reimbursement for services under the Medicare FFS program or have an employment or contractual relationship with a qualifying MA organization meeting the criteria under section 1853(l)(2) of the Act; or healthcare professionals meeting the definition of "eligible professional" under section 1903(t)(3)(B) of the Act as well as the patient-volume and non-hospital-based criteria of section 1903(t)(2)(A) of the Act) and eligible hospitals (subsection (d) hospitals as defined under subsection 1886(d)(1)(B) of the Act that either receive reimbursement for services under the Medicare FFS program or are affiliated with a qualifying MA organization as described in section 1853(m)(2) of the Act; critical access hospitals (CAHs); or acute care or children's hospitals described under section 1903(t)(2)(B) of the Act). Under all three EHR incentive programs, EPs and eligible hospitals must utilize "certified EHR technology" if they are to be considered eligible for the incentive payments. In the Medicare FFS EHR incentive program this requirement for EPs is found in section 1848(o)(2)(A)(i) of the Act, as added by section 4101(a) of the HITECH Act, and for eligible hospitals and CAHs in section 1886(3)(A)(i) of the Act, as added by section 4102(a) of the HITECH Act. In the MA EHR incentive program this requirement for EPs is found in section 1853(l)(1) of the Act, as added by section 4101(c) of the HITECH Act, and for eligible hospitals and CAHs, in section 1853(m)(1) of the Act, as added by section 4201(c) of the HITECH Act. In the Medicaid EHR incentive program this requirement for EPs and Medicaid eligible hospitals is found throughout section 1903(t) of the Act, including in section 1903(t)(6)(C) of the Act, as added by section 4201(a)(2) of the HITECH Act. While certified EHR technology is a critical component of the EHR incentive programs, under the authority given to her in the HITECH Act, the Secretary has charged ONC with developing the criteria and mechanisms for certification of EHR technology. Therefore, ONC will be defining certified EHR technology in its upcoming interim final rule and we propose to use the definition of certified EHR technology adopted by ONC.

b. Qualified Electronic Health Record

In order for an EHR technology to be eligible for certification it must first meet the definition of a qualified electronic health record. This term will be defined by ONC in its upcoming interim final rule, and we propose to use the definition of qualified electronic health record adopted by ONC.

c. Payment Year

Under section 1848(o)(1)(A)(i) of the Act, as added by section 4101(a) of the HITECH Act, the Medicare FFS EHR incentive payment is available to EPs for a "payment year." Section 1848(o)(1)(E) of the Act defines the term "payment year" as a year beginning with 2011. While the HITECH Act does not use the term, "payment year," for the Medicaid EHR incentive program, it does use the term "year of payment" throughout section 1903(t) of the Act, for example, at sections 1903(t)(3)(C), 1903(t)(4)(A), and 1903(t)(6)(C) of the Act. For all EPs, we are proposing a common definition for both "payment year" and "year of payment," as "any calendar year beginning with 2011" at § 495.4. (The only exception to this rule, is that in certain cases, Medicaid EPs would be able to participate in the Medicaid EHR incentive program starting with CY 2010, for adopting, implementing, or upgrading certified EHR technology. For further discussion of this early participation in the Medicaid EHR incentive program, we refer readers to section II.D.3.c. of this proposed rule.)

This definition, which is consistent with the statutory definition of "payment year" under Medicare FFS, will simplify the EHR incentive programs for EPs. As discussed later in this preamble, EPs may have the opportunity to participate in either the Medicare or Medicaid incentive programs, and once an EP has picked a program, they are permitted to make a one-time switch from one program to the other. A common definition will allow EPs to more easily understand both programs, and inform decisions regarding whether they are eligible for, and/or wish to participate in either program. Under section 1886(n)(1) of the Act, as added by section 4102(a) of the HITECH Act, the Medicare FFS EHR incentive payment is available to eligible hospitals and CAHs for a "payment year." Section 1886(n)(2)(G) of the Act defines the term "payment year" as a fiscal year (FY) beginning in 2011. As hospitals are paid based on the 12-month Federal fiscal year, we believe the reference to a "fiscal year" means the fiscal year beginning on October 1 of the prior year and extending to September 30 of the relevant year. Again, for the Medicaid EHR incentive program, the HITECH Act uses the term, "year of payment" (see section 1903)(t)(5)(D)(ii) of the Act), rather than "payment year." For the same reasons expressed above for EPs, and because hospitals will have the opportunity to simultaneously participate in both the Medicare and Medicaid EHR incentive programs, we propose a common definition of "payment year" and "year of payment" for both programs. For purposes of the incentive payments made to eligible hospitals under the Medicare FFS, MA and Medicaid EHR incentive programs, we propose to define payment year and year of payment at § 495.4, consistent with the statutory definition, as "any fiscal year beginning with 2011". (The only exception to this rule, is that in certain cases, Medicaid eligible hospitals would be able to participate in the Medicaid EHR incentive program starting with FY 2010, for adopting, implementing, or upgrading certified EHR technology. For further discussion of this early participation in the Medicaid EHR incentive program, we refer readers to section II.D.3.c of this proposed rule.)

The actual timing of the incentive payment for a given payment year varies depending on which EHR incentive program an EP or an eligible hospital is participating in. Details on the timing of incentive payments for a given payment year can be found in section II.B.of the proposed rule for Medicare FFS, section II.C. of the proposed rule for MA and section II.D. of the proposed rule for Medicaid.

d. First, Second, Third, Fourth, Fifth, and Sixth Payment Year

For EPs and eligible hospitals that qualify for EHR incentive payments in a payment year, the amount of the payment will depend in part on how many previous payment years, if any, an EP or eligible hospital received an incentive payment. We propose to define the first payment year to mean the first calendar or Federal fiscal year for which an EP or eligible hospital receives an incentive payment. Likewise, we propose to define the second, third, fourth, fifth, and sixth payment year, respectively, to mean the second, third, fourth, fifth, and sixth calendar or Federal fiscal year, respectively, for which an EP or eligible hospital receives an incentive payment.

e. EHR Reporting Period

In order to qualify for an incentive payment under the Medicare incentive payment program for a payment year, an EP or eligible hospital must meaningfully use certified EHR technology for the EHR reporting period of the relevant payment year. Similarly, a Medicaid EP or eligible hospital may

in the first payment year and must in subsequent payment years demonstrate meaningful use of such technology, in order to receive a payment. A Medicaid EP or eligible hospital may receive an incentive payment in their first payment year for the adoption, implementation, or upgrade of certified EHR technology. Although the Medicaid statute does not specifically use the term, "EHR reporting period," we believe that the Secretary, pursuant to sections 1903(t)(6)(C) and 1903(t)(8) of the Act, has the authority to define the period that would be used for demonstrating such adoption/implementation/upgrade or meaningful use.

In this proposed rule, we propose a definition of EHR Reporting Period for purposes of the Medicare and Medicaid incentive payments under sections 1848(o), 1853(l)(3), 1886(n), 1853(m)(3), 1814(l) and 1903(t) of the Act. For these sections, the EHR reporting period may be any continuous 90-day period within the first payment year and the entire payment year for all subsequent payment years. In future rulemaking, we will propose a definition of EHR Reporting Period for purposes of Medicare incentive payment adjustments under sections 1848(a)(7), 1853(l)(4), 1886(b)(3)(B)(ix), 1853(m)(4), and 1814(l)(4) of the Act. Unlike the former group of sections, meaningful EHR users that would not be subject to adjustments would have to be identified prior to the application of the latter group of sections. Therefore, these two groups of sections may have two different definitions of EHR Reporting Period.

For the first payment year only, we propose to define the term EHR reporting period at § 495.4 to mean any continuous 90-day period within a payment year in which an EP or eligible hospital successfully demonstrates meaningful use of certified EHR technology. The EHR reporting period therefore could be any continuous period beginning and ending within the relevant payment year. For example, for payment year 2011, an EHR reporting period of March 13, 2011 to June 11, 2011 would be just as valid as an EHR reporting period of January 1, 2011 to April 1, 2011. An example of an unallowable EHR reporting period would be for an EP to begin on November 1, 2011 and finish on January 31, 2012. Starting with the second payment year and any subsequent payment years for a given EP or eligible hospital, we propose to define the term EHR reporting period at § 495.4 to mean the entire payment year.

In defining the EHR reporting period, we considered three of its aspects: (1) Whether it should vary from one payment year to the next; (2) its length; and (3) starting point. We discuss these three aspects below.

The first aspect of the EHR reporting period discussed is whether it should be the same for each payment year. We believe that there are considerations that distinguish the first payment year from the remaining payment years. The foremost being that once an EP or eligible hospital begins to meaningfully use certified EHR technology they are unlikely to stop. As discussed below, in the first payment year a shorter EHR reporting period would provide more flexibility for when an EP or eligible hospital begins to meaningfully use certified EHR technology and still qualify for the incentive in the same year. However, in subsequent years we do not see that flexibility still being required. Therefore, for purposes of the incentive payments under sections 1848(o), 1853(l)(3), 1886(n), 1853(m)(3), 1814(l), and 1903(t) of the Act, we propose that the length of the EHR reporting period be different for the first payment year than from all other payment years. We invite interested parties to comment on this proposal if they believe that the EHR reporting period should vary from payment year to payment year.

With respect to the length of the EHR reporting period, we note that there is an inherent tradeoff between robust verification and time available to achieve compliance. A longer EHR reporting period provides a more robust verification that an EP or eligible hospital successfully met the definition of meaningful use of certified EHR technology than a shorter period. However, it reduces the time available for an EP or eligible hospital to reach the point of complying with meaningful use and still receive an incentive for a given payment year. For example, a 90-day period would allow an EP until October 1, 2011 to begin meaningful use of their certified EHR technology and receive an incentive for payment year 2011. A 180-day period (6 months) would move the date upon which the EP must begin meaningful use of their certified EHR technology forward to July 1, 2011. We are concerned that an EHR reporting period that is shorter than 90 days would be insufficient time to ensure that EPs and eligible hospitals are truly using certified EHR technology in a meaningful manner consistent with our proposed criteria for meaningful use. Moreover, as discussed later in this proposed rule, we will require EPs and hospitals to demonstrate meaningful use by meeting certain performance thresholds (for example, EPs will need to use CPOE for 80 percent of all orders, and hospitals for 10 percent of all orders). We believe a period of fewer than 90 days would not be adequate to create an accurate rate for a given EP or eligible hospital. We believe that once an EP or hospital has implemented certified EHR technology to the point of being able to comply with our proposed meaningful use criteria for 90 days, it is unlikely that they would adjust their behavior just because the EHR reporting period has ended. Beginning in the second payment year, an EP or eligible hospital will already be meaningfully using certified EHR technology so there are no limitations on the time available for compliance.

For the first payment year, therefore, we propose that the EHR reporting period will be any continuous 90-day period within the first payment year. However, beginning in the second payment year we see no compelling reason not to seek the most robust verification possible. Therefore for the second payment year and all subsequent payment years we propose the EHR reporting period be the entire payment year. As the length of the EHR reporting period is based on the discussed trade-off, we remain open to alternative lengths of time. We invite comments on the appropriate length for the EHR reporting period. We urge those commenting to either endorse our proposed initial 90-day period followed by full year EHR reporting periods or to recommend a specific alternative.

With respect to when the EHR reporting period for a payment year should begin, there are two considerations. The first is determining the earliest start date available, and the second is the flexibility given to EPs and eligible hospitals to choose their start date. This aspect is only applicable for the 90-day EHR reporting period for the first payment year. The length of the EHR reporting period for the second payment year and subsequent payment years dictate that the start date be the first day of the payment year. The earliest start date we considered was one which would allow an EP or eligible hospital to demonstrate successful meaningful use of certified EHR technology on the first day of the relevant payment year. For example, allowing an EHR reporting period to begin as early as July 3, 2010 would allow an eligible hospital to successfully demonstrate meaningful use on October 1, 2010, the first day of FY 2011. We have chosen not to propose this as the earliest start date. There are significant barriers created by the timeline in the HITECH Act. We anticipate that we will not publish a final rule until after March

2010, with the final rule effective 60 days after its publication. We do not believe this allows enough time for us, the vendor community, or the provider community to take advantage of this early start date. In addition, as discussed at sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) of the Act, the HITECH Act directs the Secretary to seek to avoid duplicative reporting of clinical quality and other measures under the Medicare EHR incentive program and other Medicare programs. If we were to allow EPs and hospitals to report these measures to CMS prior to the beginning of the FY, this reporting may be of questionable value to other Medicare programs requiring reporting of the same measures. For example, if and when the demonstration of meaningful use includes the submission of quality measures this submission could include measures currently in the RHQDAPU program. As discussed in section II.A.3. of this proposed rule, we do not desire to have a hospital report the same measure twice for two different programs. However, if a hospital reports these measures from July through September 2010 for payment year 2011 for Medicare and/or Medicaid EHR incentive program, they would not be relevant for FY 2011 under the RHQDAPU. Due to the operational challenges presented and the statutory requirement to avoid duplication of payments to the extent possible, we are proposing that the earliest start date for EHR reporting period be the first day of the payment year. The second consideration for when the EHR reporting period should begin is whether to designate specific start dates. As we are not aware of any compelling reason to limit the start dates available to EPs or eligible hospitals within the payment year, we propose to allow EPs or eligible hospitals to begin their EHR reporting period on any date starting with the first day of the payment year and ending with the latest day in the payment year that allows for the EHR reporting period to be completed by the last day of the payment year. We believe that giving EPs and eligible hospitals flexibility as to the start date of the EHR reporting is important, as unforeseen circumstances, such as delays in implementation, higher than expected training needs and other unexpected hindrances, may cause an EP or eligible hospital to potentially miss a target start date. We invite comments on the proposed start dates for the EHR reporting period.

We acknowledge that all three of these aspects will be affected by the need to determine which physicians, hospitals, critical access hospitals and managed care plans are meaningful users before application of the Medicare payment adjustments (provisions of sections 1848(a)(7), 1853(l)(4), 1886(b)(3)(B)(ix), 1853(m)(4), and 1814(l)(4) of the Act). We will specify the EHR reporting periods for these payment adjustment incentives in future rulemaking.

f. Meaningful EHR User

Section 1848(o)(1)(A)(i) of the Act, as added by section 4101(a) of the HITECH Act, limits incentive payments in the Medicare FFS EHR incentive program to an EP who is a "meaningful EHR user." Section 1886(n)(1) of the Act, as added by section 4102(a) of the HITECH Act, limits incentive payments in the Medicare FFS EHR incentive program to hospitals described in section 1886(d) of the Act. Section 1814(l) of the Act limits incentive payments in the Medicare FFS EHR incentive program to CAHs who are "meaningful EHR users." Section 1903(t)(6)(C)(i)(II) of the Act, as added by section 4201(a)(2) of the HITECH Act, limits incentive payments for payment years other than the first payment year to a Medicaid provider who "demonstrates meaningful use of certified EHR technology." We propose to define at § 495.4 the term "meaningful EHR user" as an EP or eligible hospital who, for an EHR reporting period for a payment year, demonstrates meaningful use of certified EHR technology in the form and manner consistent with our standards (discussed below). These standards would include use of certified EHR technology in a manner that is approved by us.

2. Definition of Meaningful Use

a. Background

As discussed previously, an EP or eligible hospital must be a meaningful EHR user in order to receive the incentive payments available under the EHR incentive programs, except in the first payment year for certain Medicaid EPs or eligible hospitals. This section (II.A.2.) of this proposed rule discusses the definition of meaningful use. Section II.A.3. of this proposed rule, discusses the manner for demonstrating meaningful use. In Sections 1848(o)(2)(A) and 1886(n)(3) of the Act, the Congress specified three types of requirements for meaningful use: (1) Use of certified EHR technology in a meaningful manner (for example, electronic prescribing); (2) that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of care; and (3) that, in using certified EHR technology, the provider submits to the Secretary information on clinical quality measures and such other measures selected by the Secretary.

Over the last few months, CMS and ONC have solicited input on defining meaningful use from both other government agencies and the public through dialogue, public forums, and solicitation of written comments. Below we describe the work of the National Committee on Vital and Health Statistics (NCVHS), the HIT Standards Committee and the HIT Policy Committee, as well as the public input we have received on defining meaningful use.

The NCVHS is the Department of Health and Human Services' statutory public advisory body on health data, statistics, and national health information policy. NCVHS derives its authority from 42 U.S.C. 242k, section 306(k) of the Public Health Service Act, which governs it along with the provisions of Public Law 92–463 (5 U.S.C. App.2). The full charter and membership of the NCVHS is available electronically at *http://www.ncvhs.hhs.gov/*. The NCVHS held a public hearing on April 28 and 29, 2009 to learn from a broad spectrum of stakeholders their views of "meaningful use." The NCVHS hearing brought together key healthcare and information technology stakeholder groups including: Representatives of patients, and more broadly consumers; providers; the public health community; public and private payers; vendors; and certifying entities. The hearing agenda and testimony supplied is available electronically at *http://www.ncvhs.hhs.gov/090428ag.htm*. A report on the hearing was delivered May 15, 2009 to the ONC. The report is available electronically at *http://www.ncvhs.hhs.gov/090518rpt.pdf*. Written comments from interested stakeholders submitted timely to the NCVHS were also considered by the NCVHS Executive Sub-Committee in the drafting of the report. Subsequently, the National Coordinator for HIT requested NCVHS to reflect on the testimony by supplying observations. Those observations are available electronically at *http://www.ncvhs.hhs.gov/090428rpt.pdf*.

In addition to the work completed by the NCVHS, the HIT Policy Committee, a Federal Advisory Committee to the Department of Health and Human Services (HHS) created by the HITECH Act, also worked to inform the definition of meaningful use. The full charter and membership of the HIT Policy Committee can be found at

http://healthit.hhs.gov. The HIT Policy Committee formed a Meaningful Use workgroup. On June 16, 2009, the HIT Policy Committee heard and discussed the recommendations from their Meaningful Use workgroup, and subsequently submitted its own recommendations on meaningful use to the National Coordinator for Health IT. These recommendations are available electronically at *http://healthit.hhs.gov.* At the conclusion of the June 16 meeting, ONC announced a public comment period to solicit stakeholder input on the recommendations and published a notice in the **Federal Register** (74 FR 28937). The public comment period lasted through June 26, 2009. Over 700 public comments were received by the ONC. A summary, as well as the text of the comments, is available electronically at *http://healthit.hhs.gov.* The Meaningful Use workgroup presented its revised recommendations to the full committee based on comments by the full HIT Policy Committee and by the public at the July 16, 2009 meeting. In developing its recommendations, the HIT Policy Committee considered a report entitled "National Priorities and Goals" (*http://www.nationalprioritiespartnership.org/uploadedFiles/NPP/08-253-NQF%20ReportLo%5b6%5d.pdf*) generated by the National Priorities Partnership, convened by the National Quality Forum (NQF). Of the national health care priorities set forward by the NQF report, the HIT Policy Committee chose as priority areas patient engagement; reduction of racial disparities; improved safety; increased efficiency; coordination of care; and improved population health to drive their recommendations. Those recommendations are available electronically at *http://healthit.hhs.gov.*

The HIT Standards Committee, another Federal Advisory Committee created by the HITECH Act, provided recommendations related to meaningful use to ONC. The HIT Standards Committee work focuses primarily on the standards surrounding certified EHR technology. Further information on the HIT Standards Committee role and recommendations can be found in a future rulemaking document to be provided by ONC for certification of EHR technology (HHS–0151–IFC) and at *http://healthit.hhs.gov.*

Finally, from June 22 to June 26, 2009, the ONC and CMS hosted 21 teleconference listening sessions with rural providers, small practices, small hospitals, CAHs, and urban safety net providers to hear their perspectives and obtain their input on the definition of meaningful use. Because of the documentation that these types of providers have below average adoption rates of HIT, we solicited comments directly from these communities. Section V. of this proposed rule discusses the current adoption rates of HIT. Over 200 representatives from these target audiences participated on the calls. The vast majority of callers were rural providers, although representatives from vendor organizations or provider associations also participated. One session was held to specifically hear from national organizations representing rural communities and providers. Summaries of these listening sessions are available at *http://healthit.hhs.gov/meaningfuluse.* Both CMS and the ONC have reviewed input from these and additional sources to help inform the definition of meaningful use.

b. Common Definition of Meaningful Use Under Medicare and Medicaid

Under sections 1848(o)(1)(A)(i) and 1886(n)(1) of the Act, as added by sections 4101(a) and 4102(a) of the HITECH Act, respectively, an EP or eligible hospital must be a meaningful EHR user for the relevant EHR reporting period in order to qualify for the incentive payment for a payment year. Sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act provide that an EP and an eligible hospital shall be considered a meaningful EHR user for an EHR reporting period for a payment year if they meet the following three requirements: (1) Demonstrates use of certified EHR technology in a meaningful manner; (2) demonstrates to the satisfaction of the Secretary that certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care such as promoting care coordination, in accordance with all laws and standards applicable to the exchange of information; and (3) using its certified EHR technology, submits to the Secretary, in a form and manner specified by the Secretary, information on clinical quality measures and other measures specified by the Secretary. The HITECH Act requires that to receive a Medicaid incentive payment in the initial year of payment, an EP or eligible hospital may demonstrate that they have engaged in efforts to "adopt, implement, or upgrade certified EHR technology." Details, including special timeframes, on how we define and implement "adopt, implement, and upgrade" are proposed in section II.D.7.b.2 of this proposed rule. For subsequent payment years, or the first payment year if an EP or eligible hospital chooses, section 1903(t)(6)(C)(i)(II) of the Act, as added by section 4201(a)(2) of HITECH, prohibits receipt of an incentive payment, unless "the Medicaid provider demonstrates meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary, and that may be based upon the methodologies applied under section 1848(o) or 1886(n)." (Sections 1848(o) and 1886(n) of the Act refer to the Medicare incentive programs for EPs and eligible hospitals respectively.) Under section 1903(t)(8) of the Act to the maximum extent practicable, we are directed to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology. Provisions included at section 1848(o)(1)(D)(iii) of the Act also contain a Congressional mandate to avoid duplicative requirements for meaningful use, to the extent practicable. Finally section 1903(t)(8) of the Act allows the Secretary to deem satisfaction of the requirements for meaningful use of certified EHR technology for a payment year under Medicare to qualify as meaningful use under Medicaid.

We believe that given the strong level of interaction on meaningful use encouraged by the HITECH Act, there would need to be a compelling reason to create separate definitions for Medicare and Medicaid. We have found no such reasons for disparate definitions in our internal or external discussions. To the contrary, stakeholders have expressed strong preferences to link the Medicare and Medicaid EHR incentive programs wherever possible. Hospitals are entitled to participate in both programs, and we are proposing to offer EPs an opportunity to switch between the Medicare and Medicaid EHR incentive programs. Therefore, we propose to create a common definition of meaningful use that would serve as the definition for providers participating in the Medicare FFS and MA EHR incentive program, and the minimum standard for EPs and eligible hospitals participating in the Medicaid EHR incentive program. We clarify that under Medicaid this common definition would be the minimum standard. While we would allow States to add additional objectives to the definition of meaningful use or modify how the existing objectives are measured, the Secretary would not accept any State proposed alternative that does not further promote the use of EHRs and healthcare quality or that would require additional functionality beyond that of certified EHR technology. See section

II.D.7.b.2.of this proposed rule for further details on how a State may propose an alternative.

For hospitals, we propose to exercise the option granted under section 1903(t)(8) of the Act and deem any Medicare provider who is a meaningful EHR user under the Medicare EHR incentive program and is otherwise eligible for the Medicaid incentive payment to be classified as a meaningful EHR user under the Medicaid EHR incentive program. This is applicable only to eligible hospitals, as EPs cannot receive an incentive payment under both Medicare and Medicaid.

We solicit comments as to whether there exist compelling reasons to give the states additional flexibility in creating disparate definitions beyond what is proposed. Also if commenting in favor of such disparate definitions, we ask that interested parties also comment on whether the proposal of deeming meeting Medicare as sufficient for meeting those of Medicaid remains appropriate under the disparate definitions. This is applicable only to hospitals eligible for both the Medicare and Medicaid incentive programs. Furthermore, if a State has CMS-approved additional meaningful use requirements, hospitals deemed as meaningful users by Medicare would not have to meet the State-specific additional meaningful use requirements in order to qualify for the Medicaid incentive payment.

c. Considerations in Defining Meaningful Use

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, as added by sections 4101(a) and 4102(a) of the HITECH Act, the Congress identifies the broad goal to be accomplished through the definition of meaningful use of certified EHR technology for expanding the use of EHRs. Certified EHR technology used in a meaningful way by providers is one piece of a broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. Our goal is for this ultimate vision to drive the definition of meaningful use consistent with applicable provisions of Medicare and Medicaid law.

In defining meaningful use through the creation of criteria, we have balanced competing considerations of proposing a definition that best ensures reform of health care and improved healthcare quality, encourages widespread EHR adoption, promotes innovation, and avoids imposing excessive or unnecessary burdens on healthcare providers, while at the same time recognizing the short time-frame available under the HITECH Act for providers to begin using certified EHR technology.

Based on public and stakeholder input, we consider a phased approach to be most appropriate. 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, based on anticipated technology and capabilities development. 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 certified EHR technology should result in health care that is patient-centered, evidence-based, prevention-oriented, efficient, and equitable.

Under this phased approach to meaningful use, we intend to update the criteria of meaningful use through future rulemaking. We refer to the initial meaningful use criteria as "Stage 1." We currently anticipate two additional updates, which we refer to as Stage 2 and Stage 3, respectively. We are considering updating the meaningful use criteria on a biennial basis, with the Stage 2 criteria proposed by the end of 2011 and the Stage 3 definition proposed by the end of 2013. The stages represent a graduated approach to arriving at the ultimate goal. Thus, our goals for "Stage 3" meaningful use criteria represent overarching goals which, we believe, are attainable by the end of the EHR incentive programs. We will continue to evaluate the progression of the meaningful use definition for consistency with legislative intent and new statutory requirements relating to quality measurement. We solicit comments on this proposed pathway of meaningful use.

- Stage 1: The Stage 1 meaningful use criteria focuses on electronically capturing health information in a coded 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); consistent with other provisions of Medicare and Medicaid law, implementing clinical decision support tools to facilitate disease and medication management; and reporting clinical quality measures and public health information.
- Stage 2: Our goals for the Stage 2 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, expand upon the Stage 1 criteria to 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, such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results (such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, pulmonary function tests and other such data needed to diagnose and treat disease). Additionally we may consider applying the criteria more broadly to both the inpatient and outpatient hospital settings.
- Stage 3: Our goals for the Stage 3 meaningful use criteria are, consistent with other provisions of Medicare and Medicaid law, to focus on promoting improvements in quality, safety and efficiency, focusing on decision support for national high priority conditions, patient access to self management tools, access to comprehensive patient data and improving population health.

We will continue to evaluate the progression of the meaningful use definition for consistency with legislative instructions and new statutory requirements relating to quality measurement and administrative simplification. We are aware that the appropriate approach raises complex questions and we solicit comments on the proposed approach and alternative possibilities. A different approach might, for example, move aspects of Stage 2 into Stage 3 or vice versa. We seek comments on how best to balance the relevant goals, including promoting adoption of EHRs, avoiding excessive or unnecessary burdens, and improving health care.

As the purpose of these incentives is to encourage the adoption and meaningful use of certified EHR technology, we believe it is desirable to account for whether an EP or eligible hospital is in their first, second, third, fourth, fifth, or sixth payment year when deciding which definition of meaningful use to apply in the beginning years of the program. The HIT Policy Committee in its public meeting on July 16, 2009 also voiced its approval of this approach. However, we do not wish to create an additional burden on EPs or eligible hospitals for becoming a meaningful EHR user before 2015 by creating a higher standard for them relative to an EP or eligible hospital who first becomes a meaningful EHR user in

2015. The following paragraphs describe our intended alignment in the beginning years that brings all EPs and eligible hospitals to the same level of meaningful use by 2015. As we are only proposing criteria for Stage 1 of meaningful use in this notice of proposed rulemaking, Stage 1 will be the criteria for meaningful use for all payment years until updated by future rulemaking. Medicaid EHR incentive program EPs and eligible hospitals have the option to earn their incentive for their first payment year through the adoption, implementation or upgrade of certified EHR technology. Those EPs and eligible hospitals doing so will not have to demonstrate meaningful use in their first payment year. We intend for their progression to be the same as those who demonstrate meaningful use in their first payment year. In other words, the second payment year is the second payment year regardless of how the incentive was earned in the first payment year.

We intend that Medicaid EPs and eligible hospitals who qualify for an incentive payment for adopting, implementing, or upgrading in their first payment year would follow the same meaningful use progression outlined below as if their second payment year was their first payment year. For instance a Medicaid EP who received an incentive for his or her first payment year in 2010 for adopting, implementing, or upgrading would follow the same guidance starting in their second payment year (2011) as a Medicare EP who received an incentive for their first payment year in 2011 for meaningful use of certified EHR technology. Another example would be a Medicaid eligible hospital that received an incentive for its first payment year in 2012 for adopting, implementing, and upgrading would follow the same guidance starting in their second payment year (2013) as a Medicare eligible hospital who received an incentive for their first payment year in 2013 for meaningful use of certified EHR technology.

We propose that EPs and eligible hospitals whose first payment year is 2011 must satisfy the requirements of the Stage 1 criteria of meaningful use in their first and second payment years (2011 and 2012) to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 2 in time for the 2013 payment year and therefore anticipate for their third and fourth payment years (2013 and 2014), an EP or eligible hospital whose first payment year is 2011 would have to satisfy the Stage 2 criteria of meaningful use to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for their fifth payment year (2015), if applicable, an EP or eligible hospital whose first payment year is 2011 would have to satisfy the Stage 3 criteria of meaningful use to receive the incentive payments. For their sixth payment year (2016), if applicable, an EP or eligible hospital whose first payment year is 2011 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

We propose that EPs and eligible hospitals whose first payment year is 2012 must satisfy the Stage 1 criteria of meaningful use in their first and second payment years (2012 and 2013) to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 2 in time for the 2013 payment year and anticipate for their third payment year (2014), an EP or eligible hospital whose first payment year is 2012 would have to satisfy the Stage 2 criteria of meaningful use to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for their fourth payment year (2015), if applicable, an EP or eligible hospital whose first payment year is 2012 would have to satisfy the Stage 3 criteria of meaningful use to receive the incentive payments. For their fifth and sixth payment years (2016 and 2017), if applicable, an EP or eligible hospital whose first payment year is 2012 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

We propose that EPs and eligible hospitals whose first payment year is 2013 must satisfy the Stage 1 criteria of meaningful use in their first payment year (2013) to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 2 in time for the 2013 payment year and therefore anticipate for their second payment year (2014), an EP or eligible hospital whose first payment year is 2013 would have to satisfy the Stage 2 criteria of meaningful use to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for their third payment year (2015), if applicable, an EP or eligible hospital whose first payment year is 2013 would have to satisfy the Stage 3 criteria of meaningful use to receive the incentive payments. For their fourth, fifth, and sixth payment year (2016, 2017 and 2018), if applicable, an EP or eligible hospital whose first payment year is 2013 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

We propose that EPs and eligible hospitals whose first payment year is 2014 must satisfy the Stage 1 criteria of meaningful use in their first payment year (2014) to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for their second payment year (2015), if applicable, an EP or eligible hospital whose first payment year is 2014 would have to satisfy the Stage 3 criteria of meaningful use to receive the incentive payments. For their third, fourth, fifth and sixth payment year (2016, 2017, 2018, and 2019), if applicable, an EP or eligible hospital whose first payment year is 2014 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for all their payment years, an EP or eligible hospital whose first payment year is 2015 would have to satisfy the Stage 3 criteria of meaningful use for 2015. For all subsequent payment years, if applicable, an EP or eligible hospital whose first payment year is 2015 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

In addition to the equitable concerns discussed earlier in the transition from incentive payments to payment adjustments, the primary reasoning for developing different stages of meaningful use is the current lack of HIT infrastructure and penetration of qualified EHRs necessary to support the ambitious goals of the Stage 3 criteria of meaningful use. Given the anticipated maturity of HIT infrastructure inherent in the strengthening criteria and the increased adoption of certified EHR technology predicted in section V. of this proposed rule, these barriers to meeting the Stage 3 criteria of meaningful use will be removed.

Table 1 outlines our proposal to apply the respective criteria of meaningful use for each payment year (1st, 2nd, 3rd, etc.) for EPs and eligible hospitals that

become meaningful EHR users before 2015. Please note that nothing in this discussion limits us to proposed changes to meaningful use beyond Stage 3 through future rulemaking.

TABLE 1—STAGE OF MEANINGFUL USE CRITERIA BY PAYMENT YEAR

First payment year	Payment year				
	2011	2012	2013	2014	2015 +**
2011	Stage 1	Stage 1	Stage 2	Stage 2	Stage 3.
2012		Stage 1	Stage 1	Stage 2	Stage 3.
2013			Stage 1	Stage 2	Stage 3.
2014				Stage 1	Stage 3.
2015+*					Stage 3.

* Avoids payment adjustments only for EPs in the Medicare EHR Incentive Program.
** Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking.

Please note that the number of payment years available and the last payment year that can be the first payment year for an EP or eligible hospital varies between the EHR incentive programs. The applicable payment years for each program are discussed in section II.B. of this proposed rule for the Medicare FFS EHR incentive program, in section II.D. for the MA EHR incentive program, and in section II.E. for the Medicaid EHR incentive program.

The stages of criteria of meaningful use and how they are demonstrated are described further in this proposed rule and will be updated in subsequent proposed rules to reflect advances in HIT products and infrastructure. This could include updates to the Stage 1 criteria in future rulemaking.

We invite comments on our alignment between payment year and the criteria of meaningful use particularly in regard to the need to create alignment across all EPs and eligible hospitals in all EHR incentive programs in 2015.

d. Stage 1 Criteria for Meaningful Use

To qualify as a meaningful EHR user for 2011, we propose that an EP or eligible hospital must demonstrate that they meet all of the objectives and their associated measures as set forth in § 495.6. Except as otherwise indicated, each objective must be satisfied by an individual EP as determined by unique National Provider Identifiers (NPIs) and an individual hospital as determined by unique CMS certification numbers (CCN). Below we describe each objective and its associated measures in detail. While we welcome comments on all aspects of the Stage 1 criteria of meaningful use, we specifically encourage comments on the following considerations.

While we believe that requiring satisfaction of all objectives is appropriate for the majority of providers, we are concerned that certain providers may have difficulty meeting one or more of the proposed objectives. We solicit comments on whether this may be the case, and invite commenters to identify the objectives and associated measures that may prove out of reach for certain provider types or specialties, and to suggest specific objective criteria we could use to determine whether an objective and associated measure is appropriate for different provider types or specialists.

In discussing the objectives that constitute the stage 1 criteria of meaningful use, we adopted a structure derived from recommendations of the HIT Policy Committee of grouping the objectives under care goals, which are in turn grouped under health outcomes policy priorities. We believe this structural grouping provides context to the individual objectives; however, the grouping is not itself an aspect of meaningful use. The criteria for meaningful use are based on the objectives and their associated measures. CMS and ONC have carefully reviewed the objectives and measures proposed by the HIT Policy Committee. We found many objectives to be well suited to meaningful use, while others we found to require modification or clarification. In our discussion we will focus on those areas where our proposal is a modification of the recommendation of the HIT Policy Committee. For those areas where we elected not to propose a modification to the recommendation of the HIT Policy Committee, we note that there already has been extensive public debate and explanation of these recommendations, which can be accessed at *http://healthit.hhs.gov/meaningfuluse*. Even if we do not propose to modify a specific recommendation of the HIT Policy Committee, we nevertheless welcome comment on whether to do so in the final rule.

(1) Objectives

The first health outcomes policy priority specified by the HIT Policy Committee is improving quality, safety, efficiency and reducing health disparities. The HIT Policy Committee identified the following care goals to address this priority:

- Provide access to comprehensive patient health data for patient's healthcare team.
- Use evidence-based order sets and computerized provider order entry (CPOE).
- Apply clinical decision support at the point of care.
- Generate lists of patients who need care and use them to reach out to those patients.
- Report information for quality improvement and public reporting.

With respect to this last care goal, the HIT Policy Committee proposed a goal of "Report to patient registries for quality improvement, public reporting, etc." We propose to modify this care goal because we believe that patient registries are too narrow a reporting requirement to accomplish the goals of quality improvement and public reporting. We note that the HIT Policy Committee's recommended objectives include the reporting of quality measures to CMS. We do not believe that CMS would normally be considered a "patient registry." We also removed the phrase "etc." We believe that the level of ambiguity created by "etc." is not appropriate for Federal regulations.

For EPs, we propose the following objectives in the Stage 1 criteria of meaningful use to further the care goal of improving quality, safety, efficiency and reducing health disparities.

- Use CPOE. We believe that the term "CPOE" requires additional clarification. We propose to define CPOE as entailing the provider's use of computer assistance to directly enter medical orders (for example, medications,

consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is also documented or captured in a digital, structured, and computable format for use in improving safety and organization. For Stage 1 criteria, we propose that it will not include the electronic transmittal of that order to the pharmacy, laboratory, or diagnostic imaging center. We encourage comments on whether additional specificity is required on the types of orders encompassed within CPOE.

• Implement drug-drug, drug-allergy, drug-formulary checks.

• Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT®.

We believe the term "problem list" requires additional clarification. We describe a "problem list" as a list of current and active diagnoses as well as past diagnoses relevant to the current care of the patient.

• Generate and transmit permissible prescriptions electronically (eRx).

The concept of only permissible prescriptions refers to the current restrictions established by the Department of Justice on electronic prescribing for controlled substances. (The restrictions can be found at *http://www.deadiversion.usdoj.gov/schedules/schedules.htm*.)

• Maintain active medication list.

• Maintain active medication allergy list.

• Record the following demographics: Preferred language, insurance type, gender, race and ethnicity, and date of birth.

We note that race and ethnicity codes should follow current federal standards published by the Office of Management and Budget (*http://www.whitehouse.gov/omb/inforeg_statpolicy/#dr*).

• We do not propose to include the objective "Record Advance directives."

The HIT Policy Committee recommended that EPs "record advance directives." It is unclear whether by this terminology they meant that the contents of the advance directive be recorded or merely the fact that a patient has an advance directive be noted. Depending on the interpretation, this objective could interfere with current State law which varies significantly from State to State in this matter. We also believe that this objective is only relevant to a limited and undefined patient population when compared to the patient populations to which other objectives listed here apply. The limits could be based on age, health status, whether a chronic condition is present, to patients scheduled for certain types of procedures or a host of other factors. Similarly, many EPs would not record this information under current standards of practice. Dentists, pediatricians, optometrists, chiropractors, dermatologists, and radiologists are just a few examples of EPs who would only in rare circumstances require information about a patient's advance directive. For these reasons, we do not propose to include "Record advance directives" as an objective of the Stage 1 criteria of meaningful use for EPs.

• Record and chart changes in the following vital signs: Height, weight and blood pressure and calculate and display body mass index (BMI) for ages 2 and over; plot and display growth charts for children 2–20 years, including BMI.

This is a modification to the HIT Policy Committee recommendation to require eligible professionals to record vital signs: Height, weight, blood pressure and calculate BMI. We added "plot and display growth charts for children 2–20 years, including BMI" to the objective recommended by the HIT Policy Committee, as BMI itself does not provide adequate information for children. Trends in height, weight, and BMI among children must be interpreted and understood in the context of expected parameters of children of the same age and sex to determine whether the child is growing appropriately. For example, a BMI of 18 is normal for a 12-year-old boy, and a marker of obesity for a 5-year-old (*http://www.cdc.gov/growthcharts/data/set1clinical/cj411023.pdf*).

• Record smoking status for patients 13 years old or older.

The HIT Policy Committee recommended the objective of recording smoking status for patients. We propose to add "for patients 13 years old or older," as we do not believe this objective is applicable to patients of all ages and there is not consensus in the health care community as to what the appropriate cut off age may be. We encourage comments on whether this age limit should be lowered or raised.

• Incorporate clinical lab-test results into EHR as structured data. Structured data are data that have specified data type and response categories within an electronic record or file.

• Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach.

• Report ambulatory quality measures to CMS (or, for EPs seeking the Medicaid incentive payment, the States). The HIT Policy Committee did not include "or the States" in its recommended objective. We propose to add the option to report directly to the States for EPs participating in the Medicaid EHR incentive program. Additional discussion of this objective can be found in section II.A.3 of this proposed rule.

• Send reminders to patients per patient preference for preventive/follow-up care. Patient preference refers to the patient's choice of delivery method between internet based delivery or delivery not requiring internet access.

• Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.

This is a modification to the HIT Policy Committee recommendation to require EPs to implement one clinical decision support rule relevant to specialty or high clinical priority. We made this change to align with and support eligible professionals in reporting their clinical quality measures proposed in section II.A.3. of this proposed rule. We anticipate that EPs will report on at least five clinical quality measures.

We propose to describe clinical decision support as health information technology functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care.

• We do not propose to include the objective "Document a progress note for each encounter". Documentation of progress notes is a medical-legal requirement and a component of basic EHR functionality, and is not directly related to advanced processes of care or improvements in quality, safety, or efficiency.

Finally, the HIT Policy Committee further recommended the following two objectives related to administrative simplification. Consistent with that recommendation—and consistent with any forthcoming statutory requirements regarding administrative simplifications—we propose the following objectives, with slight modification.

• Check insurance eligibility electronically from public and private payers. Deleted "where possible" from the HIT Policy Committee recommendation. The checking for

eligibility electronically is already a HIPAA Standard Exchange.

• Submit claims electronically to public and private payers.

For eligible hospitals, we propose the following objectives in the stage 1 criteria of meaningful use to further these care goals:

• Use CPOE for orders (any type) directly entered by the authorizing provider (for example, MD, DO, RN, PA, NP).

We believe that the term "CPOE" requires additional clarification. We propose to define CPOE as entailing the provider's use of computer assistance to directly enter medical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is also documented or captured in a digital, structured, and computable format for use in improving safety and organization. It does not include the electronic transmittal of that order to the pharmacy, laboratory, or diagnostic imaging center in 2011 or 2012. CPOE is the same as defined above for EPs. We welcome comment on whether use of CPOE varies between hospitals and EPs in ways that should be addressed.

• Implement drug-drug, drug-allergy, drug-formulary checks.

• Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT®.

We believe the term "problem list" requires additional clarification. We describe a "problem list" as a list of current and active diagnoses, as well as past diagnoses relevant to the current care of the patient.

• Maintain active medication list.

• Maintain active medication allergy list.

• Record the following demographics: preferred language, insurance type, gender, race and ethnicity, date of birth, and date and cause of death in the event of mortality.

We are interested in public comments on how States and hospitals could work together to facilitate linkage between the EHR and the full birth and death certificate information that States currently require hospitals to collect. We note that race and ethnicity codes should follow current federal standards published by the Office of Management and Budget (*http://www.whitehouse.gov/omb/inforeg_statpolicy/#dr*).

• We do not propose to include the objective "Record Advance directives." The HIT Policy Committee recommended that eligible hospitals "record advance directives." It is unclear whether by this terminology they meant that the contents of the advance directive be recorded or merely the fact that a patient has an advance directive be noted. Depending on the interpretation, this objective could interfere with current State law which varies significantly from state to state in this matter. We also believe that this objective is only relevant to a limited and undefined patient population when compared to the patient populations to which other objectives listed here apply. The limits could be based on age, health status, whether a chronic condition is present, to patients scheduled for certain types of procedures or a host of other factors. For these reasons, we do not propose to include "Record advance directives" as an objective of the Stage 1 criteria of meaningful use for eligible hospitals.

• Record the following vital signs: height, weight and blood pressure and calculate and display body mass index (BMI) for patients 2 and over; plot and display growth charts for children 2–20 years, including BMI.

We added "plot and display growth charts for children 2–20 years, including BMI" to the objective recommended by the HIT Policy Committee, as BMI itself does not provide adequate information for children. Trends in height, weight, and BMI among children must be interpreted and understood in the context of expected parameters of children of the same age and sex to determine whether the child is growing appropriately. For example, a BMI of 18 is normal for a 12-year-old boy, and a marker of obesity for a 5-year-old (ref. *http://www.cdc.gov/growthcharts/data/set1clinical/cj41l023.pdf*).

• Record smoking status for patients 13 years old or older.

We added "for patients 13 years old or older" as this objective is not applicable to patients of all ages. The discussion as to why we chose 13 can be found under the EP objective for "Record smoking status".

• Incorporate clinical lab-test results into EHR as structured data. Structured data are data that have specified data type and response categories within a record or file.

• Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach.

The HIT Policy Committee did not recommend the phrase "to use for quality improvement, reduction of disparities, and outreach" for eligible hospitals as they did for EPs. We believe this aspect of the objective is just as relevant to eligible hospitals as EPs and therefore includes it for both. We invite comments as to why this phrase may not be applicable to eligible hospitals.

• Report ambulatory quality measures to CMS (or, for eligible hospitals seeking the Medicaid incentive payment, the States). The HIT Policy Committee did not include "or the States" in their recommended objective. We propose to add the option to report directly to the States for Medicaid eligible hospitals participating in the Medicaid EHR incentive program. Additional discussion can be found in section II.A.3. of this proposed rule.

• Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.

This is a modification to the HIT Policy Committee recommendation to require eligible professionals to implement one clinical decision support rule relevant to specialty or high clinical priority. We made this change to align with and support eligible professionals in reporting their clinical quality measures proposed in section II.A.3. of this proposed rule. We anticipate that most EPs will report on at least five clinical quality measures from section II.A.3 of this proposed rule and eligible hospitals will all report on at least five.

We believe greater clarification is required around the term clinical decision support. We propose to describe clinical decision support as health information technology functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care.

Finally, the HIT Policy Committee further recommended the following two objectives related to administrative simplification. Consistent with that recommendation—and consistent with any forthcoming statutory requirements regarding administrative simplifications—we propose the following objectives, with slight modification.

• Check insurance eligibility electronically from public and private payers. Deleted "where possible" from the HIT Policy Committee recommendation. The checking for eligibility electronically is already a HIPAA Standard Exchange.

• Submit claims electronically to public and private payers.

The second health outcomes policy priority identified by the HIT Policy

Committee is to engage patients and families in their healthcare. The following care goal for meaningful use addresses this priority:

• Provide patients and families with timely access to data, knowledge, and tools to make informed decisions and to manage their health. We do not propose to preempt any existing Federal or State law regarding the disclosure of information to minors, their parents, or their guardians in setting the requirements for meaningful use. For this reason when it comes to information provided to the family, we let existing Federal and State laws dictate what is appropriate for disclosure to the patient or the family. For purposes of all objectives of the Stage 1 criteria of meaningful use involving the disclosure of information to a patient, a disclosure made to a family member or a patient's guardian consistent with Federal and State law may substitute for a disclosure to the patient.

For EPs, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

• Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, allergies) upon request.

Consistent with the HIT Policy Committee's recommendations, we propose the following additional clarification of this objective. Electronic copies may be provided through a number of secure electronic methods (for example, personal health record (PHR), patient portal, CD, USB drive).

• Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP.

Also, consistent with the HIT Policy Committee recommendations, we propose the following additional clarification of this objective. Electronic access may be provided by a number of secure electronic methods (for example, PHR, patient portal, CD, USB drive). Timely is defined as within 96 hours of the information being available to the EP either through the receipt of final lab results or a patient interaction that updates the EP's knowledge of the patient's health. We judge 96 hours to be a reasonable amount of time to ensure that certified EHR technology is up to date. We welcome comment on if a shorter or longer time is advantageous.

• We do not propose to include the objective "Provide access to patient-specific education resources upon request." Providing patients with information and education that is relevant to their condition, actionable, culturally competent, and of the appropriate health literacy level is a critical component of patient engagement and empowerment. Unfortunately, there is currently a paucity of knowledge resources that are integrated within EHRs, that are widely available, and that meet these criteria, particularly in multiple languages. We intend to work with the policy committee, the National Library of Medicine (provider of Medline Plus), and experts in this area to ensure the feasibility of this measure in the future.

• Provide clinical summaries for patients for each office visit.

Changed from encounter to office visit. The HIT Policy Committee recommended the objective "Provide clinical summaries for patients for each encounter." We believe this objective requires further clarification in order to make the distinction that it is not meant to apply to alternative encounters such as telephone or Web visits. As a result, we propose to revise this objective to "Provide clinical summaries for patients for each office visit."

For eligible hospitals, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

• Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request. Consistent with the HIT Policy Committee's recommendations, we propose the following additional clarification of this objective. Electronic copies may be provided through a number of secure electronic methods (for example, Personal Health Record (PHR), patient portal, CD, USB drive).

• Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

Also, consistent with the HIT Policy Committee recommendations, we propose the following additional clarification of this objective. Electronic access may be provided by a number of secure electronic methods (for example, PHR, patient portal, CD, USB drive).

• We do not propose to include the objective "Provide access to patient-specific education resources upon request." Providing patients with information and education that is relevant to their condition, actionable, culturally competent, and of the appropriate health literacy level is a critical component of patient engagement and empowerment. Unfortunately, there is currently a paucity of knowledge resources that are integrated within EHRs, that are widely available, and that meet these criteria, particularly in multiple languages. We intend to work with the policy committee, the National Library of Medicine (provider of Medline Plus), and experts in this area to ensure the feasibility of this measure in the future.

The third health outcomes policy priority identified by the HIT Policy Committee is to improve care coordination. The HIT Policy Committee recommended the following care goals to address this priority:

• Exchange meaningful clinical information among professional health care team.

For EPs and eligible hospitals, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

• Capability to exchange key clinical information (for example, problem list, medication list, allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.

By "diagnostic test results" we mean all data needed to diagnose and treat disease, such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, and pulmonary function tests. Where available in structured electronic format (for example, drug and clinical lab data), we expect that this information would be exchanged in electronic format. However, where the information is available only in unstructured electronic formats (for example, free text and scanned images), we would allow the exchange of unstructured information. Patient authorized entities could include any individual or organization to which the patient has granted access to their clinical information. Examples would include an insurance company that covers the patient or a personal health record vendor identified by the patient.

• Perform medication reconciliation at relevant encounters and each transition of care.

We believe greater clarification is needed around the term "medication reconciliation". Public input received by the NCVHS Executive Subcommittee and the HIT Policy Committee and our prior experiences indicate confusion in the healthcare industry as to what constitutes medication reconciliation. We propose to describe 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. Also we would clarify transition of care as transfer of a patient from one clinical setting (inpatient, outpatient, physician office, home health, rehab, long-term care facility, etc.) to another or from one EP or eligible hospital (as defined by CCN) to another. A relevant encounter would be any encounter that the EP or eligible hospital judges performs a medication reconciliation due to new medication or long gaps in time between patient encounters or other reasons determined by the EP or eligible hospital. We encourage comments on whether our descriptions of "transition of care" and "relevant encounter" are sufficiently clear and medically relevant.

• Provide summary care record for each transition of care or referral.

This objective was not explicitly included in the HIT Policy Committee's recommended objectives. However, they did include a measure for the "percent of transitions in care for which summary care record is shared. We believe that in order for a measure to be relevant it must correspond to an objective in the definition of meaningful use. Therefore, we propose to add this objective in order to be able to include the recommended measure. Furthermore, we add referrals because the sharing of the patient care summary from one provider to another communicates important information that the patient may not have been able to provide, and can significantly improve the quality and safety of referral care, and reduce unnecessary and redundant testing.

The fourth health outcomes policy priority identified by the HIT Policy Committee is improving population and public health. The HIT Policy Committee identified the following care goal to address this priority:

• The patient's health care team communicates with public health agencies. The goal as recommended by the HIT Policy Committee is "communicate with public health agencies." We found this goal to be somewhat ambiguous, as it does not specify who must communicate with public health agencies. We propose to specify "the patient's health care team" as who would communicate with public health agencies.

For EPs, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

• Capability to submit electronic data to immunization registries and actual submission where possible and accepted.

• Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

For eligible hospitals, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

• Capability to submit electronic data to immunization registries and actual submission where required and accepted.

• Capability to provide electronic submission of reportable (as required by state or local law) lab results to public health agencies and actual submission where it can be received.

• Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

The fifth health outcomes policy priority is to ensure adequate privacy and security protections for personal health information. The following care goals for meaningful use address this priority:

• Ensure privacy and security protections for confidential information through operating policies, procedures, and technologies and compliance with applicable law.

• Provide transparency of data sharing to patient.

For EPs and eligible hospitals, we propose the following objective in the stage 1 criteria of meaningful use to further these care goals:

• Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

This objective is different from the two objectives recommended by the HIT Policy Committee. Those objectives were "Compliance with HIPAA Privacy and Security Rules" and "Compliance with fair data sharing practices set forth in the Nationwide Privacy and Security Framework". While we presume that the HIT Policy Committee is referring to the certified EHR technology and its use being in compliance with the HIPAA Privacy and Security Rules, it is not explicit. Compliance with HIPAA privacy and security rules is required for all covered entities, regardless of whether they participate in the EHR incentive programs or not. Furthermore, compliance constitutes a wide range of activities, procedures, and infrastructure. We propose to rephrase the objective to ensure that meaningful use of the certified EHR technology supports compliance with the HIPAA Privacy and Security Rules and compliance with fair sharing data practices outlined in the Nationwide Privacy and Security Framework (*http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848088_0_0_18/NationwidePS_Framework-5.pdf*), but do not believe meaningful use of certified EHR technology is the appropriate regulatory tool to ensure such compliance with the HIPAA Privacy and Security Rules.

(2) Health IT Functionality Measures

In order for an EP or an eligible hospital to demonstrate that it meets these proposed objectives, we believe a measure is necessary for each objective. To provide structure to these measures, we group the measures into two categories: Health IT functionality measures and clinical quality measures. The health IT functionality measures are discussed in this section, while the clinical quality measures are discussed in section II.A.3 of this proposed rule.

Without a measure for each objective, we believe that the definition of meaningful use becomes too ambiguous to fulfill its purpose. The use of measures also creates the flexibility to account for realities of current HIT products and infrastructure and the ability to account for future advances. The HIT Policy Committee did recommend some measures; however, they did not explicitly link each measure to an objective. Therefore, the proposed measures set forth below are a significant departure from the recommendation of the HIT Policy Committee.

For each of these measures utilizing a percentage and the reporting of clinical quality measures, we propose at § 495.10 that EPs and eligible hospitals submit numerator and denominator information to CMS. We invite comment on our burden estimates associated with reporting these measures (see section III. of this proposed rule).

EP Objective: Use CPOE.

EP Measure: CPOE is used for at least 80 percent of all orders.

CPOE is a capability included in the certification criteria for certified EHR technology (to be defined by the ONC in its upcoming interim final rule). We believe it is important to ensure that this capability is continuously utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate use of this capability once, but rather, an EP must utilize this capability as part of his or her daily work process.

We consider two methods of for measuring use of the CPOE functionality: the percentage of orders entered using CPOE or a count of orders entered using CPOE. To illustrate the difference, an example of measuring percentage use of the CPOE functionality would be 80 percent of all of an EP's orders were entered using the CPOE functionality of certified EHR technology during the EHR reporting period. An example of counting orders using the CPOE functionality would be requiring that the EP entered at least 100 orders using CPOE during the EHR reporting period. A count of orders entered using CPOE would be easier to document than a percentage of orders, as an EP would only have to count the number of times he or she entered an order using CPOE, as opposed to tabulating both when he or she did so and when he or she failed to do so. However, a count does not enable variations between EPs to be accounted for. For instance, a count-based measurement would not take into consideration differences in patient volume among EPs, which may be a concern to those EPs with a low patient volume. A percentage-based measurement would account for variations in volume and would allow for a more revealing measurement of an EP's individual performance in meeting the objective. Therefore, we are proposing that an EP's successful completion of this objective be based on a percentage.

To calculate the percentage, CMS and ONC have worked together to define the following:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is orders issued by the EP entered using the CPOE functionality of certified EHR technology during the EHR reporting period. The denominator for this objective is all orders issued by the EP during the EHR reporting period. These are orders issued by an EP for both their Medicare/Medicaid population and all other patients. We believe it is unlikely that an EP would use one record keeping system for one patient population and another system for another patient population at one location. Requiring reporting differences based on payers would actually increase the burden of meeting meaningful use. We are concerned about the application of this denominator for EPs who see patients in multiple practices or multiple locations. If an EP does not have certified EHR technology available at each location/practice where they see patients it could become impossible to reach the thresholds set for measuring the objectives. We do not seek to exclude EPs who meaningfully use certified EHR technology when it is available because they also provide care in another practice where certified EHR technology is not available. Therefore we are proposing all measures be limited to actions taken at practices/locations equipped with certified EHR technology. A practice is equipped if certified EHR technology is available at the beginning of the EHR reporting period for a given location. Equipped does not mean the certified EHR technology is functioning on any given day in the EHR reporting period. Allowances for downtime and other technical issues with certified EHR technology are made in the establishment of the measure thresholds. We are concerned that seeing a patient without certified EHR technology available does not advance the health care policy priorities of the definition of meaningful use. We are also concerned about possible inequality between EPs receiving the same incentive, but using certified EHR technology for different proportions of their patient population. We believe that an EP would have the greatest control of whether certified EHR technology is available in the practice in which they see the greatest proportion of their patients. We are proposing that to be a meaningful EHR user an EP must have 50 percent or more of their patient encounters during the EHR reporting period at a practice/location or practices/locations equipped with certified EHR technology. An EP for who does not conduct 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. While control is less assured in this situation, CMS still needs to advance the health care priorities of the definition of meaningful use and provide some level of equity. We invite comments as to whether this denominator is feasible to obtain for EPs, whether this exclusion (the denominator for patients seen when certified EHR technology is not available) is appropriate, whether a minimum threshold is necessary and whether 50 percent is an appropriate threshold. We note that in evaluating the 50 percent threshold, our proposal is to review all locations/organizations at which an EP practices. So, for example, if the EP practices at both an FQHC and within his or her individual practice, we would include in our review both of these locations.

As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of information, we believe it would be appropriate to set a high percentage threshold. We therefore propose to set the percentage required for successful demonstration at 80 percent. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

For other objectives that are reliant on the electronic exchange of information, we are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is not yet currently available. We anticipate raising the threshold for these objectives in future definitions of meaningful use as the capabilities of HIT infrastructure increases. The intent and policy goal with raising this threshold is to ensure that meaningful use encourages patient-centric, interoperable health information exchange across provider organizations regardless of provider's business affiliation or EHR platform.

Eligible Hospital Objective: Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP).

Eligible Hospital Measure: CPOE is used for at least 10 percent of all orders.

To calculate the percentage, CMS and ONC have worked together to define the following:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is orders entered in an inpatient facility/department that falls under the eligible hospital's CCN and by an authorized provider using CPOE functionality of certified EHR technology during the EHR reporting period. Inpatient facility/department is defined by the place of service code 21. Further discussion about POS 21 is available at section II.A.6. of this proposed rule and at *http://www.cms.hhs.gov/PlaceofServiceCodes/.* The denominator for this objective is all orders entered in an inpatient facility/department that falls under the eligible hospital's CCN and issued by the authorized providers in the hospital during the EHR reporting period. These are orders are those issued are for both their Medicare/Medicaid population and all other

patients. The rationale for the establishment of this measure is identical to that of the EP, except in the establishment of the threshold percentage. In considering CPOE, the HIT Policy Committee did specify this lower percentage (10 percent) for eligible hospitals. Public input described previously in this proposed rule indicated that CPOE is traditionally one of the last capabilities implemented at hospitals. Also, many hospitals choose to implement one department at a time. Detailed comments can be found at *http://healthit.hhs.gov/meaningfuluse.* For these reasons the HIT Policy Committee recommended this lower threshold. We agree with the lower threshold for the same reasons.

EP/Eligible Hospital Objective: Implement drug-drug, drug-allergy, drug-formulary checks.

EP/Eligible Hospital Measure: The EP/eligible hospital has enabled this functionality.

The capability of conducting automated drug-drug, drug-allergy, and drug-formulary checks is included in the certification criteria for certified EHR technology (to be determined by ONC in its upcoming interim final rule). This automated check provides information to advise the EP or eligible hospital's decisions in prescribing drugs to a patient. The only action taken by the EP or eligible hospital is to consider this information. Many current EHR technologies have the option to disable these checks and the certification process does not require the removal of this option. Therefore, in order to meet this objective, an EP or eligible hospital would be required to enable this functionality. While this does not ensure that an EP or an eligible hospital is considering the information provided, it does ensure that the information is available.

EP/Eligible Hospital Objective: Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT®.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry or an indication of none recorded as structured data.

The capability to maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT® is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or an eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by an EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period that have at least one ICD–9–CM or SNOMED CT® -coded entry or an indication of none in the problem list. A unique patient means that even if a patient is seen multiple times during the EHR reporting period they are only counted once. The reason we propose to base the measure on unique patients as opposed to every patient encounter, is that a problem list would not necessarily have to be updated at every visit. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP Objective: Generate and transmit permissible prescriptions electronically (eRx).

EP Measure: At least 75 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.

The capability to generate and transmit permissible prescriptions electronically is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of prescriptions for other than controlled substances generated and transmitted electronically during the EHR reporting period. The denominator for this objective is the number of prescriptions written for other than controlled substances during the EHR reporting period. While this measure does rely on the electronic exchange of information based on the public input previously discussed and our own experiences with e-Rx programs, we believe this is the most robust electronic exchange currently occurring and propose 75 percent as an achievable threshold for the Stage 1 criteria of meaningful use. Though full compliance (that is, 100 percent) is the ultimate goal, 75 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Maintain active medication list.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients seen by the EP or admitted by the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data.

The capability to maintain an active medication list is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.

- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data in their medication list. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Maintain active medication allergy list.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry (or an indication of "none" if the patient has no medication allergies) recorded as structured data.

The capability to maintain an active medication allergy list using structured data is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have at least one entry (or an indication of "none") recorded as structured data in their medication allergy list. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Record demographics.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data.

The capability to record demographics as structured data is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have all required demographic elements (preferred language, insurance type, gender, race, and ethnicity, date of birth and, for hospitals, date and cause of death in the case of mortality) recorded as structured data in their electronic record. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs.

EP/Eligible Hospital Objective: Record and chart changes in vital signs.

EP/Eligible Hospital Measure: For at least 80 percent of all unique patients age 2 and over seen by the EP or admitted to the eligible hospital, record blood pressure and BMI; additionally, plot growth chart for children age 2 to 20.

The capability to record vital signs is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients age 2 and over seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have a record of their blood pressure, and BMI (growth chart for children 2–20) in their record. A unique patient is discussed under the objective of maintaining an up-to-date problem

list. The denominator for this objective is the number of unique patients age 2 or over seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Record smoking status for patients 13 years old or older.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital have "smoking status" recorded.

The capability to record smoking status is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients age 13 or older seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have a record of their smoking status. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients age 13 or older seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE by the EP. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Incorporate clinical lab-test results into EHR as structured data.

EP/Eligible Hospital Measure: At least 50 percent of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital during the EHR reporting period whose results are in either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

The capability to incorporate lab-test results is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of lab tests ordered during the EHR reporting period by the EP or authorized providers of the eligible hospital for patients admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN whose results are expressed in a positive or negative affirmation or as a number and are incorporated as structured data into certified EHR technology. The denominator for this objective is the number of lab tests ordered during the EHR reporting period by the EP or authorized providers of the eligible hospital for patients admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN whose results are expressed in a positive or negative affirmation or as a number. This objective is reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, we believe that 80 percent is too high a threshold for the Stage 1 criteria of meaningful use. We propose 50 percent as the threshold based on our discussions with EHR vendors, current EHR users, and laboratories. We invite comment on whether this 50 percent is feasible for the Stage 1 criteria of meaningful use. We anticipate raising the threshold for this objective in future stages of the criteria of meaningful use as the capabilities of HIT infrastructure increases.

EP/Eligible Hospital Objective: Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach.

EP/Eligible Hospital Measure: Generate at least one report listing patients of the EP or eligible hospital with a specific condition.

The capability to generate lists of patients by specific conditions is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective an EP or eligible hospital should utilize this capability at least once during the EHR reporting period so this information would be available to them for their use. An EP or eligible hospital 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, but rather to require EPs and hospitals to attest to the ability of the EP or eligible hospital to do so and to attest that they have actually done so at least once.

EP Objective: Report ambulatory quality measures to CMS or the States.

EP Measure: For 2011, an EP would provide the aggregate numerator and denominator through attestation as discussed in section II.A.3 of this proposed rule. For 2012, an EP would electronically submit the measures are discussed in section II.A.3. of this proposed rule.

Eligible Hospital Objective: Report hospital quality measures to CMS or the States.

Eligible Hospital Measure: For 2011, an eligible hospital would provide the aggregate numerator and denominator

through attestation as discussed in section II.A.3 of this proposed rule. For 2012, an eligible hospital would electronically submit the measures are discussed in section II.A.3. of this proposed rule.

EP Objective: Send reminders to patients per patient preference for preventive/follow-up care.

EP Measure: Reminder sent to at least 50 percent of all unique patients seen by the EP or admitted to the eligible hospital that are 50 and over.

The capability to generate reminders for preventive/follow-up care is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective an EP must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients age 50 or over seen by the EP during the EHR reporting period who are provided reminders. A unique patient is discussed under the objective of maintaining an up-to-date problem list. We propose to limit the patient population for this measure to patients age 50 or over as they are more likely than the norm to require additional preventive or follow-up care. The denominator for this objective is the number of unique patients seen by the EP during the EHR reporting period. We propose to set the percentage required for successful demonstration at 50 percent. While the objective relies on a capability included as part of certified EHR technology there is still the added component of determining patient preference. Also while we believe we greatly increase the likelihood that additional preventive or follow up care will be required by limiting the patient population to age 50 or over, there may still be instances where there is not an additional preventive or follow up care step needed. For these reasons, we propose the lower threshold of 50 percent. We specifically invite comments on whether limiting the patient population by age is the best approach.

EP/Eligible Hospital Objective: Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.

EP/Eligible Hospital Measure: Implement five clinical decision support rules relevant to the clinical quality metrics the EP/Eligible Hospital is responsible for as described further in section II.A.3.

The capability to provide clinical decision support is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Clinical decision support at the point of care is a critical aspect of improving quality, safety, and efficiency. Research has shown that decision support must be targeted and actionable to be effective, and that "alert fatigue" must be avoided. Establishing decision supports for a small set of high priority conditions, ideally linked to quality measures being reported, is feasible and desirable. Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective an EP or eligible hospital should implement five clinical decision support rules relevant to the clinical quality metrics described in section II.A.3 before the end of the EHR reporting period and attest to that implementation.

EP/Eligible Hospital Objective: Check insurance eligibility electronically from public and private payers.

EP/Eligible Hospital Measure: Insurance eligibility checked electronically for at least 80 percent of all unique patients seen by the EP or admitted to an eligible hospital.

The capability to check insurance eligibility electronically is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period whose insurance eligibility is checked electronically. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period whose insurer allows for the electronic verification of eligibility. While this objective does rely on the electronic exchange of information this particular exchange is an established HIPAA standard transaction, therefore we propose to set the percentage required for successful demonstration at 80 percent. The additional reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Submit claims electronically to public and private payers.

EP/Eligible Hospital Measure: At least 80 percent of all claims filed electronically by the EP or the eligible hospital.

The capability to submit claims electronically to public and private payers is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of claims submitted

electronically using certified EHR technology for patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. The denominator for this objective is the number of claims filed seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. While this objective relies on the electronic exchange of information, nearly all public and private payers accept electronic claims. Given the advance state of this aspect of electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The additional reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP Objective: Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, and allergies) upon request.

Eligible Hospital Objective: Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, and procedures), upon request.

EP/Eligible Hospital Measure: At least 80 percent of all patients who request an electronic copy of their health information are provided it within 48 hours.

The capability to create an electronic copy of a patient's health information is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process. In addition, all patients have a right under ARRA to an electronic copy of their health information. This measure seeks to ensure that this requirement is met in a timely fashion. Providing patients with an electronic copy of their health information demonstrates one of the many benefits health information technology can provide and we believe that it is an important part of becoming a meaningful EHR user. We also believe that certified EHR technology will provide EPs and eligible hospitals more efficient means of providing copies of health information to patients which is why we have proposed that a request for an electronic copy be provided to the patient within 48 hours.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period that request an electronic copy of their health information and receive it within 48 hours. The denominator for this objective is the number of patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN who request an electronic copy of their health information during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of structured information between health care providers, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

Eligible Hospital Objective: Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

Eligible Hospital Measure: At least 80 percent of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it.

The capability to produce an electronic copy of discharge instructions and procedures is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective an eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of patients discharged from an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period that request an electronic copy of their discharge instructions and procedures and receive it. The denominator for this objective is the number of patients discharged from an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN who request an electronic copy of their discharge instructions and procedures during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange between health care providers of structured information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP Objective: Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies).

EP Measure: At least 10 percent of all unique patients seen by the EP are provided timely electronic access to their health information

The capability to provide timely electronic access to health information is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen during the EHR reporting period who have timely, electronic access to their health information (for example, have established a user account and password on a patient portal). A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen during the EHR reporting period. We recognize that many patients may not have internet access, may not be able or interested to use a patient portal. Health systems that have actively promoted such technologies have been able to achieve active use by over 30 percent of their patients, but this may not be realistic for many practices in the short term.

EP Objective: Provide clinical summaries to patients for each office visit.

EP Measure: Clinical summaries provided to patients for at least 80 percent of all office visits.

The capability to provide a clinical summary is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen in the office during the EHR reporting period who are provided a clinical summary of their visit. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The clinical summary can be provided through a PHR, patient portal on the Web site, secure e-mail, electronic media such as CD or USB fob, or printed copy. The after-visit clinical summary contains an updated medication list, laboratory and other diagnostic test orders, procedures and other instructions based on clinical discussions that took place during the office visit. The denominator for this objective is the number of unique patients seen in the office during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of structured information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP Objective: Capability to exchange key clinical information (for example, problem list, medication list, allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.

Eligible Hospital Objective: Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically.

EP/Eligible Hospital Measure: Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

The capability to send key clinical information electronically is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we propose that EPs and eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. If multiple EPs are using the same certified EHR technology in a shared physical setting, the testing would only have to occur once for a given certified EHR technology, as we do not see any value to running the same test multiple times just because multiple EPs use the same certified EHR technology. To be considered an "exchange" in this section alone the clinical information must be sent between different clinical entities with distinct certified EHR technology and not between organizations that share a certified EHR.

EP/Eligible Hospital Objective: Perform medication reconciliation at relevant encounters and each transition of care.

EP/Eligible Hospital Measure: Perform medication reconciliation for at least 80 percent of relevant encounters and transitions of care.

The capability to perform medication reconciliation is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of relevant encounters and transitions of care for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was a participant during the EHR reporting period where medication reconciliation was performed. Relevant encounter and transition of care are defined in the previous discussion of this objective in this proposed rule. The denominator for this objective is the number of relevant encounters and transitions of care for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was a participant during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for the purposes of Stage 1 criteria, reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is

the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Provide summary care record for each transition of care and referral.

EP/Eligible Hospital Measure: Provide summary of care record for at least 80 percent of transitions of care and referrals.

The capability to provide a summary of care record is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of transitions of care and referrals for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was the transferring or referring provider during the EHR reporting period where a summary of care record was provided. Summary of care record and transitions of care are defined in the discussion of this objective in this proposed rule. The summary of care record can be provided through an electronic exchange, accessed through a secure portal, secure e-mail, electronic media such as CD or USB fob, or printed copy. The denominator for this objective is the number of transitions of care for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was the transferring or referring provider during the EHR reporting period. As this objective can be completed with or without the use of electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Capability to submit electronic data to immunization registries and actual submission where required and accepted.

EP/Eligible Hospital Measure: Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries.

The capability to send electronic data to immunization registries is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is reliant on the electronic exchange of information. We are cognizant that in many areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we propose that EPs and eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. EPs in a group setting using identical certified EHR technology would only need to conduct a single test, not one test per EP. More stringent requirements may be established for EPs and hospitals under the Medicaid program in states where this capability exists. This is just one example of a possible State proposed modification to meaningful use in the Medicaid EHR incentive program. States may propose any modification or addition to CMS in accordance with the discussion in II.A.2.c. of this proposed rule.

Eligible Hospital Objective: Capability to provide electronic submission of reportable lab results to public health agencies and actual submission where it can be received.

Eligible Hospital Measure: Performed at least one test of certified EHR technology capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically).

The capability to send reportable lab results is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we propose that eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. More stringent requirements may be established for hospitals under the Medicaid program in States where this capability exists. This is just one example of a possible State proposed modification to meaningful use in the Medicaid EHR incentive program. States may propose any modification or addition to CMS in accordance with the discussion in II.A.2.c. of this proposed rule.

EP/Eligible Hospital Objective: Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

EP/Eligible Hospital Measure: Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or eligible hospital submits such information have the capacity to receive the information electronically).

The capability to send electronic data to immunization registries is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we are proposing that EPs and eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. EPs in a group setting using identical certified EHR technology would only need to conduct a single test, not one test per EP. More stringent requirements may be established for EPs and hospitals under the Medicaid program in States where this capability exists. This is just one example of a possible State proposed modification to meaningful use in the Medicaid EHR incentive program. States may propose any

modification or addition to CMS in accordance with the discussion in II.A.2.c. of this proposed rule.

EP/Eligible Hospital Objective: Protect electronic health information maintained using certified EHR technology through the implementation of appropriate technical capabilities.

EP/Eligible Hospital Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary.

The capability to protect electronic health information maintained using certified EHR technology is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. While certified EHR technology provides tools for protecting health information, it is not a full protection solution. Processes and possibly tools outside the scope of certified EHR technology are required. Therefore, for the Stage 1 criteria of meaningful use we propose that EPs and eligible hospitals conduct or review a security risk analysis of certified EHR technology and implement updates as necessary at least once prior to the end of the EHR reporting period and attest to that conduct or review. The testing could occur prior to the beginning of the EHR reporting period. This is to ensure that the certified EHR technology is playing its role in the overall strategy of the EP or eligible hospital in protecting health information.

TABLE 2—STAGE 1 CRITERIA FOR MEANINGFUL USE

Health outcomes policy priority	Care goals	Stage 1 objectives		Stage 1 measures
		Eligible professionals	Hospitals	
Improving quality, safety, efficiency, and reducing health disparities.	Provide access to comprehensive patient health data for patient's health care team.	Use CPOE	Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP).	For EPs, CPOE is used for at least 80% of all orders. For eligible hospitals, CPOE is used for 10% of all orders.
	Use evidence-based order sets and CPOE.	Implement drug-drug, drug-allergy, drug-formulary checks.	Implement drug-drug, drug-allergy, drug-formulary checks.	The EP/eligible hospital has enabled this functionality.
	Apply clinical decision support at the point of care. Generate lists of patients who need care and use them to reach out to patients.	Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT®.	Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT®.	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry or an indication of none recorded as structured data.
	Report information for quality improvement and public reporting.	Generate and transmit permissible prescriptions electronically (eRx).		At least 75% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.
		Maintain active medication list.	Maintain active medication list.	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data.
		Maintain active medication allergy list.	Maintain active medication allergy list.	At least 80% of all unique patients seen, by the EP or admitted to the eligible hospital have at least one entry or (an indication of "none" if the patient has no medication allergies) recorded as structured data.
		Record demographics ○ preferred language ○ insurance type ○ gender ○ race ○ ethnicity ○ date of birth	Record demographics ○ preferred language ○ insurance type ○ gender ○ race ○ ethnicity ○ date of birth ○ date and cause of death in the event of mortality	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data.

TABLE 2—STAGE 1 CRITERIA FOR MEANINGFUL USE—Continued

Health outcomes policy priority	Care goals	Stage 1 objectives		Stage 1 measures
		Eligible professionals	Hospitals	
		Record and chart changes in vital signs: ○ height ○ weight ○ blood pressure ○ Calculate and display: BMI. ○ Plot and display growth charts for children 2–20 years, including BMI.	Record and chart changes in vital signs: ○ height ○ weight ○ blood pressure ○ Calculate and display: BMI. ○ Plot and display growth charts for children 2–20 years, including BMI.	For at least 80% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital, record blood pressure and BMI; additionally plot growth chart for children age 2–20.
		Record smoking status for patients 13 years old or older.	Record smoking status for patients 13 years old or older.	At least 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital have "smoking status" recorded.
		Incorporate clinical lab-test results into EHR as structured data.	Incorporate clinical lab-test results into EHR as structured data.	At least 50% of all clinical lab tests ordered whose results are in a positive/negative 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, and outreach.	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach.	Generate at least one report listing patients of the EP or eligible hospital with a specific condition.
		Report ambulatory quality measures to CMS or the States.	Report hospital quality measures to CMS or the States.	For 2011, provide aggregate numerator and denominator through attestation as discussed in section II(A)(3) of this proposed rule. For 2012, electronically submit the measures as discussed in section II(A)(3) of this proposed rule.
		Send reminders to patients per patient preference for preventive/follow up care.	.....	Reminder sent to at least 50% of all unique patients seen by the EP that are age 50 or over.
		Implement 5 clinical decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules.	Implement 5 clinical decision support rules related to a high priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules.	Implement 5 clinical decision support rules relevant to the clinical quality metrics the EP/Eligible Hospital is responsible for as described further in section II(A)(3).
		Check insurance eligibility electronically from public and private payers.	Check insurance eligibility electronically from public and private payers.	Insurance eligibility checked electronically for at least 80% of all unique patients seen by the EP or admitted to the eligible hospital.
		Submit claims electronically to public and private payers.	Submit claims electronically to public and private payers.	At least 80% of all claims filed electronically by the EP or the eligible hospital.
Engage patients and families in their health care.	Provide patients and families with timely access to data, knowledge, and tools to make informed decisions and to manage their health.	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies), upon request.	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request.	At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours.

TABLE 2—STAGE 1 CRITERIA FOR MEANINGFUL USE—Continued

Health outcomes policy priority	Care goals	Stage 1 objectives		Stage 1 measures
		Eligible professionals	Hospitals	
			Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.	At least 80% of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it.
		Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP.	.....	At least 10% of all unique patients seen by the EP are provided timely electronic access to their health information.
		Provide clinical summaries for patients for each office visit.	.....	Clinical summaries are provided for at least 80% of all office visits.
Improve care coordination.	Exchange meaningful clinical information among professional health care team.	Capability to exchange key clinical information (for example, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically.	Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically.	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.
		Perform medication reconciliation at relevant encounters and each transition of care.	Perform medication reconciliation at relevant encounters and each transition of care.	Perform medication reconciliation for at least 80% of relevant encounters and transitions of care.
		Provide summary care record for each transition of care and referral.	Provide summary care record for each transition of care and referral.	Provide summary of care record for at least 80% of transitions of care and referrals.
Improve population and public health.	Communicate with public health agencies.	Capability to submit electronic data to immunization registries and actual submission where required and accepted.	Capability to submit electronic data to immunization registries and actual submission where required and accepted.	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries.
			Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received.	Performed at least one test of the EHR system's capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically).
		Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.	Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or eligible hospital submits such information have the capacity to receive the information electronically).

TABLE 2—STAGE 1 CRITERIA FOR MEANINGFUL USE—Continued

Health outcomes policy priority	Care goals	Stage 1 objectives		Stage 1 measures
		Eligible professionals	Hospitals	
Ensure adequate privacy and security protections for personal health information.	Ensure privacy and security protections for confidential information through operating policies, procedures, and technologies and compliance with applicable law. Provide transparency of data sharing to patient.	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 per 45 CFR 164.308(a)(1) and implement security updates as necessary.

e. Request for Public Comment on Potential Health IT Functionality Measures for Eligible Professionals and Eligible Hospitals in 2013 Payment Year and Subsequent Years

As noted previously, we are cognizant that in most areas of the country, the infrastructure necessary to support the electronic exchange of structured information is not yet currently available. For that reason, we excluded the electronic exchange of structured information from many Stage 1 objectives or set relatively low performance thresholds for measures that do rely on the electronic exchange of structured data. For example, we set the threshold at 50 percent for the incorporation of lab data in structured format, and we excluded other types of diagnostic test data (for example, radiology reports, pathology reports, etc.) from that measure. We also excluded the transmission of orders from the definition of "CPOE use" for Stage 1 criteria.

In future rulemaking (for example, for Stage 2 and Stage 3 criteria), however, we anticipate raising the threshold for these objectives as the capabilities of HIT infrastructure increases. We also anticipate redefining our objectives to include not only the capturing of data in electronic format but also the exchange (both transmission and receipt) of that data in increasingly structured formats. The intent and policy goal with raising these thresholds and expectations is to ensure that meaningful use encourages patient-centric, interoperable health information exchange across provider organizations regardless of provider's business affiliation or EHR platform.

We specifically intend to build up the following health IT functionality measures for Stage 2 meaningful use criteria:

- "CPOE use" will include not only the percentage of orders entered directly by providers through CPOEs but also the electronic transmission of those orders;
- "Incorporate clinical lab-test results into EHR as structured data" will be expanded to include the full array of diagnostic test data used for the treatment and diagnosis of disease, where feasible, including blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, and pulmonary function tests;
- Measures that currently allow the provision and exchange of unstructured data (for example, the provision of clinical care summaries on paper) will require the provision and exchange of electronic and structured data, where feasible;
- Measures that currently require the performance of a capability test (for example, capability to provide electronic syndromic surveillance data to public health agencies) will be revised to require the actual submission of that data;

We invite comment on our intent to propose the above measure for Stage 2 in future rulemaking and also invite comment on any other health IT functionality measures not included in this list.

3. Sections 4101(a) and 4102(a)(1) of HITECH Act: Reporting on Clinical Quality Measures Using EHRs by EPs and Eligible Hospitals

a. General

As discussed in the meaningful use background section, there are three elements of meaningful use. In this section, we discuss the third requirement using its certified EHR technology, the EP or eligible hospital submits to the Secretary, in a form and manner specified by the Secretary, information for the EHR reporting period on clinical quality measures and other measures specified by the Secretary. The submission of other measures is discussed in section II.A.2.d.2 of this proposed rule and the other two requirements are discussed in section II.A.2.d.1 of this proposed rule.

b. Requirements for the Submission of Clinical Quality Measures by EPs and Eligible Hospitals

Sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii) of the Act provide that the Secretary may not require the electronic reporting of information on clinical quality measures unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

We do not anticipate that HHS will complete the necessary steps for us to have the capacity to electronically accept data on clinical quality measures from EHRs for the 2011 payment year. It is unlikely that by 2011 there will be adequate testing and demonstration of the ability to receive the required transmitted information on a widespread basis. The capacity to accept information on clinical quality measures also depends upon the Secretary promulgating technical specifications for EHR vendors with respect to the transmission of information on clinical quality measures sufficiently in advance of the EHR reporting period for 2011, so that adequate time has been provided either for such specifications to be certified, or for EHR vendors to code such specifications into certified systems. Therefore, for 2011, we propose that EPs and eligible hospitals use an attestation methodology to submit summary information to CMS on clinical quality measures as a condition of demonstrating meaningful use of certified EHR technology.

From the Medicaid perspective, delaying the onset of clinical quality measures reporting until 2012 addresses concerns about States having the ready infrastructure to receive and store

clinical quality measures data before then. More importantly, we recognize that since Medicaid providers are eligible to receive incentive payments for adopting, implementing, or upgrading certified EHR technology. Medicaid EPs may not be focused on demonstrating meaningful use until 2012 or later.

We anticipate that for the 2012 payment year we will have completed the necessary steps to have the capacity to receive electronically information on clinical quality measures from EHRs including the promulgation of technical specifications for EHR vendors to use for obtaining certification of their systems. Therefore, for the Medicare EHR incentive program, we propose that beginning in CY 2012 an EP using a certified EHR technology or beginning in FY 2012 an eligible hospital using a certified EHR technology, as appropriate for clinical quality measures, must submit information on clinical quality measures electronically in addition to submitting other measures described in section II.2.d.2 of this proposed rule in order for the EP or eligible hospital to be a meaningful EHR user, regardless of whether CY 2012 is their first or second payment year. However, if the Secretary does not have the capacity to accept the information on clinical quality measures electronically in 2012, consistent with sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii) of the Act, we will continue to rely on an attestation methodology for reporting of clinical quality measures as a requirement for demonstrating meaningful use of certified EHR technology for payment year 2012. Should we not have the capacity to accept information on clinical quality measures electronically in 2012, we will inform the public of this fact by publishing a notice in the **Federal Register** and providing instructions on how this information should be submitted to us.

For purposes of the requirements under sections 1848(o)(2)(A)(iii) and 1886 (n)(3)(iii) of the Act, we define "clinical quality measures" to consist of measures of processes, experience, and/or outcomes of patient care, observations or treatment that relate to one or more quality aims for health care such as effective, safe, efficient, patient-centered, equitable, and timely care. We note that certain statutory limitations apply only to the reporting of clinical quality measures, such as the requirement discussed in the previous paragraph prohibiting the Secretary from requiring the electronic reporting of information on clinical quality measures unless the Secretary has the capacity to accept the information electronically, as well as other statutory requirements for clinical quality measures that are discussed below in section II.A.3.c.1 of this proposed rule. These limitations apply solely to the submission of clinical quality measures, and do not apply to other measures of meaningful EHR use. The proposed clinical quality measures on which EPs or eligible hospitals will be required to submit information using certified EHR technology, the statutory requirements and other considerations that were used to select these proposed measures, and the proposed reporting requirements are described below.

With respect to Medicaid EPs and eligible hospitals, we note that section 1903(t)(6) of the Act recognizes that the demonstration of meaningful use may also include the reporting of clinical quality measures to the States. In the interest of simplifying the program and guarding against duplication of meaningful use criteria, we propose that the clinical quality measures adopted for the Medicare EHR incentive program, listed in Tables 3 and 20, will also apply to EPs and eligible hospitals in the Medicaid EHR incentive program. However, we are including alternative Medicaid-specific measures for use by eligible hospitals as shown in Table 21.

Despite the statutory limitation prohibiting the Secretary from requiring the electronic submission of clinical quality measures if HHS does not have the capacity to accept this information electronically, as previously discussed, the Secretary has broad discretion to establish requirements for meaningful use of certified EHR technology and for the demonstration of such use by EPs and eligible hospitals. Although we propose to first require the electronic submission of information on clinical quality measures in 2012, we do not desire this to delay the use of certified EHR technology by EPs and eligible hospitals to measure and improve clinical quality. Specifically, we believe that the use of those functionalities that support measurement of clinical quality is highly important to an overall goal of the HITECH Act, to improve health care quality. We believe that measurement and acting on the results of such measurement is an important aspect to improving quality.

Accordingly, although we are not proposing under sections 1848(o)(2)(A)(iii) and 1886(n)(3)(A)(iii) of the Act to require that for 2011 EPs and eligible hospitals report clinical quality measures to CMS or States electronically, we propose to require as an additional condition of demonstrating meaningful use of certified EHR technology under sections 1848(o)(2)(A)(i) and 1886(n)(3)(A)(ii) of the Act that EPs and eligible hospitals use certified EHR technology to capture the data elements and calculate the results for the applicable clinical quality measures discussed below. We further propose that EPs and eligible hospitals demonstrate that they have satisfied this requirement during the EHR reporting period for 2011 through attestation. We further propose to require that Medicare EPs and eligible hospital attest to the accuracy and completeness of the numerators and denominators for each of the applicable measure. Finally, in accordance with our authority under sections 1848(o)(C)(i)(V) and 1886(n)(3)(C)(i)(V) of the Act, which grants us broad discretion to specify the means through which EPs and eligible hospitals demonstrate compliance with the meaningful use criteria, we propose that EPs and eligible hospitals demonstrate their use of certified EHR technology to capture the data elements and calculate the results for the applicable clinical quality measures by reporting the results to CMS for all applicable patients. For the Medicaid incentive program, States may accept provider attestations in the same manner to demonstrate meaningful use in 2011. However, we expect that Medicaid providers will qualify for the incentive payment by adopting, implementing, or upgrading to certified EHR technology, and therefore; will not need to attest to meaningful use of EHRs in 2011, for their first payment year.

We recognize that considerable work needs to be done by measure owners and developers with respect to the clinical quality measures included in this proposed rule. This includes completing electronic specifications for measures, implementing such specifications into EHR technology to capture and calculate the results, and implementing the systems, themselves. We also recognize that some measures are further developed than others, as discussed in the proposed measures section. Nevertheless, we believe that overall there is sufficient time to complete work on measures and measures specifications to allow vendors, and EPs and eligible hospitals to implement such systems. Should the necessary work on measure specification not be completed for particular measures according to the timetable we discuss below, it is our intent not to finalize those specific measures.

c. Statutory Requirements and Other Considerations for the Proposed Selection of Clinical Quality Measures Proposed for Electronic Submission by EPs or Eligible Hospitals

(1) Statutory Requirements for the Selection of Clinical Quality Measures Proposed for Electronic Submission by EPs and Eligible Hospitals

Sections 1848(o)(2)(B)(i)(II) and 1886(n)(3)(B)(i) of the Act also require that prior to any clinical quality measure being selected, the Secretary will publish in the **Federal Register** such measure and provide for a period of public comment on such measure. The proposed clinical quality measures for EPs and eligible hospitals for 2011 and 2012 payment are listed in Tables 3 through 21.

For purposes of selecting clinical quality measures on which EPs will be required to submit information using certified EHR technology, section 1848(o)(2)(B)(i)(I) of the Act, as added by section 4101 of the HITECH Act, states that the Secretary shall provide preference to clinical quality measures that have been endorsed by the entity with a contract with the Secretary under section1890(a) of the Act, as added by section 183 of the Medicare Improvement for Patients and Providers Act (MIPPA) of 2008. For submission of clinical quality measures by eligible hospitals, section 1886(n)(3)(B)(i)(I) of the Act, as added by section 4102(a) of the HITECH Act, requires the Secretary to provide preference to those clinical quality measures that have been endorsed by the entity with a contract with the Secretary under subsection 1890(a) of the Act, as added by section 183 of the MIPPA, or clinical quality measures 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 Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program.

On January 14, 2009, the U.S. Department of Health and Human Services awarded the contract required under section 1890(a) of the Act to the National Quality Forum (NQF). Therefore, when selecting the clinical quality measures EPs must report in order to demonstrate meaningful use of certified EHR technology in accordance with section 1848(o)(2)(B)(i)(I) of the Act, we propose to give preference to the clinical quality measures endorsed by the NQF, including NQF endorsed measures that have previously been selected for the Physician Quality Reporting Initiative (PQRI) program. Similarly when selecting the clinical quality measures eligible hospitals must report in order to demonstrate meaningful use of certified EHR technology in accordance with section 1886(n)(3)(B)(i)(I) of the Act, we propose to give preference to the clinical quality measures selected from those endorsed by the NQF or that have previously been selected for the RHQDAPU program. In some instances we have proposed measures for EPs and eligible hospitals that are not currently NQF endorsed in an effort to include a broader set of clinical quality measures. However, the HITECH Act does not require the use of NQF endorsed measures, nor limit the measures to those included in PQRI or RHQDAPU. If we, professional societies, or other stakeholders identify clinical quality measures which may be appropriate for the EHR incentive programs, we will consider those measures even if they are not endorsed by the NQF or have not been selected for the PQRI or RHQDAPU programs, subject to the requirement to publish in the **Federal Register** such measure(s) for a period of public comment.

We propose the clinical quality measures for EPs and eligible hospitals in Tables 3 through 21 of this proposed rule for use in the 2011 and 2012 payment years for the Medicare EHR incentive program will be effective 60 days after the publication of the final rule in the **Federal Register**. No changes (that is, additions or deletions of clinical quality measures) will be made after publication of the final rule, except through further rulemaking. However, we may make administrative and/or technical modifications or refinements, such as revisions to the clinical quality measures titles and code additions, corrections, or revisions to the detailed specifications for the 2011 and 2012 payment year measures. The 2011 specifications for user submission of clinical quality measures will be available on our Web site when they are sufficiently developed or finalized. Specifications for the EHR incentive programs, even if already published as a part of another incentive payment programs, must be obtained *only* from the specifications documents for the EHR incentive program clinical quality measures. We note also that the final clinical quality measure specifications for eligible hospitals for any given clinical quality measure may be different from specifications for the same clinical quality measure used for the previously described testing of EHR-based data submission. We are targeting finalization and publication of the detailed specifications documents for all 2011 payment year Medicare EHR incentive program clinical quality measures for eligible hospitals on the CMS Web site on or before April 1, 2010. We intend that a detailed specifications document for all 2012 payment year Medicare EHR incentive program clinical quality measures for EPs be posted on the our Web site on or before April 1, 2011. This would provide final specifications documents at least 9 months in advance of the start of the applicable payment year for clinical quality measure EHR reporting period. We invite comments on our proposed timelines to post specification documents for these clinical quality measures to the CMS Web site.

(2) Other Considerations for the Proposed Selection of Clinical Quality Measures for Electronic Submission by EPs and Eligible Hospitals

In addition to the requirements under sections 1848(o)(2)(B)(i)(I) and 1886(n)(3)(B)(i)(I) of the Act and the other statutory requirements described above, other considerations that we applied to the selection of the proposed clinical quality measures for electronic submission under the Medicare and Medicaid EHR incentive programs include the following:

- Clinical quality measures that are included in, facilitate alignment with, or allow determination of satisfactory reporting in other Medicare (for example, PQRI or the RHQDAPU program), Medicaid, and Children's Health Insurance Program (CHIP) program priorities.
- Clinical quality measures that are widely applicable to EPs and eligible hospitals based on the services provided for the population of patients seen.
- Clinical quality measures that promote CMS and HHS policy priorities related to improved quality and efficiency of care for the Medicare and Medicaid populations that would allow us to track improvement in care over time. These current and long term priority topics include: Prevention; management of chronic conditions; high cost and high volume conditions; elimination of health disparities; healthcare-associated infections and other conditions; improved care coordination; improved efficiency; improved patient and family experience of care; improved end-of-life/palliative care; effective management of acute and chronic episodes of care; reduced unwarranted geographic variation in quality and efficiency; and adoption and use of interoperable HIT.
- Clinical quality measures that address or relate to known gaps in the quality of care and measures that

through the PQRI program, performed at low or highly variable rates.

• Clinical quality measures that have been recommended to CMS for inclusion in the EHR incentive by FACA committees, such as the HIT Policy Committee.

In addition, we note that the statutory requirements under sections 1848(o) and 1886(n) of the Act discussed above do not provide guidance with respect to the development of the clinical quality measures which may then be submitted to the NQF for endorsement. The basic steps for developing clinical quality measures applicable to EPs may be carried out by a variety of different organizations. We do not believe there needs to be any special restrictions on the type or infrastructure of the organizations carrying out this basic development of EP or eligible hospital measures, such as restricting the initial development to EP or eligible hospital organizations. Any such restriction would unduly limit the basic development of clinical quality measures, and the scope and utility of such measures that may be considered for NQF endorsement as voluntary consensus standards.

With respect to the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111–3) Title IV, section 401 requires that the Secretary publish a core set of clinical quality measures for the pediatric population. To the extent possible, we will align the clinical quality measures selected under this Medicaid EHR incentive program with the measures selected under the CHIPRA core measure set. Included in the proposed definition of meaningful use are nine proposed clinical quality measures that pertain to pediatric providers. Four of the nine measures are also on the list of CHIPRA initial core measures that were recommended to the Secretary by the Subcommittee to AHRQ's National Advisory Committee (SNAC). Not all CHIPRA initial measures recommended to the Secretary are applicable to EHR technology or to the Medicaid EHR incentive payment program. For example, some of the measures are population-based, survey-derived, or not yet NQF-endorsed. New or additional measures for the next iteration of the CHIPRA core set will have EHR-extractability as a priority. The full CHIPRA core measure set will be published for comment in a forthcoming **Federal Register** notice that is expected out before the end of the year.

However, as many providers, including primary care professionals, hospitals, dentists, and specialists provide care to the pediatric population in the Medicaid and CHIP programs. We saw consistency as paramount to avoid redundancy and duplication for these providers and States.

Provider quality measure reporting under CHIPRA for this initial core measure set will initially be voluntary. The intent is to begin standardizing measurement data collection. Due to the concurrent CHIPRA and ARRA HIT implementation activities, we believe there is an exciting opportunity to align the two programs and strive to create efficiencies for States and pediatric providers, where applicable. As both programs move forward, we will continue to prioritize consistency in measure selection for pediatric providers when possible.

We welcome comments on the inclusion or exclusion of any given clinical quality measure or measures proposed herein in the EHR incentive programs clinical quality measure set for EPs or eligible hospitals for the 2011 and 2012 payment years, and to our approach in selecting clinical quality measures. Our goal is for EPs and eligible hospitals to use EHRs to transmit clinical quality measures to the Secretary that would allow determination of their satisfactory reporting under the PQRI and RHQDAPU programs. Even if the clinical quality measures are not the same for PQRI and RHQDAPU satisfactory reporting and EHR meaningful use, our aim is to encourage EPs and eligible hospitals to use EHRs as the mechanism to report PQRI and RHQDAPU measures rather than reporting measures on claims and other reporting mechanisms. We plan to move to this approach as soon as practicable. To the extent that the same clinical quality measures are used in the PQRI and RHQDAPU programs and for EHR meaningful use, we believe that this approach would be consistent with the statutory requirement to avoid duplicate reporting to the extent practicable. We believe that allowing the measures reporting for the PQRI and RHQDAPU program to be reported via EHRs would provide an added incentive for EPs and eligible hospitals to adopt EHRs.

In addition, we do not intend to use notice and comment rulemaking as a means to update or modify clinical quality measure specifications. A clinical quality measure that has completed the consensus process through NQF has a designated party (usually, the measure developer/owner) who has accepted responsibility for maintenance of the clinical quality measure. In general, it is the role of the clinical quality measure owner, developer, or maintainer to make basic changes to a clinical quality measure in terms of the numerator, denominator, and exclusions. However, the clinical quality measures selected for the 2011 and 2012 payment year will be supplemented by CMS technical specifications for EHR submission. As discussed earlier, we propose to post the complete clinical quality measures specifications including technical specifications on our Web site and solicit comment on our approach.

d. Proposed Clinical Quality Measures for Electronic Submission Using Certified EHR Technology by EPs

For the 2011 and 2012 EHR reporting periods, based upon the considerations for selecting clinical quality measures discussed above, we propose the set of clinical quality measures identified in Table 3. The Table 3 lists the applicable PQRI and NQF measure number, title, description, the owner/developer, and a link to existing electronic specifications where applicable. Tables 4 through 19 describes further the reporting requirements of the Core and Specialty measure groups.

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TABLE 3: Proposed Clinical Quality Measures for Electronic Submission by Medicare or Medicaid Eligible Professionals for the 2011 and 2012 Payment Year

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 1 NQF 0059	**Title:** Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus **Description:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%	**National Committee for Quality Assurance (NCQA)** **Contact Information:** www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Endocrinology, Primary Care
PQRI 2 NQF 0064	**Title:** Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus **Description:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dl)	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Endocrinology
PQRI 3 NQF 0061	**Title:** Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus **Description:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/80 mmHg)	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Endocrinology
PQRI 5 NQF 0081	**Title:** Heart Failure: 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 and LVSD who were prescribed ACE inhibitor or ARB therapy	**American Medical Association-sponsored Physician Consortium for Performance Improvement (AMA-PCPI)** **Contact Information:** cpe@ama-assn.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Cardiology
PQRI 7 NQF 0070	**Title:** Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI) **Description:** Percentage of patients aged 18 years and older with a diagnosis of CAD and prior MI who were prescribed beta-blocker therapy	**AMA-PCPI** **Contact Information**: cpe@ama-assn.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Cardiology
PQRI 110 NQF 0041	**Title:** Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old **Description:** Percentage of patients aged 50 years and older who received an influenza immunization during the flu season (September through February)	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Primary Care

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 111 NQF 0043	**Title:** Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older **Description:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Pulmonology
PQRI 112 NQF 0031	**Title:** Preventive Care and Screening: Screening Mammography **Description:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer within 24 months	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Oncology, Primary Care, Obstetrics and Gynecology
PQRI 113 NQF 0034	**Title:** Preventive Care and Screening: Colorectal Cancer Screening **Description:** Percentage of patients aged 50 through 80 years who received the appropriate colorectal cancer screening	**NCQA** **Contact Information:** www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Oncology, Primary Care, Gastroenterology
PQRI 6 NQF 0067	**Title**: Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD **Description**: Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed oral antiplatelet therapy	**AMA-PCPI** **Contact Information**: cpe@ama-assn.org		Cardiology
PQRI 8 NQF 0083	**Title:** Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) **Description:** Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD and who were prescribed beta-blocker therapy	**AMA-PCPI** **Contact Information**: cpe@ama-assn.org		Cardiology
PQRI 9 NQF 0105	**Title:** Major Depressive Disorder (MDD): Antidepressant Medication During Acute Phase for Patients with MDD **Description:** Percentage of patients aged 18 years and older diagnosed with new episode of MDD and documented as treated with antidepressant medication during the entire 84-day (12-week) acute treatment phase	**NCQA** **Contact Information:** www.ncqa.org		Psychiatry

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 10 NQF 0246	**Title:** Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports **Description:** Percentage of final reports for CT or MRI studies of the brain performed within 24 hours of arrival to the hospital for patients aged 18 years and older with either a diagnosis of ischemic stroke or transient ischemic attack (TIA) or intracranial hemorrhage or at least one documented symptom consistent with ischemic stroke or TIA or intracranial hemorrhage that includes documentation of the presence or absence or each of the following: hemorrhage and mass lesion and acute infarction.	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Radiology
PQRI 12 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/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Ophthalmology
PQRI 18 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/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Ophthalmology
PQRI 19 NQF 0089	**Title:** Diabetic Retinopathy: Communication with the Physician Managing On-going 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 on-going care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Ophthalmology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 20 NQF 0270	**Title:** Perioperative Care: Timing of Antibiotic Prophylaxis – Ordering Physician **Description:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required)	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Proceduralists/Surgery
PQRI 21 NQF 0268	**Title:** Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin **Description:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin OR cefuroxime for antimicrobial prophylaxis	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Proceduralists/Surgery
PQRI 22 NQF 0271	**Title:** Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures) **Description**: Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic antibiotics AND who received a prophylactic antibiotic, who have an order for discontinuation of prophylactic antibiotics within 24 hours of surgical end time	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Proceduralists/Surgery
PQRI 23 NQF 0239	**Title:** Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) **Description:**Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Proceduralists/Surgery
PQRI 33 NQF 0241	**Title:** Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge **Description:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Neurology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 52 NQF 0102	**Title:** Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy **Description:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Pulmonology
PQRI 53 NQF 0047	**Title:** Asthma: Pharmacologic Therapy **Description:** Percentage of patients aged 5 through 40 years with a diagnosis of mild, moderate, or severe persistent asthma who were prescribed either the preferred long-term control medication (inhaled corticosteroid) or an acceptable alternative treatment	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Pulmonology
PQRI 65 NQF 0069	**Title:** Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use **Description:** Percentage of children aged 3 months through 18 years with a diagnosis of URI who were not prescribed or dispensed an antibiotic prescription on or within 3 days of the initial date of service	**NCQA** **Contact Information:** www.ncqa.org		Primary Care
PQRI 66 NQF 0002	**Title:** Appropriate Testing for Children with Pharyngitis **Description:** Percentage of children aged 2 through 18 years with a diagnosis of pharyngitis, who were prescribed an antibiotic and who received a group A streptococcus (strep) test for the episode	**NCQA** **Contact Information:** www.ncqa.org		Pediatrics, Primary Care
PQRI 71 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/American Society of Clinical Oncology (ASCO)-National Comprehensive Cancer Network (NCCN):** **Contact Information:** cpe@ama-assn.org http://www.asco.org/		Oncology
PQRI 72 NQF 0385	**Title:** Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients **Description:** Percentage of patients aged 18 years and older with Stage IIIA through IIIC colon cancer who are referred for adjuvant, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period	**AMA-PCPI/ASCO-NCCN** **Contact Information:** cpe@ama-assn.org http://www.asco.org/		Oncology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 81 NQF 0323	**Title:** End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis in ESRD Patients **Description:** Percentage of calendar months during the 12-month reporting period in which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis have a Kt/V ≥ 1.2 OR patients who have a Kt/V < 1.2 with a documented plan of care for inadequate hemodialysis	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Nephrology
PQRI 82 NQF 0321	**Title:** End Stage Renal Disease (ESRD): Plan of Care for Inadequate Peritoneal Dialysis **Description:** Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a Kt/V ≥ 1.7 OR patients who have a Kt/V < 1.7 with a documented plan of care for inadequate peritoneal dialysis at least three times (every 4 months) during the 12-month reporting period	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Nephrology
PQRI 86 NQF 0397	**Title:** Hepatitis C: Antiviral Treatment Prescribed **Description**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed peginterferon and ribavirin therapy within the 12-month reporting period	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Gastroenterology
PQRI 89 NQF 0401	**Title:** Hepatitis C: Counseling Regarding Risk of Alcohol Consumption **Description:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within the 12-month reporting period	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Gastroenterology
PQRI 102 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		Oncology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 106 NQF 0103	**Title:** Major Depressive Disorder (MDD): Diagnostic Evaluation **Description:** Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of MDD who met the DSM-IV criteria during the visit in which the new diagnosis or recurrent episode was identified during the measurement period	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Psychiatry
PQRI 107 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		Psychiatry
PQRI 114 NQF 0028	**Title:** Preventive Care and Screening: Inquiry Regarding Tobacco Use **Description:** Percentage of patients aged 18 years or older who were queried about tobacco use one or more times within 24 months	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Core, Pulmonology, Primary Care
PQRI 115 NQF 0027	**Title:** Preventive Care and Screening: Advising Smokers to Quit **Description:** Percentage of patients aged 18 years and older and are smokers who received advice to quit smoking	**NCQA** **Contact Information:** www.ncqa.org		Pulmonology, Primary Care
PQRI 117 NQF 0055	**Title:** Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient **Description:** Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Endocrinology
PQRI 118 NQF 0066	**Title:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD) **Description:** Percentage of patients aged 18 years and older with a diagnosis of CAD who also have diabetes mellitus and/or LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Cardiology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 119 NQF 0062	**Title:** Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients **Description:** Percentage of patients aged 18 through 75 years with diabetes mellitus who received urine protein screening or medical attention for nephropathy during at least one office visit within 12 months	**NCQA** **Contact Information:** www.ncqa.org		Endocrinology
PQRI 121 Ambulatory Quality Alliance (AQA) adopted	**Title:** Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorus, Intact Parathyroid Hormone (iPTH) and Lipid Profile) **Description:** Percentage of patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]), who had the following laboratory testing ordered within 12 months: serum levels of calcium, phosphorus and intact PTH, and lipid profile	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Nephrology
PQRI 122 AQA adopted	**Title:** Chronic Kidney Disease (CKD): Blood Pressure Management **Description:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]), with a blood pressure < 130/80 mmHg OR blood pressure ≥ 130/80 mmHg with a documented plan of care	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Nephrology
PQRI 123 AQA adopted	**Title:** Chronic Kidney Disease (CKD): Plan of Care – Elevated Hemoglobin for Patients Receiving Erythropoiesis-Stimulating Agents (ESA) **Description:** Percentage of calendar months during the 12-month reporting period in which patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]), receiving ESA therapy, have a hemoglobin < 13 g/dL OR patients whose hemoglobin is ≥ 13 g/dL and have a documented plan of care	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Nephrology
PQRI 127 NQF 0416	**Title:** Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear **Description:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing	**American Podiatric Medical Association (APMA)** **Contact Information:** http://www.apma.org/		Podiatry

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 128 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 visit documented in the medical record AND if the most recent BMI is outside parameters, a follow-up plan is documented Parameters: Age 65 and older BMI ≥30 or <22 Age 18 – 64 BMI ≥25 or <18.5	**CMS/Quality Insights of Pennsylvania (QIP)** **Contact Information:** PQRI_inquiry@cms.hhs.gov		Cardiology, Endocrinology, Primary Care, Obstetrics and Gynecology
PQRI 145 NQF 0510	**Title:** Radiology: Exposure Time Reported for Procedures Using Fluoroscopy **Description:** Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Radiology
PQRI 146 NQF 0508	**Title:** Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening **Description:** Percentage of final reports for screening mammograms that are classified as "probably benign"	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Radiology
PQRI 147 NQF 0511	**Title:** Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy **Description:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Radiology
PQRI 153 AQA adopted	**Title:** Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula **Description:** Percentage of patients aged 18 years and older with the diagnosis of advanced CKD (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]), who were referred for AV fistula at least once during the 12-month reporting period	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Nephrology
PQRI 163 NQF 0056	**Title:** Diabetes Mellitus: Foot Exam **Description:** The percentage of patients aged 18 through 75 years with diabetes who had a foot examination	**NCQA** **Contact Information:** www.ncqa.org		Podiatry

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 183 NQF 0399	**Title**: Hepatitis C: Hepatitis A Vaccination in Patients with HCV **Description:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Gastroenterology
PQRI 184 NQF 0400	**Title:** Hepatitis C: Hepatitis B Vaccination in Patients with HCV **Description:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Gastroenterology
PQRI 185 AQA adopted	**Title:** Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use **Description:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy and a history of colonic polyp(s) in a previous colonoscopy, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Gastroenterology
PQRI 195 NQF 0507	**Title:** Stenosis Measurement in Carotid Imaging Reports **Description:** Percentage of final reports for carotid imaging studies (neck MR angiography [MRA], neck CT angiography [CTA], neck duplex ultrasound, carotid angiogram) performed for patients aged 18 years and older with the diagnosis of ischemic stroke or transient ischemic attack (TIA) that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement	**AMA-PCPI/NCQA** **Contact Information**: cpe@ama-assn.org www.ncqa.org		Radiology
PQRI 197 NQF 0074	**Title:** Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol **Description:** Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed a lipid-lowering therapy (based on current ACC/AHA guidelines)	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Cardiology, Primary Care
PQRI 200 NQF 0084	**Title:** Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation **Description:** Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy	**AMA-PCPI** **Contact Information:** cpe@ama-assn.org		Cardiology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 201 NQF 0073	**Title:** Ischemic Vascular Disease (IVD): Blood Pressure Management Control **Description:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg)	**NCQA** **Contact Information:** www.ncqa.org		Neurology
PQRI 202 NQF 0075	**Title:** Ischemic Vascular Disease (IVD): Complete Lipid Profile **Description:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months	**NCQA** **Contact Information:** www.ncqa.org		Primary Care, Neurology
PQRI 203 NQF 0075	**Title:** Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL–C) Control **Description:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who had most recent LDL-C level in control (less than 100 mg/dl)	**NCQA** **Contact Information:** www.ncqa.org		Primary Care, Neurology
PQRI 204 NQF 0068	**Title:** Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic **Description:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) with documented use of aspirin or other antithrombotic	**NCQA** **Contact Information:** www.ncqa.org		Cardiology, Endocrinology, Primary Care, Neurology
NQF 0001	**Title:** Asthma assessment **Description:** Percentage of patients who were evaluated during at least one office visit for the frequency (numeric) of daytime and nocturnal asthma symptoms	**AMA-PCPI** **Contact Information:** www.ama-assn.org		Pulmonology, Primary Care
NQF 0004	**Title:** Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement **Description:** Percentage of adults aged 18 and over diagnosed with AOD abuse or dependence and receiving a related service who initiate treatment Assessment of the degree to which members engage in treatment with two additional AOD treatments within 30 days after initiating treatment.	**NCQA** **Contact Information:** www.ncqa.org		Primary Care, Psychiatry
NQF 0012	**Title:** Prenatal Screening for Human Immunodeficiency Virus (HIV) **Description:** Percentage of patients who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal care visit	**AMA-PCPI** **Contact Information:** www.ama-assn.org		Obstetrics and Gynecology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0013	**Title:** Blood pressure measurement **Description:** Percentage of patient visits with blood pressure measurement recorded among all patient visits for patients aged > 18 years with diagnosed hypertension.	**AMA-PCPI** **Contact Information:** www.ama-assn.org		Core
NQF 0014	**Title:** Prenatal Anti-D Immune Globulin **Description:** Percentage of D-negative, unsensitized patients who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation	**AMA-PCPI** **Contact Information:** www.ama-assn.org		Obstetrics and Gynecology
NQF 0018	**Title:** Controlling High Blood Pressure **Description:** Percentage of patients with last BP < 140/80 mm Hg.	**NCQA** **Contact Information:** www.ncqa.org		Primary Care
NQF 0022	**Title:** Drugs to be avoided in the elderly: a. Patients who receive at least one drug to be avoided, b. Patients who receive at least two different drugs to be avoided. **Description:** Percentage of patients ages 65 years and older who received at least one drug to be avoided in the elderly in the measurement year. Percentage of patients 65 years of age and older who received at least two different drugs to be avoided in the elderly in the measurement year.	**NCQA** **Contact Information:** www.ncqa.org		Core
NQF 0024	**Title:** Body Mass Index (BMI) 2 through 18 years of age **Description:** Percentage children, 2 through 18 years of age, whose weight is classified based on BMI percentile for age and gender	**National Initiative for Children's Healthcare Quality** **Contact Information:** http://www.nichq.org/		Pediatrics, Primary Care
NQF 0026	**Title:** Measure pair - a. Tobacco use prevention for infants, children and adolescents, b. Tobacco use cessation for infants, children and adolescents **Description:** Percentage of patients' charts showing either that there is no tobacco use/exposure or (if a user) that the current use was documented at the most recent clinic visit. Percentage of patients with documented tobacco use or exposure at the latest visit who also have documentation that their cessation interest was assessed or that they received advice to quit.	**Institute for Clinical Systems Improvement (ICSI)** **Contact Information:** http://www.icsi.org/		Pediatrics

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0032	**Title:** Cervical Cancer Screening **Description:** Percentage of women 18-64 years of age, who received one or more Pap tests during the measurement year or the 2 years prior to the measurement year.	**NCQA** **Contact Information:** www.ncqa.org		Oncology, Primary Care, Obstetrics and Gynecology
NQF 0033	**Title:** Chlamydia screening in women **Description:** Percentage of eligible women who were identified as sexually active who had at least one test for chlamydia during the measurement year.	**NCQA** **Contact Information:** www.ncqa.org		Obstetrics and Gynecology
NQF 0036	**Title:** Use of appropriate medications for people with asthma **Description:** Percentage of patients who were identified as having persistent asthma during the measurement year and the year prior to the measurement year and who were dispensed a prescription for either an inhaled corticosteroid or acceptable alternative medication during the measurement year.	**NCQA** **Contact Information:** www.ncqa.org		Pulmonology, Primary Care
NQF 0038	**Title:** Childhood Immunization Status **Description:** Percentage of children 2 years of age who had four DtaP/DT, three IPV, one MMR, three H influenza type B, three hepatitis B, one chicken pox vaccine (VZV) and four pneumococcal conjugate vaccines by their second birthday. The measure calculates a rate for each vaccine and two separate combination rates.	**NCQA** **Contact Information:** www.ncqa.org		Primary Care, Pediatrics
NQF 0052	**Title:** Low back pain: use of imaging studies **Description:** Percentage of patients with new low back pain who received an imaging study (plain x-ray, MRI, CT scan) conducted on the episode start date or in the 28 days following the episode start date.	**NCQA** **Contact Information:** www.ncqa.org		Primary Care, Radiology
NQF 0060	**Title:** Hemoglobin A1c test for pediatric patients **Description:** Percentage of pediatric patients with diabetes with a HBA1c test in a 12-month measurement period.	**NCQA** **Contact Information:** www.ncqa.org		Endocrinology, Pediatrics, Primary Care

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0105	**Title:** New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management, (b) Effective Acute Phase Treatment,(c)Effective Continuation Phase Treatment **Description:** Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication, and who had at least three follow-up contacts with a practitioner during the 84-day (12-week) Acute Treatment Phase b. Percentage of patients who were diagnosed with a new episode of depression, were treated with antidepressant medication and remained on an antidepressant drug during the entire 84-day Acute Treatment Phase c. Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication and who remained on an antidepressant drug for at least 180 days.	**NCQA** **Contact Information:** www.ncqa.org		Psychiatry, Primary Care
NQF 0106	**Title:** Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents **Description:** Percentage of patients newly diagnosed with attention deficit hyperactivity disorder (ADHD) whose medical record contains documentation of Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or Diagnostic and Statistical Manual for Primary Care (DSM-PC) criteria being addressed.	**ICSI** **Contact Information:** http://www.icsi.org/		Pediatrics, Primary Care
NQF 0107	**Title:** Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents **Description:** Percentage of patients diagnosed with attention deficit hyperactivity disorder (ADHD) and on first-line medication whose medical record contains documentation of a follow-up visit twice a year.	**ICSI** **Contact Information:** http://www.icsi.org/		Pediatrics, Primary Care

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0108	**Title:** ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication. **Description:** a. Initiation Phase: Percentage of children 6 – 12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for and ADHD medication and who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase b. Continuation and Maintenance (C&M) Phase: Percentage of children 6 – 12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for ADHD medication who remained on the 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 ends.	**NCQA** **Contact Information:** www.ncqa.org		Pediatrics, Primary Care
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** **Contact Information:** http://www.cqaimh.org/		Psychiatry, Primary Care
NQF 0299	**Title:** Surgical Site Infection Rate **Description:** Percentage of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place or with one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure.	**Centers for Disease Control and Prevention (CDC)** **Contact Information:** http://www.cdc.gov/		Proceduralists/Surgery

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0471	**Title:** Cesarean Rate for low-risk first birth women (aka NTSV CS rate) **Description:** Percentage of low-risk first birth women (aka NTSV CS rate: nulliparous, term, singleton, vertex) with a Cesarean rate that has the most variation among practicioners, hospitals, regions and states. Unlike other cesarean measures, it focuses attention on the proportion of cesarean births that is affected by elective medical practices such as induction and early labor admission. Furthermore, the success (or lack thereof) of management of the first labor directly impacts the remainder of the woman's reproductive life (especially given the current high rate of repeat cesarean births).	**California Maternal Quality Care Collaborative (CMQCC)** **Contact Information:** http://cmqcc.org/		Obstetrics and Gynecology
NQF 0513	**Title:** Use of Contrast: Thorax CT **Description:** Thorax CT – Use of combined studies (with and without contrast)	**CMS** **Contact Information:** http://www.cms.hhs.gov/		Radiology
NQF 0519	**Title:** Diabetic Foot Care and Patient Education Implemented **Description:** Percent of diabetic patients for whom physician-ordered monitoring for the presence of skin lesions on the lower extremities and patient education on proper foot care were implemented during their episode of care	**CMS** **Contact Information:** http://www.cms.hhs.gov/		Podiatry
NQF EC-013-08	**Title:** Comprehensive Diabetes Care: HbA1c Control (<8.0%) **Description:** The percentage of members 18-75 years of age with diabetes (Type 1 and Type 2) who had HbA1c control (<8.0%).	**NCQA** **Contact Information:** www.ncqa.org		Endocrinology, Primary Care
Not applicable	**Title:** Hysterectomy rates **Description:**			Obstetrics and Gynecology
Not applicable	**Title:** Appropriate antibiotic use for ear infections **Description:**			Pediatrics, Primary Care
Not applicable	**Title:** Statin after Myocardial Infarction **Description:**			Cardiology
Not Applicable	**Title:** 30 day Readmission Rate **Description:**			Proceduralists/Surgery
Not Applicable	**Title:** 30 Readmission Rate following deliveries **Description**:			Obstetrics and Gynecology
Not Applicable	**Title**: Use of CT scans **Description**: Number of repeat CT scans within 60 days			Pulmonology

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As previously stated, we believe that there is sufficient time to implement the measures in EHR systems for 2011 through 2012. However, we recognize also that there are measures that we propose, which are in a lower state of readiness, for implementation in certified EHR's and present a higher degree of risk in terms of completion of the necessary work. We would note that the purpose of this quality reporting is to begin the process of quality benchmarking and iterative improvements in the ability of providers to benchmark themselves against their peers. As part of the public comment process, we welcome comment on not only the clinical utility of the measures we have proposed, but also their state of readiness for use in the EHR incentive programs. For those measures where electronic specifications do not currently exist, we solicit comment on how quickly electronic specifications can be developed and the period of time that might be required for effective implementation from the time the electronic specifications of final measures are posted and made available to vendors. We intend to publish electronic specifications for the proposed clinical quality measures on the CMS Web site as soon as they become available from the measure developer(s). Electronic specifications may be developed concurrently with the development of measures themselves and potentially with the NQF endorsement processes.

All of the PQRI measures included in the above clinical quality measures meet one or more of the criteria previously discussed. These measures have been through notice and comment rulemaking for PQRI. Nearly all proposed PQRI clinical quality measures are NQF endorsed. Additionally, they have broad applicability to the range of Medicare designated specialties, and the services provided by EPs who render services to Medicare and Medicaid beneficiaries and many others. Further, 9 of the 90 clinical quality measures listed above (PQRI numbers 1, 2, 3, 5, 7, 110, 111, 112, and 113) have specifications for the electronic submission of these clinical quality measures have already been developed for the purpose of testing the electronic submission of clinical quality data extracted from an EHR for the PQRI program. The user specifications for the electronic submission of these 9 clinical quality measures for the most current PQRI program year can be found on the PQRI section of the CMS Web site at *http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage*.

In terms of CMS and HHS healthcare quality priorities, clinical quality PQRI measures numbered 1, 2, 3, 5, and 7 address high priority chronic conditions, namely diabetes, coronary artery disease, and heart disease. Clinical quality PQRI measures numbered 110, 111, 112, 113, 114, 115, and 128 support prevention which is a high CMS and HHS priority. The PQRI clinical quality measure specifications for claims-based or registry-based submission of these clinical quality measures for the most current PQRI program year can be found on the PQRI section of the CMS Web site at *http://www.cms.hhs.gov/PQRI/15_MeasuresCodes.asp#TopOfPage*. A description of the clinical quality measure, including the clinical quality measure's numerator and denominator, can be found in the PQRI clinical quality measure specifications.

The PQRI clinical quality measures that we have included largely align with the recommendations of the HIT Standards Committee. However, we have also included certain clinical quality measures not part of PQRI that we believe are of high importance to the overall population. These clinical quality measures are IVD: Use of Aspirin or another Antithrombotic; IVD: Complete Lipid Profile; IVD: Low Density Lipoprotein (LDL–C) Control, and Blood Pressure Management. Finally, we have included an array of other measures which address important aspects of clinical quality.

In summary, we believe that this initial set of clinical quality measures is broad enough to allow for reporting for EPs and addresses high priority conditions. We recognize the importance of integrating the measures into certified EHR products for calculation of measures results, and that not all measures may be feasible for 2011 and 2012. We invite comment on the advisability of including the measures proposed for payment years 2011 and 2012. Although we recognize many other important clinical quality measures of health care provided by EPs, we anticipate expanding the set of clinical quality measures in future years and list a number of clinical quality measures for future consideration in section II.A.3.g of this preamble, on which we also invite comment.

We invite comments on our proposed clinical quality measures for EPs.

e. Clinical Quality Measures Reporting Criteria for EPs

For the 2011 and 2012 EHR reporting periods, to satisfy the requirements for reporting on clinical quality measures for Medicare under section 1848(o)(2)(A)(i) and (iii) of the Act and for Medicaid under section 1903(t)(6)(C) of the Act for the 2012 payment year, we propose to require each EP submit information on two measure groups, as shown in Table 4 and Tables 5 through 19, of this proposed rule. These are the core measures group in Table 4, and the subset of clinical measures most appropriate given the EPs specialty as described further in Tables 5 through 19 specialty group measures below. For the core measure group, in Table 4, we believe that the clinical quality measures are sufficiently general in application and of such importance to population health, we propose to require that all EPs treating Medicare and Medicaid patients in the ambulatory setting report on all of the core measures as applicable for their patients.

TABLE 4—MEASURE GROUP: CORE FOR ALL EPS, MEDICARE OR MEDICAID

Measure No.	Clinical quality measure title
PQRI 114	Title: Preventive Care and Screening: Inquiry Regarding Tobacco Use.
NQF 0028	
NQF 0013	Title: Blood pressure measurement.
NQF 0022	Title: Drugs to be avoided in the elderly: a. Patients who receive at least one drug to be avoided. b. Patients who receive at least two different drugs to be avoided.

The second required measure set for each EP is to submit information on at least one of the sets listed in Tables 5 and 19 as specialty groups. The specialty groups are Cardiology, Pulmonology, Endocrinology, Oncology,

Proceduralist/Surgery, Primary Care Physicians, Pediatrics, Obstetrics and Gynecology, Neurology, Psychiatry, Ophthalmology, Podiatry, Radiology, Gastroenterology, and Nephrology.

We recognize that clinical quality measures as specified by measures developers and as endorsed by the NQF are not specialty specific. Rather, the denominator of clinical quality measures and the applicability of a measure is determined by the patient population to whom the measure applies and the services rendered by the particular EP.

Nevertheless, we have grouped measures according to the types of patients commonly treated and services rendered by EPs of various specialties. We have done this for purposes similar to measures groups used in PQRI which, however, are based on clinical conditions, rather than specialty types. The general purpose of each type of measures grouping is to have standardized sets of measures all of which must be reported by the EP in order to meet the reporting requirements. We expect to narrow down each proposed set to a required subset of 3 to 5 measures based on the availability of electronic measure specifications and comments received.

We propose to require for 2011 and 2012 that EP's will select a specialty measures group, on which to report on all applicable cases for each of the measures in the specialty group. The same specialty measures group selected for the first payment year would be required for reporting for the second payment year. We invite comment on whether there are EPs who believe no specialty group will be applicable to them. In accordance with public comments, we will specify in the final rule which EP specialties will be exempt from selecting and reporting on a specialty measures group. EPs that are so-designated will be required to attest, to CMS or the State, to the inapplicability of any of the specialty groups and will not be required to report information on clinical quality measures from a specialty group for 2011 or 2012, though the EP will still be required to report information on all of the clinical quality measures listed in the core measure set in, Table 4, as applicable for their patients.

TABLE 5—MEASURE GROUP: CARDIOLOGY

Measure No.	Clinical quality measure title
PQRI 5 NQF 0081	Title: Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).
PQRI 6 NQF 0067	Title: Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD.
PQRI 7 NQF 0070	Title: Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).
PQRI 8 NQF 0083	Title: Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
PQRI 118 NQF 0066	Title: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD).
PQRI 128 NQF 0421	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
PQRI 197 NQF 0074	Title: Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol.
PQRI 200 NQF 0084	Title: Heart Failure: Warfarin Therapy Patients with Atrial Fibrillation.
PQRI 204 NQF 0068	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
Not applicable	Title: Statin after Myocardial Infarction.

TABLE 6—MEASURE GROUP: PULMONOLOGY

Measure No.	Clinical quality measure title
PQRI 52 NQF 0102	Title: Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.
PQRI 53 NQF 0047	Title: Asthma: Pharmacologic Therapy.
PQRI 111 NQF 0043	Title: Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.
PQRI 114 NQF 0028	Title: Preventive Care and Screening: Inquiry Regarding Tobacco Use.
PQRI 115 NQF 0027	Title: Preventive Care and Screening: Advising Smokers to Quit.
NQF 0001	Title: Asthma assessment.
NQF 0036	Title: Use of appropriate medications for people with asthma.
Not applicable	Title: Use of CT scans.

TABLE 7—MEASURE GROUP: ENDOCRINOLOGY

Measure No.	Clinical quality measure title
PQRI 1 NQF 0059	Title: Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus.
PQRI 2 NQF 0064	Title: Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus.

TABLE 7—MEASURE GROUP: ENDOCRINOLOGY—Continued

Measure No.	Clinical quality measure title
PQRI 3	Title: Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus.
NQF 0061	
PQRI 117	Title: Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient.
NQF 0055	
PQRI 119	Title: Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients.
NQF 0062	
PQRI 128	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
NQF 0421	
PQRI 204	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
NQF 0068	
NQF 0060	Title: Hemoglobin A1c test for pediatric patients.
Not applicable	Title: Comprehensive Diabetes Care: HbA1c Control (<8.0 percent).

TABLE 8—MEASURE GROUP: ONCOLOGY

Measure No.	Clinical quality measure title & description
PQRI 71	Title: Breast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.
NQF 0387	
PQRI 72	Title: Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients.
NQF 0385	
PQRI 102	Title: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients.
NQF 0389	
PQRI 112	Title: Preventive Care and Screening: Screening Mammography.
NQF 0031	
PQRI 113	Title: Preventive Care and Screening: Colorectal Cancer Screening.
NQF 0034	
NQF 0032	Title: Cervical Cancer Screening.

TABLE 9—MEASURE GROUP: PROCEDURALIST/SURGERY

Measure No.	Clinical quality measure title & description
PQRI 20	Title: Perioperative Care: Timing of Antibiotic Prophylaxis—Ordering Physician.
NQF 0270	
PQRI 21	Title: Perioperative Care: Selection of Prophylactic Antibiotic—First OR Second Generation Cephalosporin.
NQF 0268	
PQRI 22	Title: Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures).
NQF 0271	
PQRI 23	Title: Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients).
NQF 0239	
NQF 0299	Title: Surgical Site Infection Rate.
Not Applicable	Title: 30 day Readmission Rate.

TABLE 10—MEASURE GROUP: PRIMARY CARE

Measure No.	Clinical quality measure title & description
PQRI 114	Title: Preventive Care and Screening: Inquiry Regarding Tobacco Use.
NQF 0028	
PQRI 115	Title: Preventive Care and Screening: Advising Smokers to Quit.
NQF 0027	
PQRI 202	Title: Ischemic Vascular Disease (IVD): Complete Lipid Profile.
NQF 0075	
PQRI 203	Title: Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL–C) Control.
NQF 0075	
PQRI 204	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
NQF 0068	
NQF 0038	Title: Childhood Immunization Status.
PQRI 112	Title: Preventive Care and Screening: Screening Mammography.
NQF 0031	
PQRI 113	Title: Preventive Care and Screening: Colorectal Cancer Screening.
NQF 0034	
PQRI 1	Title: Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus.
NQF 0059	
NQF 0052	Title: Low back pain: use of imaging studies.
NQF 0018	Title: Controlling High Blood Pressure.
PQRI 128	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
NQF 0421	

TABLE 10—MEASURE GROUP: PRIMARY CARE—Continued

Measure No.	Clinical quality measure title & description
PQRI 65 NQF 0069	Title: Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use.
PQRI 66 NQF 0002	Title: Appropriate Testing for Children with Pharyngitis.
PQRI 110 NQF 0041	Title: Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old.
PQRI 197 NQF 0074	Title: Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol.
NQF 0001	Title: Asthma Assessment
NQF 0004	Title: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement.
NQF 0024	Title: Body Mass Index (BMI) 2 through 18 years of age.
NQF 0032	Title: Cervical Cancer Screening.
NQF 0036	Title: Use of appropriate medications for people with asthma.
NQF 0060	Title: Hemoglobin A1c test for pediatric patients.
NQF 0105	Title: New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management. (b) Effective Acute Phase Treatment. (c) Effective Continuation Phase Treatment.
NQF 0106	Title: Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents.
NQF 0107	Title: Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents.
NQF 0108	Title: ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication.
NQF 0110	Title: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use.
Not applicable	Title: Comprehensive Diabetes Care: HbA1c Control (< 8.0 percent).
Not applicable	Title: Appropriate antibiotic use for ear infections.

TABLE 11—MEASURE GROUP: PEDIATRICS

Measure No.	Clinical quality measure title & description
PQRI 66 NQF 0002	Title: Appropriate Testing for Children with Pharyngitis.
NQF 0060	Title: Hemoglobin A1c test for pediatric patients.
NQF 0106	Title: Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents.
NQF 0107	Title: Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents.
NQF 0108	Title: ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication.
NQF 0024	Title: Body Mass Index (BMI) 2 through 18 years of age.
NQF 0026	Title: Measure pair— a. Tobacco use prevention for infants, children and adolescents, b. Tobacco use cessation for infants, children and adolescents.
NQF 0038	Title: Childhood Immunization Status.
Not applicable	Title: Appropriate antibiotic use for ear infections.

TABLE 12—MEASURE GROUP: OBSTETRICS AND GYNECOLOGY

Measure No.	Clinical quality measure title & description
PQRI 112 NQF 0031	Title: Preventive Care and Screening: Screening Mammography.
PQRI 128 NQF 0421	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
NQF 0032	Title: Cervical Cancer Screening.
NQF 0033	Title: Chlamydia screening in women.
NQF 0471	Title: Cesarean Rate for low-risk first birth women (aka NTSV CS rate).
NQF 0012	Title: Prenatal Screening for Human Immunodeficiency Virus (HIV).
NQF 0014	Title: Prenatal Anti-D Immune Globulin.
Not applicable	Title: Hysterectomy rates.
Not applicable	Title: 30 Readmission Rate following deliveries.

TABLE 13—MEASURE GROUP: NEUROLOGY

Measure No.	Clinical quality measure title & description
PQRI 33 NQF 0241	Title: Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge.
PQRI 201 NQF 0073	Title: Ischemic Vascular Disease (IVD): Blood Pressure Management Control.
PQRI 202 NQF 0075	Title: Ischemic Vascular Disease (IVD): Complete Lipid Profile.
PQRI 203 NQF 0075	Title: Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL–C) Control.
PQRI 204 NQF 0068	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.

TABLE 14—MEASURE GROUP: PSYCHIATRY

Measure No.	Clinical quality measure title & description
PQRI 9 NQF 0105	Title: Major Depressive Disorder (MDD): Antidepressant Medication During Acute Phase for Patients with MDD.
PQRI 106 NQF 0103	Title: Major Depressive Disorder (MDD): Diagnostic Evaluation.
PQRI 107 NQF 0104	Title: Major Depressive Disorder (MDD): Suicide Risk Assessment.
NQF 0004	Title: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement.
NQF 0105	Title: New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management, (b) Effective Acute Phase Treatment, (c) Effective Continuation Phase Treatment.
NQF 0110	Title: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use.

TABLE 15—MEASURE GROUP: OPHTHALMOLOGY

Measure No.	Clinical quality measure title & description
PQRI 12 NQF 0086	Title: Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation.
PQRI 18 NQF 0088	Title: Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy.
PQRI 19 NQF 0089	Title: Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care.

TABLE 16—MEASURE GROUP: PODIATRY

Measure No.	Clinical quality measure title & description
PQRI 127 NQF 0416	Title: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention—Evaluation of Footwear.
PQRI 163 NQF 0056	Title: Diabetes Mellitus: Foot Exam.
NQF 0519	Title: Diabetic Foot Care and Patient Education Implemented.

TABLE 17—MEASURE GROUP: RADIOLOGY

Measure No.	Clinical quality measure title & description
PQRI 10 NQF 0246	Title: Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports.
PQRI 195 NQF 0507	Title: Stenosis Measurement in Carotid Imaging Studies.
PQRI 145 NQF 0510	Title: Radiology: Exposure Time Reported for Procedures Using Fluoroscopy.
PQRI 146 NQF 0508	Title: Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening.
PQRI 147 NQF 0511	Title: Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy.
NQF 0052	Title: Low back pain: use of imaging studies.
NQF 0513	Title: Use of Contrast: Thorax CT.

TABLE 18—MEASURE GROUP: GASTROENTEROLOGY

Measure No.	Clinical quality measure title & description
PQRI 86 NQF 0397	Title: Hepatitis C: Antiviral Treatment Prescribed.
PQRI 89 NQF 0401	Title: Hepatitis C: Counseling Regarding Risk of Alcohol Consumption.
PQRI 113 NQF 0034	Title: Preventive Care and Screening: Colorectal Cancer Screening.
PQRI 183 NQF 0399	Title: Hepatitis C: Hepatitis A Vaccination in Patients with HCV.
PQRI 184 NQF 0400	Title: Hepatitis C: Hepatitis B Vaccination in Patients with HCV.
PQRI 185 AQA adopted	Title: Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.

TABLE 19—MEASURE GROUP: NEPHROLOGY

Measure No.	Clinical quality measure title & description
PQRI 81 NQF 0323	Title: End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis in ESRD Patients.
PQRI 82 NQF 0321	Title: End Stage Renal Disease (ESRD): Plan of Care for Inadequate Peritoneal Dialysis.
PQRI 121 AQA adopted	Title: Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorus, Intact Parathyroid Hormone (iPTH) and Lipid Profile).
PQRI 122 AQA adopted	Title: Chronic Kidney Disease (CKD): Blood Pressure Management.
PQRI 123 AQA adopted	Title: Chronic Kidney Disease (CKD): Plan of Care—Elevated Hemoglobin for Patients Receiving Erythropoiesis-Stimulating Agents (ESA).
PQRI 153 AQA adopted	Title: Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula.

With the inclusion of measures applicable to targeting children and adolescents and the wide applicability of the measures like Blood Pressure Management, we believe this core set of clinical quality measures and specialty measures is broad enough to enable reporting by all EPs. However, if the public believes that other EPs would not have sufficient patients in the denominator of these core measures, we encourage commenters to identify the EPs in question and propose specific remedies.

Although we do not propose to require clinical quality measure reporting electronically until 2012, we propose to begin clinical quality reporting through attestation in the 2011 payment year. We solicit comment on whether it may be more appropriate to defer some or all clinical quality reporting until the 2012 payment year. If reporting on some but not all measures in 2011 is feasible, we solicit comment on which key measures should be chosen for 2011 and which should be deferred until 2012 and why.

We further propose that starting in payment year 2012, in addition to meeting requirements for measures on meaningful EHR use and other requirements, EPs would be required to electronically submit this quality reporting information directly to CMS and States using certified EHR technology. We encourage comments on these reporting criteria, particularly on the requirement that all EPs–would report on the set of "core measures." We are also interested in comments as to whether some Medicare or Medicaid EPs may not be able to meet the proposed reporting requirements, why that might be the case, and whether commenters believe other alternative options are preferable.

f. Proposed Clinical Quality Measures for Electronic Submission by Eligible Hospitals

Based on the considerations for clinical quality measures previously discussed in this proposed rule, we propose that eligible hospitals will be required to report summary data to CMS on the set of clinical quality measures identified in Table 20 starting in the 2011 payment year. We further propose that for the 2012 payment year, hospitals will be required to submit these measures to CMS electronically using certified EHR technology on a set of clinical quality measures identified in Table 20, which would be sufficient to meet the requirements for both the Medicare and the Medicaid EHR incentive (for hospitals eligible for both incentive programs), with respect to the requirement to report clinical quality measures. For hospitals eligible for only the Medicaid EHR incentive program, such reporting will be to States. For eligible hospitals to which the measures in Table 20 do not apply to their patient population, hospitals have the option to select clinical quality measures identified in Table 21 to meet the requirements for the reporting of clinical quality measures for the Medicaid program incentive. Tables 20 and 21, convey the clinical quality measure's title, number, owner/developer and contact information, and a link to existing electronic specifications where applicable.

TABLE 20—PROPOSED CLINICAL QUALITY MEASURES FOR ELECTRONIC SUBMISSION BY ELIGIBLE HOSPITALS FOR PAYMENT YEAR 2011–2012

Measure No. identifier	Measure title, description & measure developer	Electronic measure specifications information
ED–1	Title: Emergency Department Throughput—admitted patients. Median time from ED arrival to ED departure for admitted patients.	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0495	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. Measure Developer: CMS/Oklahoma Foundation for Medical Quality (OFMQC).	
ED–2	Title: Emergency Department Throughput—admitted patients. Admission decision time to ED departure time for admitted patients.	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0497	Description: Median time from admit decision time to time of departure from the emergency department of emergency department patients admitted to inpatient status. Measure Developer: CMS/OFMQ.	
ED–3	Title: Emergency Department Throughput—discharged patients. Median Time from ED Arrival to ED Departure for Discharged ED Patients.	
NQF 0496	Description: Median Time from ED arrival to time of departure from the ED for patients discharged from the ED. Measure Developer: CMS/OFMQ.	
Stroke-2	Title: Ischemic stroke—Discharge on anti-thrombotics	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0435	Description: Ischemic stroke patients prescribed antithrombotic therapy at hospital discharge. Measure Developer: The Joint Commission.	
Stroke-3	Title: Ischemic stroke—Anticoagulation for A-fib/flutter	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0436	Description: Ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge. Measure Developer: The Joint Commission.	
Stroke-4	Title: Ischemic stroke—Thrombolytic therapy for patients arriving within 2 hours of symptom onset.	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0437	Description: Acute ischemic stroke patients who arrive at this hospital within 2 hours of time last known well and for whom IV t-PA was initiated at this hospital within 3 hours of time last known well. Measure Developer: The Joint Commission.	
Stroke-5	Title: Ischemic or hemorrhagic stroke—Antithrombotic therapy by day 2	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0438	Description: Ischemic stroke patients administered antithrombotic therapy by the end of hospital day 2. Measure Developer: The Joint Commission.	
Stroke-6	Title: Ischemic stroke—Discharge on statins	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0439	Description: Ischemic stroke patients with LDL > 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. Measure Developer: The Joint Commission.	
Stroke-8	Title: Ischemic or hemorrhagic stroke—Stroke education	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*

TABLE 20—PROPOSED CLINICAL QUALITY MEASURES FOR ELECTRONIC SUBMISSION BY ELIGIBLE HOSPITALS FOR PAYMENT YEAR 2011–2012—Continued

Measure No. identifier	Measure title, description & measure developer	Electronic measure specifications information
NQF 0440	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. Measure Developer: The Joint Commission.	
Stroke-10	Title: Ischemic or hemorrhagic stroke—Rehabilitation assessment	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0441	Description: Ischemic or hemorrhagic stroke patients who were assessed for rehabilitation services. Measure Developer: The Joint Commission.	
VTE–1	Title: VTE prophylaxis within 24 hours of arrival	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0371	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. Measure Developer: The Joint Commission.	
VTE–2	Title: ICU VTE prophylaxis	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0372	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). Measure Developer: The Joint Commission.	
VTE–3	Title: Anticoagulation overlap therapy	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0373	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. Overlap therapy must be administered for at least five days with an international normalized ratio (INR) $\geq$ 2 prior to discontinuation of the parenteral anticoagulation therapy or the patient must be discharged on both medications. Measure Developer: The Joint Commission.	
VTE–4	Title: Platelet monitoring on unfractionated heparin	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0374	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. Measure Developer: The Joint Commission.	
VTE–5	Title: VTE discharge instructions	*http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.*
NQF 0375	Description: This measure assesses the number of patients diagnosed with confirmed VTE that are discharged to home, to home with home health, home hospice or discharged/transferred to court/law enforcement 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.	

TABLE 20—PROPOSED CLINICAL QUALITY MEASURES FOR ELECTRONIC SUBMISSION BY ELIGIBLE HOSPITALS FOR PAYMENT YEAR 2011–2012—Continued

Measure No. identifier	Measure title, description & measure developer	Electronic measure specifications information
VTE–6	Measure Developer: The Joint Commission. Title: Incidence of potentially preventable VTE	*http://www.hitsp.org/ConstructSet_Details.aspx?&Prefix Alpha=5&Prefix Numeric=906.*
NQF 0376	Description: This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date. Measure Developer: The Joint Commission.	
RHQDAPU AMI–8a	Title: Primary PCI Received Within 90 Minutes of Hospital Arrival.	
NQF 0163	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. Measure Developer: CMS/OFMQ.	
RHQDAPU PN–3b	Title: Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	
NQF 0148	Description: Pneumonia patients whose initial emergency room blood culture specimen was collected prior to first hospital dose of antibiotics. This measure focuses on the treatment provided to Emergency Department patients prior to admission orders. Measure Developer: CMS/OFMQ.	
RHQDAPU AMI–2	Title: Aspirin Prescribed at Discharge.	
NQF 0142	Description: Acute myocardial infarction (AMI) patients who are prescribed aspirin at hospital discharge. Measure Developer: CMS/OFMQ.	
RHQDAPU AMI–3	Title: Angiotensin Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) for Left Ventricular Systolic Dysfunction (LVSD).	
NQF 0137	Description: Acute myocardial infarction (AMI) patients with left ventricular systolic dysfunction (LVSD) who are prescribed an ACEI or ARB at hospital discharge. For purposes of this measure, LVSD is defined as chart documentation of a left ventricular ejection fraction (LVEF) less than 40% or a narrative description of left ventricular systolic (LVS) function consistent with moderate or severe systolic dysfunction. Measure Developer: CMS/OFMQ.	
RHQDAPU AMI–5	Title: Beta-Blocker Prescribed at Discharge.	
NQF 0160	Description: Acute myocardial infarction (AMI) patients who are prescribed a betablocker at hospital discharge. Measure Developer: CMS/OFMQ.	
RHQDAPU AMI–READ	Title & Description: Hospital Specific 30 day Risk-Standardized Readmission Rate following AMI admission.	
NQF 0505	Measure Developer: CMS.	
Not applicable	Title: Hospital Specific 30 day Rate following AMI admission.	
RHQDAPU HF–READ	Title & Description: Hospital Specific 30 day Risk-Standardized Readmission Rate following Heart Failure admission.	
NQF 0330	Measure Developer: CMS/OFMQ.	
Not applicable	Title: Hospital Specific 30 day Rate following Heart Failure admission.	
RHQDAPU PNE–READ	Title & Description: Hospital Specific 30 day Risk-Standardized Readmission Rate following Pneumonia admission.	
NQF 0506	Measure Developer: CMS.	
Not applicable	Title: Hospital Specific 30 day Rate following Pneumonia admission.	
NQF 0528	Title: Infection SCIP Inf-2 Prophylactic antibiotics consistent with current recommendations. Description: Surgical patients who received prophylactic antibiotics consistent with current guidelines (specific to each type of surgical procedure). Measure Developer: CMS/OFMQ.	
NQF 0302	Title: Ventilator Bundle. Description: Percentage of intensive care unit patients on mechanical ventilation at time of survey for whom all four elements of the ventilator bundle are documented and in place. The ventilator bundle elements are: • Head of bed (HOB) elevation 30 degrees or greater (unless medically contraindicated); noted on 2 different shifts within a 24 hour period.	

TABLE 20—PROPOSED CLINICAL QUALITY MEASURES FOR ELECTRONIC SUBMISSION BY ELIGIBLE HOSPITALS FOR PAYMENT YEAR 2011–2012—Continued

Measure No. identifier	Measure title, description & measure developer	Electronic measure specifications information
	• Daily "sedation interruption" and daily assessment of readiness to extubate; process includes interrupting sedation until patient follow commands and patient is assessed for discontinuation of mechanical ventilation; Parameters of discontinuation include: resolution of reason for intubation; inspired oxygen content roughly 40%; assessment of patients ability to defend airway after extubation due to heavy sedation; minute ventilation less than equal to 15 liters/minute; and respiratory rate/tidal volume less than or equal to 105/min/L (RR/TV < 105). • SUD (peptic ulcer disease) prophylaxis DVT (deep venous thrombosis) prophylaxis. Measure Developer: IHI.	
NQF 0298	Title: Central Line Bundle Compliance. Description: Percentage of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place. The central line bundle elements include: • Hand hygiene. • Maximal barrier precautions upon insertion. • Chlorhexidine skin antisepsis. • Optimal catheter site selection, with subclavian vein as the preferred site for non-tunneled catheters in patients 18 years and older. • Daily review of line necessity with prompt removal of unnecessary lines. Measure Developer: IHI.	
NQF 0140	Title: Ventilator-associated pneumonia for ICU and high-risk nursery (HRN) patients. Description: Percentage of ICU and HRN patients who over a certain amount of days have ventilator-associated pneumonia. Measure Developer: CDC.	
NQF 0138	Title: Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients. Description: Percentage of intensive care unit patients with urinary catheter-associated urinary tract infections. Measure Developer: CDC.	
NQF 0139	Title: Central line catheter-associated blood stream infection rate for ICU and high-risk nursery (HRN) patients. Description: Percentage of ICU and high-risk nursery patients, who over a certain amount of days acquired a central line catheter-associated blood stream infections over a specified amount of line-days. Measure Developer: CDC.	
NQF 0329	Title: All-Cause Readmission Index (risk adjusted). Description: Overall inpatient 30-day hospital readmission rate. Measure Developer: United Health Group.	
Not applicable	Title: All-Cause Readmission Index. Description: Overall inpatient 30-day hospital readmission rate.	

TABLE 21—PROPOSED ALTERNATIVE MEDICAID CLINICAL QUALITY MEASURES FOR MEDICAID ELIGIBLE HOSPITALS

NQF No.	Measure title, description & measure developer	Electronic measure specifications information
0341	Title: PICU Pain Assessment on Admission. Description: Percentage of PICU patients receiving: a. Pain assessment on admission. b. Periodic pain assessment. Measure Developer: Vermont Oxford Network.	
0348	Title: Iotrogenic pneumothorax in non-neonates (pediatric up to 17 years of age). Description: Percent of medical and surgical discharges, age under 18 years, with ICD–9–CM code of iatrogenic pneumothorax in any secondary diagnosis field. Measure Developer: AHRQ.	
0362	Title: Foreign body left after procedure, age under 18 years. Description: Discharges with foreign body accidentally left in during procedure per 1,000 discharges. Measure Developer: AHRQ.	
0151	Title: Pneumonia Care PNE–5c Antibiotic. Description: Percentage of pneumonia patients 18 years of age and older who receive their first dose of antibiotics within 6 hours after arrival at the hospital. Measure Developer: CMS/OFMQ.	
0147	Title: Pneumonia Care PN–6 Antibiotic selection. Description: Percentage of pneumonia patients 18 years of age or older selected for initial receipts of antibiotics for community-acquired pneumonia (CAP).	

TABLE 21—PROPOSED ALTERNATIVE MEDICAID CLINICAL QUALITY MEASURES FOR MEDICAID ELIGIBLE HOSPITALS—Continued

NQF No.	Measure title, description & measure developer	Electronic measure specifications information
0356	Measure Developer: CMS/OFMQ. Title: Pneumonia Care PN–3a Blood culture. Description: Percent of pneumonia patients, age 18 years or older, transferred or admitted to the ICU within 24 hours of hospital arrival who had blood cultures performed within 24 hours prior to or 24 hours after arrival at the hospital. Measure Developer: CMS/OFMQ.	
0527	Title: Infection SCIP Inf-1 Prophylactic antibiotic received within 1 hour prior to surgical incision. Description: Surgical patients with prophylactic antibiotics initiated within 1 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. Measure Developer: CMS/OFMQ.	
0529	Title: Infection SCIP Inf-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time. Description: Surgical patients whose prophylactic antibiotics were discontinued within 24 hours after *Anesthesia End Time.* Measure Developer: CMS/OFMQ.	

We have included in the hospital measures set several clinical quality measures which have undergone development of electronic specifications. These clinical quality measures have been developed for future RHQDAPU consideration. The electronic specifications were developed through an interagency agreement with ONC to develop interoperable standards for EHR submission of the ED throughput, stroke, and VTE clinical quality measures on Table 20, to be determined by a future rulemaking document provided by ONC. We also have planned to test the submission of these clinical quality measures in Medicare (see 74 FR 43893). The specifications for the RHQDAPU clinical quality measures for eligible hospitals that are being used for testing EHR-based submission of these clinical quality measures can be found at *http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906.* A description of the clinical quality measure, including the clinical quality measure's numerator and denominator, can be found here as well. Other measures are currently in the RHQDAPU program or are measures of importance for measuring or preventing adverse outcomes. In addition to Risk Standardized readmission clinical quality measures, we have proposed Readmission rates to be reported which are not risk adjusted. We have also reviewed the recommendations of the HIT Standards Committee that apply to hospitals which include Atrial Fibrillation Receiving Anticoagulation Therapy. We note that Atrial Fibrillation Receiving Anticoagulation Therapy is one of the clinical quality measures included on Table 20, identified in the table as Stroke-3. We note that we have not included the HIT Standards Committee recommended clinical quality measure on surgery patients who received VTE prophylaxis within 24 hours period to surgery to 24 hours after surgery end time because it is a current clinical quality measure collected in the RHQDAPU program through chart abstraction for all applicable patients (SCIP–VTE–2). The VTE–2 clinical quality measure in Table 20 is a parallel clinical quality measure to SCIP–VTE–2, includes non-surgical patients, and is a more feasible to implement because the electronic specifications have been completed. We have however added SCIP–VTE–2 for future consideration.

To satisfy the requirements of reporting on clinical quality measures under sections 1886(n)(3)(A)(iii) and 1903(t)(6)(C) of the Act for the 2011–2012 payment year, we propose to require eligible hospitals to report on all EHR incentive clinical quality measures for which they have applicable cases, without regard to payer. Medicare eligible hospitals, who are also participating in the Medicaid EHR incentive program, will also be required to report on all Medicaid clinical quality measures for which the eligible hospital has applicable cases. To demonstrate that it is an eligible meaningful EHR user, the eligible hospital is required to electronically submit information on each clinical quality measures for each patient to whom the clinical quality measure applies, regardless of payer, discharged from the hospital during the EHR reporting period and for whom the clinical quality measure is applicable. Although we do not propose to require clinical quality reporting electronically until 2012, we propose to begin clinical quality reporting though attestation in the 2011 payment year. We solicit comment on whether it may be more appropriate to defer some or all clinical quality reporting until the 2012 payment year. If reporting on some but not all measures in 2011 is feasible, we solicit comment on which key measures should be chosen for 2011 and which should be deferred until 2012 and why.

We invite comments on these proposed clinical quality measures for eligible hospitals and our proposed timelines to post specification documents for these clinical quality measures to the CMS Web site.

g. Request for Public Comment on Potential Measures for EPs and Eligible Hospitals in 2013 Payment Year and Subsequent Years

We expect that the number of clinical quality measures for which EPs and eligible hospitals will be able to electronically submit information will rapidly expand in 2013 and beyond.

We plan to consider measures from the 2010 PQRI program. These clinical quality measures can be found at *http://www.cms.hhs.gov/PQRI/05_StatuteRegulationsProgramInstructions.asp*

For future considerations of clinical quality measures for 2013 and beyond for eligible hospitals, we will also

consider other clinical quality measures from the RHQDAPU program which are identified in the FY 2010 IPPS final rule (74 FR 43868 through 43882). We invite comments on inclusion of clinical quality measures for the 2013 and beyond HITECH Act Medicare and Medicaid incentive program, based on Stage 2 and Stage 3 meaningful use criteria.

For the 2013 payment year, we are considering expanding the Medicaid EHR incentive programs clinical quality measure set for EPs and eligible hospitals to include clinical quality measures that address the following clinical areas, to address quality of care for additional patient populations, and facilitate alignment with Medicaid and CHIP programs:

- Additional pediatrics measures (such as completed growth charts, electronic prescriptions with weight-based dosing support and documentation of newborn screening).
- Long-term care measures.
- Additional obstetrics measure.
- Dental care/oral health measures.
- Additional mental health and substance abuse measures.

The above lists do not constitute a comprehensive list of all clinical quality measures that may be considered. Specific measures for payment years 2013 and beyond will be addressed by CMS in future notice and comment rulemaking. To assist us in identifying potential clinical quality measures for future consideration for years 2013 and beyond, we welcome comments on the potential topics and/or clinical quality measures listed above as well as suggestions for additional clinical quality measure topics and/or specific clinical quality measures.

h. Proposed Reporting Method for Clinical Quality Measures for 2011 and 2012 Payment Year

(1) Reporting Method for 2011 Payment Year

As we previously discussed, we propose to use attestation as a means for EPs and eligible hospitals, for purposes of the Medicare incentive program, to demonstrate the meaningful use requirement for the calculation and submission of clinical quality measure results to CMS.

Specifically, for 2011, we propose to require that Medicare EPs and hospitals attest to the use of a certified EHR system to capture the data elements and calculate the results for the applicable clinical quality measures.

We further propose to require that Medicare EPs and eligible hospitals attest to the accuracy and completeness of the numerators, denominators, and exclusions submitted for each of the applicable measures, and report the results to CMS for all applicable patients.

Attestation will utilize the same system for other attestation for meaningful use, and we propose to require for Medicare EPs that they attest to the following:

- The information submitted with respect to clinical quality measures was generated as output of an identified certified electronic health record.
- The information submitted is accurate to the best of the knowledge and belief of the EP.
- The information submitted includes information on all patients to whom the clinical quality measure applies.
- The NPI and TIN of the EP submitting the information, and the specialty group of clinical quality measures that are being submitted.
- For an EP who is exempt from reporting each of the core measures, an attestation that one or more of the core measures do not apply to the scope of practice of the EP.
- For an EP who is exempt from reporting on a specialty group, an attestation that none of the specialty groups applies to the scope of practice of the EP.
- For an EP who does report on a specialty group, but is exempt from reporting on each of the clinical quality measures in the group, an attestation that the clinical quality measures not reported do not apply to any patients treated by the EP.
- The numerators, denominators, and exclusions for each clinical quality measure result reported, providing separate information for each clinical quality measure including the numerators, denominators, and exclusions for all patients irrespective third party payer or lack thereof; for Medicare FFS patients; for Medicare Advantage patients; and for Medicaid patients.
- The beginning and end dates for which the numerators, denominators, and exclusions apply.

For eligible hospitals, we propose to require that they attest to the following:

- The information submitted with respect to clinical quality measures was generated as output from an identified certified EHR.
- The information submitted to the knowledge and belief of the official submitting on behalf of the eligible hospital.
- The information submitted includes information on all patients to whom the measure applies.
- The identifying information for the eligible hospital.
- For eligible hospitals that do not report one or more measures an attestation that the clinical quality measures not reported do not apply to any patients treated by the eligible hospital during the reporting period.
- The numerators, denominators, and exclusions for each clinical quality measure result reported, providing separate information for each clinical quality measure including the numerators, denominators, and exclusions for all patients irrespective third party payer or lack thereof; for Medicare FFS patients; for Medicare Advantage patients; and for Medicaid patients.
- The beginning and end dates for which the numerators, denominators, and exclusions apply.

(2) Reporting Method for 2012

In accordance with sections 1848(o)(2)(A)(iii) and 1886(n)(3)(A)(iii) of the Act, an EP or eligible hospital, respectively, must submit summary information (that is, information that is not personally identifiable) on the clinical quality measures selected by the Secretary using certified EHR technology in order to demonstrate their meaningful use of certified EHR technology. Additionally, for the 2012 payment year, we propose that EPs and eligible hospitals be required to electronically submit the summary information for a selected clinical quality measure from those listed in Tables 3 through 21 using certified EHR technology as defined in section II.A.1.a of this proposed rule for the Medicare and Medicaid incentives. The required Medicare incentive information will be identified in the measures specifications, which we intend will be on our Web site 9 months before the start of the payment year. For Medicaid, EPs and hospitals eligible only for the Medicaid EHR incentive program must report their clinical quality measures data to States. States will propose to CMS how they plan to accept and validate Medicaid providers' clinical quality measures data in their State Medicaid HIT Plans, subject to CMS review and approval, as described in section II.D.7. of this proposed rule.

Sections 1848(o)(A)(2)(iii) and 1886(n)(3)(A)(iii) of the Act broadly state that as a condition of demonstrating meaningful use of certified EHR technology, an EP, CAH or eligible hospital must "submit information" for the EHR reporting period on the clinical quality or other measures selected by the Secretary "in a form and manner specified by the

Secretary." This language does not limit us to collecting only that information pertaining to Medicare and Medicaid beneficiaries. Therefore, we believe that we have the authority to collect summarized clinical quality measures selected by the Secretary, with respect to all patients to whom the clinical quality measure applies, treated by the EP or eligible hospital. We believe that it is necessary for the EP or eligible hospital to report on all cases to which a clinical quality measures applies in order to accurately assess the quality of care rendered by the particular EP or eligible hospital generally. Otherwise it would only be possible to evaluate the care being rendered for a portion of patients and lessen the ability to improve quality generally. We solicit comments on the impact of requiring the submission of clinical quality measures data on all patients, not just Medicare and Medicaid beneficiaries.

Sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) of the Act requires that in selecting clinical quality measures, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under section 1848(k)(2)(C) of the Act (the PQRI program) and eligible reporting under section 1886(b)(3)(B)(viii) of the Act (RHQDAPU program). We interpret "redundant or duplicative reporting" to mean requiring the reporting of data on the same clinical quality measure separately for two or more quality reporting programs under Medicare. Similarly, we seek to align clinical quality measure reporting activities under CHIPRA with those proposed here, to avoid duplication of reporting and to strengthen the quality reporting infrastructure more broadly. Therefore, when a clinical quality measure is included in more than one quality reporting incentive program, we will seek to avoid requiring EPs and eligible hospitals to report the same clinical quality measure under separate programs. In instances in which a particular clinical quality measure is included in the Medicare EHR incentive program and another Medicare quality reporting incentive program, an EP or eligible hospital would only need to report the measure under the Medicare EHR incentive program, and the reporting of such clinical quality measure using certified EHR technology would be considered as the EP or eligible hospitals having satisfied the parallel reporting requirement under all other applicable Medicare programs. With respect to any clinical quality measures that may be included in the measure sets for both the Medicare EHR Incentive Programs for EPs and the PQRI, we note that there is no existing statutory authority to make PQRI incentive payments for services furnished in 2011 and subsequent years.

We propose that Medicare EPs and eligible hospitals would be required to report the required clinical quality measures information electronically using certified EHR technology via one of three methods. The primary method would require the EP or eligible hospital to log into a CMS-designated portal. Once the EP or eligible hospital has logged into the portal, they would be required to submit, through an upload process, data payload based on specified structures, such as Clinical Data Architecture (CDA), and accompanying templates produced as output from their certified EHR technology.

As an alternative to this data submission method, we propose to permit Medicare EPs and eligible hospitals to submit the required clinical quality measures data using certified EHR technology through Health Information Exchange (HIE)/Health Information Organization (HIO). This alternative data submission method would be dependent on the Secretary's ability to collect data through a HIE/HIO network and would require the EP or eligible hospital who chooses to submit data via an HIE/HIO network to be a participating member of the HIE/HIO network. Medicare EPs and eligible hospitals would be required to submit their data payload based on specified structures or profiles, such as Clinical Data Architecture (CDA), and accompanying templates. The EP's or eligible hospital's data payload should be an output from their respective certified EHR products, in the form and manner specified from their HIE/HIO adopted architecture into the CMS HIE/HIO adopted architecture.

As another potential alternative, we propose to accept submission through registries dependent upon the development of the necessary capacity and infrastructure to do so using certified EHRs.

We intend to post the technical requirements for portal submission and the alternative HIE/HIO submission, the HIE/HIO participating member definition, and other specifications for submission on our Web site for Medicare EPs on or before July 1, 2011 and for Medicare eligible hospitals on or before April 1, 2011 for EHR adoption and incorporation and to accommodate EHR vendors.

We invite comments on our three proposed clinical quality measures data submission methodologies as they pertain to CMS for Medicare and to States for Medicaid.

i. Alternative Reporting Methods for Clinical Quality Measures

There are several alternative reporting methods we considered to create a dataset of provider-submitted summary data. One such alternative is the development of a distributed network of EHRs where health information is retained locally in individual EP or eligible hospital EHRs and only summary reports are submitted to CMS. Another alternative is the creation of databases of patient-level EHR data stored at the state or regional level. We invite comment on our proposed approach, as well as our two alternatives. We also invite comment on all other alternative reporting methods.

j. Proposed Reporting Criteria for EPs and Eligible Hospitals

Sections 1848(o)(A)(2)(iii) and 1886(n)(3)(A)(iii) of the Act state that to demonstrate meaningful use of certified EHR technology for an EHR reporting period, an EP and eligible hospital must submit information "for such period" on the clinical quality measures and other measures selected by the Secretary. We therefore propose that for 2011 and 2012, the reporting period for the clinical quality measures selected by the Secretary be the EHR reporting period as previously defined in section II.A.1.e. of this proposed rule.

Another alternative we considered was a fixed reporting period of four quarterly reporting periods, or 2, 6-month reporting periods. In terms of practice and precedent for other Medicare clinical quality measure reporting programs, all submit data to us at specific reporting intervals.

We invite industry and interested stakeholder comments on our proposal, especially those who may feel that a fixed period would be more advantageous.

k. Addressing Dually Eligible Medicare/Medicaid Beneficiaries Under HITECH

Since the EHR incentives are based on Medicare or Medicaid EPs choosing one program or the other, we are concerned that the Medicare and Medicaid incentive programs address the HIT needs of dually eligible program beneficiaries. Since this population requires special coordination between the State and Federal government, we intend to engage in new efforts to promote Medicare health information exchange with States, as well as look for other new ways to meet the care management objectives of this population through HIT. As such, we

are requesting comments on potential measures to reach our goal.

4. Demonstration of Meaningful Use

Section 1848(o)(3)(C) of the Act, as added by section 4101(a) of the HITECH Act, requires that as a condition of eligibility for the incentive payment, an EP must demonstrate meaningful use of certified EHR technology (other than the reporting on clinical quality and other measures) as discussed in section II.A.3 of this proposed rule in the manner specified by the Secretary, which may include the following: An attestation, the submission of claims with appropriate coding, a survey response, reporting of clinical quality or other measures, or other means. Similarly, section 1886(n)(3)(c) of the Act, as added by section 4102(a) of the HITECH Act, requires that hospitals seeking the incentive payment demonstrate meaningful use of certified EHR technology in the manner specified by the Secretary. Section 1903(t)(6)(C)(i)(II) of the Act, as added by section 4201(a)(2) under the HITECH Act, states that a Medicaid EP or eligible hospital must demonstrate meaningful use through a "means that is approved by the State and acceptable to the Secretary." In addition, pursuant to section 1903(t)(9) of the Act, a State must demonstrate to the satisfaction of the Secretary that the State is conducting adequate oversight, including the routine tracking of meaningful use attestations and reporting mechanisms.

a. Common Methods of Demonstration in Medicare and Medicaid

We propose to create a common method for demonstrating meaningful use in both the Medicare and Medicaid EHR incentive programs, for the same reasons we have proposed a uniform definition of meaningful use. The demonstration methods we adopt for Medicare would automatically be available to the States for use in their Medicaid programs. The Medicare methods are segmented into two parts, as discussed below. States seeking to modify or propose alternative demonstration methods must submit the proposed methods for prior CMS approval. This process is discussed more fully in Section II.D.7.b.2.c. of this proposed rule.

b. Methods for Demonstration of the Stage 1 Criteria of Meaningful Use

We are proposing at § 495.8 that for CY 2011 and FY 2011, EPs and eligible hospitals demonstrate that they satisfy each of the proposed meaningful use objectives specified in § 495.6 through attestation. For payment years beginning in CY and FY 2012 and subsequent years, we are proposing at § 495.8 that EPs and eligible hospitals demonstrate that they satisfy each of the proposed meaningful use objectives other than "Submitting quality measures to CMS or the States" through attestation, and demonstrate that they satisfy the objective "Submitting quality measure to CMS or the States" through electronic reporting of clinical quality measures to CMS or the States, as specified in section II.A.3 of this proposed rule. Specifically, we propose that EPs and eligible hospitals provide attestation through a secure mechanism, such as through claims based reporting or an online portal. We propose that an EP or eligible hospital would through a one-time attestation following the completion of the EHR reporting period for a given payment year identify the certified EHR technology they are utilizing and the results of their performance on all the measures associated with the objectives of meaningful use. We chose to propose attestation through a secure mechanism because we do not believe that HIT will advance enough from its current state to allow for more automated and/or documented options of demonstrating meaningful use. As HIT matures we expect to base demonstration more on automated reporting by certified EHR technologies, such as the direct electronic reporting of measures both clinical and non clinical and documented participation in HIE. The first example is to the move from attestation for clinical quality measures to direct reporting in 2012 and subsequent years for EPs and eligible hospitals. As HIT advances we expect to move more of the objectives away from being demonstrated through attestation. However, given the current state of HIT, we believe that imposing such demonstration requirements for 2011 would pose significant barriers to participation in the EHR incentive programs.

We believe that the means by which EPs and eligible hospitals demonstrate meaningful use should work for all provider types. We also believe that uniform means of demonstration for EPs and eligible hospitals are preferable and that a greater burden should not be placed on one or the other. In addition, we do not believe that demonstration of meaningful use should require use of certified EHR technology beyond the capabilities certified to be determined by a future rulemaking document provided by ONC.

In addition to requiring electronic reporting of clinical quality measures in 2012 in Medicare and Medicaid, we also propose for CMS and/or the States to test options to utilize existing and emerging HIT products and infrastructure capabilities to satisfy other objectives of the meaningful use definition. The optional testing could involve the use of registries or the direct electronic reporting of some measures associated with the objectives of the meaningful use definition. We do not propose to require any EP or eligible hospital to participate in this testing in either 2011 or 2012 in order to receive an incentive payment. However, in order to make progress towards our goal of meaningful use being demonstrated through the electronic exchange of information we encourage States to explore the available options. The state of electronic exchange varies widely across the country and is dependent on numerous Federal, State, local, non-profit and for-profit initiatives. Given this high state of flux, CMS and/or the States would have to issue considerable updated guidance to EPs and eligible hospitals who wish to join in our efforts to explore the electronic exchange of information. Any testing should be based on the principal of electronic exchange of information from certified EHR technology either directly to the States or through an intermediary. For purposes of the programs in this proposed rule it would be counterproductive for an intermediary to collect information through paper abstraction.

We will issue further instructions on the specifics for submitting attestation through established outreach venues.

5. Data Collection for Online Posting, Program Coordination, and Accurate Payments

As described below, the HITECH Act requires the Secretary to post online the names of Medicare EPs and eligible hospitals and CAHs who are meaningful EHR users for the relevant payment year. Section 1903(t)(2) of the Act also requires us to ensure that EPs do not receive an EHR incentive payment under both Medicare and Medicaid. To fulfill these mandates, we must collect several data elements from EPs and eligible hospitals. Beyond these two direct HITECH Act requirements, CMS and the States also require certain data in order to accurately calculate and distribute the incentive payments.

a. Online Posting

Section 1848(o)(3)(D) of the Act requires the Secretary to list in an easily understandable format the names, business addresses, and business phone numbers of the Medicare EPs and, as

determined appropriate by the Secretary, of group practices receiving incentive payments for being meaningful EHR users under the Medicare FFS program on our internet Web site. We do not propose to post information on group practices because we do not propose to base incentive payments at the group practice level. Section 1886(n)(4)(B) of the Act, as added by section 4102(c) of the HITECH Act, requires the Secretary to list in an easily understandable format the names and other relevant data, as she determines appropriate, of eligible hospitals and CAHs who are meaningful EHR users under the Medicare FFS program, on our internet Web site. Eligible hospitals and CAHs will have the opportunity to review the list before the list is publicly posted. Sections 1853(m)(5) and 1853(l)(7) of the Act, as added by sections 4101(c) and 4102(c) of the HITECH Act, require the Secretary to post the same information for EPs and eligible hospitals in the MA program as would be required if they were in the Medicare FFS program. Additionally, the Secretary must post the names of the MA organizations receiving the incentive payment or payments. We propose to collect the information necessary to post the name, business address and business phone numbers of all EPs, eligible hospitals and CAHs participating in the Medicare FFS and MA EHR incentive programs, and to post this information on our Web site.

b. Program Election Between Medicare FFS/MA and Medicaid for EPs

Section 1903(t)(2) of the Act prohibits an EP from receiving incentive payments under the Medicaid program unless the EP has waived any rights to incentive payments under the Medicare FFS or MA programs. Furthermore, section 1903(t)(7) of the Act requires the Secretary to assure no duplication of funding with respect to the Medicaid program, and the physician and MA incentive payments under sections 1848(o) and 1853(l) of the Act. This waiver and non-duplication requirement applies only to EPs meeting both the Medicare FFS/MA and Medicaid EHR incentive programs eligibility criteria, and does not apply to hospitals (which are eligible to receive incentive payments from both Medicare and Medicaid simultaneously). Proposed § 495.10 would allow an EP meeting the eligibility criteria for both the Medicare FFS/MA and Medicaid programs to participate in either program. Further, the EP would be permitted to change his or her election once during the life of the EHR incentive programs after making the initial election. We believe this one-time election rule would allow an EP whose patient volume no longer makes him or her eligible for the Medicaid program to nevertheless continue to receive incentive payments that would encourage the meaningful use of certified EHR technology. For example, an EP who moves to a different practice or geographically relocates practices may reduce his or her Medicaid patient volume, and therefore become ineligible for the Medicaid incentive payments. Allowing this EP to continue to receive incentive payments under Medicare (if eligible) would continue the incentive for meaningfully using EHR technology, and would allow EPs a certain amount of flexibility in their operations. While allowing this flexibility creates administrative complexity, we believe a significant number of EPs could have their participation in the EHR incentive programs endangered due to changing circumstances unrelated to the EHR incentive programs.

Under our proposal, if an EP does decide to switch programs, we propose that the EP would continue in the next program at whichever payment year he or she would have attained had the EP not chosen to switch. For example, if an EP decides to switch after receiving his or her Medicare FFS incentive payment for their second payment year, then the EP would be in its third payment year for purposes of the Medicaid incentive payments. Even after lining up the payment years, it is possible for an EP to exceed the payment cap under Medicaid by switching programs at the right time. We do not believe that the Congress intended for the payment caps to be exceeded under any circumstance, and therefore propose that no EP should receive more than the maximum incentive available to them under Medicaid, which is the higher of the two caps. The last year incentive payment would be reduced if awarding the EP the full amount would exceed the overall maximum available under Medicaid. This is possible if an EP receives their first two payment years from Medicare and then the last four from Medicaid, as the cap would be exceeded by $250. An EP who switches from Medicaid to Medicare could exceed the Medicare threshold in a number of circumstances; however, since they cannot exceed the Medicaid threshold under any circumstance, we propose to pay the incentive for which they are eligible for a given payment year in whichever program they are in for that payment year. Finally, we propose that the last year for making an incentive payment program switch would be CY 2014. In making this proposal, we considered that it is both the last year an EP can enroll in the Medicare EHR incentive program, and also the last year before the payment adjustments under Medicare can begin. We request comments on the necessity of the ability to switch and the allowed timing for such switches.

c. Data To Be Collected

In addition to information regarding the demonstration of meaningful use, in § 495.10 of this proposed rule we propose to collect the following administrative data for the Medicare and Medicaid EHR incentive programs to fulfill our requirements of online posting, avoidance of duplication of incentive payments, and to ensure accurate and timely incentive payments:

- Name, NPI, business address, and business phone of each EP or eligible hospital.
- Taxpayer Identification Number (TIN) to which the EP or eligible hospital wants the incentive payment made. For Medicaid EPs this must be consistent with assignment rules at § 495.10.
- For EPs, whether they elect to participate in the Medicare EHR incentive programs or the Medicaid EHR incentive program.
- For eligible hospitals, their CCN.

To coordinate with the States to avoid duplication of payments, we further propose to make available to the States through a single repository the following additional data:

- Whether an EP or eligible hospital is a meaningful EHR user, and
- The remittance date and amount of any incentive payments made to an EP or eligible hospital.

CMS, our contractors, and the States will have access to these six data elements through a single repository maintained by CMS. The States will have to provide information to us on whether EPs or eligible hospitals are eligible for the Medicaid incentive program, whether EPs or eligible hospitals participating in the Medicaid program are meaningful EHR users, and when any Medicaid incentive payments are made and the amount of the payment. We will put in place processes for an EP or eligible hospital to change their information, including the one-time switch in EHR incentive program election by EPs.

6. Hospital-Based Eligible Professionals

Section 1848(o)(1)(C)(i) of the Act, as added by section 4101(a) of the HITECH Act, states that hospital-based EPs are not eligible for the Medicare incentive

payments. Similarly, the majority of hospital-based EPs will not be eligible for Medicaid incentive payments under 1903(t)(2)(A) of the Act (the only exception to this rule is for those practicing predominantly in an FQHC or RHC). Section 1848(o)(1)(C)(ii) of the Act defines the term "hospital-based eligible professional" to mean an EP, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of his or her Medicare-covered professional services during the relevant EHR reporting period in a hospital setting (whether inpatient or outpatient) through the use of the facilities and equipment of the hospital, including the hospital's qualified EHRs. This section indicates that the determination of whether an EP is a hospital-based EP shall be made on the basis of the site of service, as defined by the Secretary, and without regard to the type of service provided by the EP or any employment or billing arrangement between the EP and any other provider (for example, the hospital-based determination for an EP would not be affected by whether the EP is an employee of the hospital, under a contractual relationship with the hospital, or with respect to where he or she has made a reassignment to the hospital for Part B billing purposes). Section 1903(t)(3)(D) of the Act defines hospital-based EP in nearly identical terms.

In addition, as discussed below, section 1848(a)(7)(D) of the Act, as added by section 4101(b) of the HITECH Act, exempts hospital-based EPs from the downward payment adjustment applied under section 1848(a)(7)(A)(i) of the Act to covered professional services provided during a payment year by EPs who are not meaningful EHR users for the relevant payment year beginning in 2015.

If an EP is providing "substantially all" of their services in the hospital, we believe it is reasonable to assume that the EP is also using the facilities and equipment of the hospital, including any qualified EHR implemented by the hospital. The statute uses "facilities and equipment" to determine whether an EP is a hospital-based EP. As "facilities and equipment" would generally be understood to apply to the hospital building and its medical and other equipment that is used in furnishing medical services, we believe it is reasonable to assume that an EP providing substantially all of their services in a hospital is providing these services in the hospital building and generally is also using its equipment, including qualified EHRs, and not bringing his or her own equipment to the hospital to provide medical services. Similarly, it seems reasonable to assume that the statute contemplates that an EP that uses the hospital's facilities and equipment would also be using the hospital's EHR system and should be ineligible for an incentive payment. We seek comment as to whether EPs are using qualified EHR of the hospital in ambulatory care settings.

As noted previously, the statute provides that hospital-based EPs, "such as a pathologist, anesthesiologist, or emergency physician," are those EPs that provide substantially all of their Medicare-covered professional services in a "hospital setting (whether inpatient or outpatient)." Because the HITECH Act does not define the term "hospital setting," we looked to existing statutes and regulations that define and describe hospital settings for guidance in defining "hospital setting" for purposes of this proposed rule. We welcome comments on alternative approaches to interpreting the meaning of "hospital setting."

First, section 1861(e) of the Act defines the term a "hospital" to mean an institution that "is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons." Therefore, we propose that EPs that practice primarily in inpatient hospital settings, as referenced in section 1861(e) of the Act, be considered hospital-based EPs.

Because the parenthetical after the term "hospital setting" in the statutory definition of hospital-based EP specifically refers to both inpatient and outpatient hospital settings, we believe the term "hospital setting" should be defined to also include the outpatient setting. So although a "hospital" is an institution that primarily provides inpatient services, we propose to define the term "hospital setting" for purposes of the Medicare and Medicaid EHR incentive payment programs to also include all outpatient settings where hospital care is furnished to registered hospital outpatients. For purposes of Medicare payment and conditions of participation, it is CMS's longstanding policy to consider as outpatient hospital settings those outpatient settings that are owned by and integrated both operationally and financially into the entity, or main provider, that owns and operates the inpatient setting. For example, we consider as outpatient hospital settings all types of outpatient care settings in the main provider, on-campus and off-campus provider-based departments (PBDs) of the hospital, and entities having provider-based status, as these entities are defined in § 413.65.

In accordance with our regulations at § 413.65, a provider-based department or entity must operate under the ownership and financial and administrative control of the main provider. We also note that the provider-based department or entity of the hospital comprises both the physical facility where services are furnished and the personnel and equipment used to care for patients in those settings. In addition, § 413.65(d) specifies that the financial operations of provider-based departments or entities must be fully integrated within the financial system of the main provider. Medicare makes payment to the hospital under the outpatient payment system for the facility resources required for care that is furnished to hospital outpatients in its provider-based departments and entities, regardless of the specific type of hospital outpatient setting. Moreover, Medicare pays EPs for their professional services furnished to hospital outpatients at the facility rate under the Medicare Physician Fee Schedule (MPFS), also regardless of the specific type of hospital outpatient setting, recognizing that in all hospital outpatient settings the hospital bears the cost of personnel, equipment, and supplies for which payment would otherwise be made to the EP under the MPFS for services furnished in a non-facility setting. Section 413.65(d) also requires that the medical records for patients treated in the provider-based department or entity must be integrated into a unified retrieval system (or cross reference) of the main provider. Moreover, an eligible hospital will receive an incentive payment for its medical records system if such system is considered certified EHR technology and is meaningfully used by the hospital consistent with the requirements of the final rule to this rule. Because, by definition of the requirements for provider-based departments and entities, EPs who furnish substantially all of their covered professional services to hospital outpatients use the hospital's facility and equipment, including the integrated medical record system, for which payment is made by Medicare to the hospital, we believe these EPs should be considered hospital-based EPs, and thus excluded from the Medicare EP EHR incentive payments. This is fully consistent with the definition of hospital-based EPs in section 1848(o)(1)(C)(ii) of the Act.

In summary, we propose that EPs that provide substantially all of their professional services in the inpatient hospital setting, in any type of outpatient hospital setting, or in any combination of inpatient and outpatient hospital settings, be considered hospital-based EPs.

We propose to consider the use of place of service (POS) codes on physician claims to determine whether an EP furnishes substantially all of their professional services in a hospital setting and is, therefore, hospital-based. This code set is required for use in the implementation guide adopted as the national standard for electronic transmission of professional health care claims under the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA directed the Secretary of HHS to adopt national standards for electronic transactions. These standard transactions require all health plans and providers to use standard code sets to populate data elements in each transaction. The Transaction and Code Set Rule (65 FR 50312) adopted the ASC X12N–837 Health Care Claim: Professional, volumes 1 and 2, version 4010, as the standard for electronic submission of professional claims. This standard names the POS code set currently maintained by CMS as the code set to be used for describing sites of service in such claims and is available at *http://www.cms.hhs.gov/PlaceofServiceCodes/Downloads/POS_09_10_07_Rev_2_508.pdf*.

From this code set, we propose to consider the use of the following POS codes indicating that the EP provided the service in an inpatient or any type of outpatient hospital setting (including a PBD of a hospital) to determine whether an EP is a hospital-based eligible professional:

- 21—Inpatient Hospital—is a facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians, to patients admitted for a variety of medical conditions.
- 22—Outpatient Hospital—is a portion of a hospital which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
- 23—Emergency Room, Hospital—is a portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.

Place of service codes 22 (Outpatient Hospital) and 23 (Emergency Room, Hospital) are commonly recognized to be outpatient departments of the hospital. An outpatient department of a hospital will either meet the definition of the "main provider," a "department of a provider," or of having "provider-based status" as those terms are used in § 413.65. Place of service codes 22 and 23 are used to describe hospital outpatient settings that meet these definitions under § 413.65 and are also subject to the conditions of participation under part 482.

The statutory definition of hospital-based EP provides that to be considered a hospital-based EP, the EP must provide "substantially all" of his or her covered professional services in a hospital setting, which we propose to encompass all hospital inpatient and outpatient settings, including all settings that meet the definition of the main provider, department of a provider, or of having provider-based status. Therefore, we must identify the minimum percentage of an EP's covered professional services that must be provided in a hospital setting in order for the EP to be considered as providing "substantially all" of his or her covered professional services in a hospital setting. We would define "substantially all" as furnishing at least 90 percent of services in a hospital setting, either inpatient or outpatient. We believe this threshold appropriately balances our competing goals of ensuring that professionals are encouraged to participate in the incentive program and avoid duplicate payments to a professional who is primarily using the EHR technology of the hospital in which he or she furnishes services. While we considered using 75 percent as a threshold for determining whether an EP is an hospital-based EP, we are concerned that such a standard could exclude EPs from receiving incentive payments that perform a minority but significant percentage of their services outside of inpatient or outpatient hospital settings and would have offices separate and independent from the hospital where they provide patient care services and for which they would have costs to obtain an EHR system. Based on an analysis of 2008 Medicare claims data, if we define "substantially all" of covered services in a hospital setting to mean that 75 percent or more of an EP's allowed services are associated with one of the place of service codes listed above, we estimate that 65 percent of EPs would be considered eligible to receive an EHR incentive payment. If we increase this criterion to 90 percent, we estimate that 68 of percent of EPs would be eligible for the EHR incentive payment. In other words, 3 percent fewer EPs would be ineligible for the EHR incentive payments if we define "substantially all" to mean at least 90 percent rather than at least 75 percent.

Because EPs providing 90 percent or more of their services in one of these sites as described above are not likely to expend significant resources related to EHRs in other, non-hospital settings, we believe this proposal is most consistent with the law's intent of not providing incentive payments to EPs that are providing substantially all of their services in a hospital setting (whether inpatient or outpatient). However, we are open to comments on other proposals that are consistent with the law's intent of not providing incentive payments to hospital-based physicians as defined in HITECH. In our proposed approach, a hospital-based eligible professional would be ineligible to receive an EHR incentive payment under either Medicare or Medicaid, regardless of the type of service provided, if more than 90 percent of their services are identified as being provided in places of service classified under place of service codes 21, 22, or 23.

Accordingly, for both Medicare and Medicaid incentive payment purposes, we propose that a hospital-based eligible professional is defined as an EP who furnishes 90 percent or more of their covered professional services in any of the above listed places of service. A hospital-based EP would be ineligible to receive EHR incentive payments. (Based on preliminary claims data from the first 9 months of 2009, CMS currently estimates that, under this proposed definition, about 27 percent of Medicare EPs (physicians) would be considered hospital-based and thus not eligible to receive any incentive payments. We do not have any data on Medicaid practitioners.) We propose to make this determination, for Medicare incentive payment purposes, as to whether or not an EP is hospital-based by annually analyzing an EP's claims history from the prior year. Therefore, for example, based on such analysis, an otherwise EP would be considered a hospital-based EP and be ineligible for incentive payments in 2011 if he/she provided 90 percent or more of his/her allowed services in one of the above listed places of service based on their 2010 Medicare claims data. The hospital-based status of each EP would be reassessed each year, using claims data from the year immediately preceding the payment year. For Medicaid purposes, we are proposing that State Medicaid agencies make the determination about whether or not an

EP is hospital-based by analyzing an EP's Medicaid claims data, or in the case of EPs who deliver care via Medicaid managed care programs, by analyzing either encounter data or other equivalent data sources, at the State's option. There is an interest in assuring that nearly all primary care providers are meaningful users of EHR technology by 2014. However, this objective may not be reached because of several factors.

- Some primary care EPs who provide services to Medicare and Medicaid beneficiaries would be ineligible for the incentive payments. For example, we currently estimate that under this proposal, 12–13 percent of family practitioners under Medicare would be considered hospital-based under our proposed definition of hospital-based EP, and therefore would not be eligible for the EHR incentive payments. (Note that we believe that these data could be applied generally to Medicaid physicians as well. However, Medicaid EPs include other practitioners who also must meet hospital-based eligibility requirements, some of whom provide primary care services such as nurse practitioners.) Although many of these family practitioners may be serving in nonprimary care roles within the hospital setting (such as in emergency departments or functioning as hospitalists), those EPs performing primary care services in the hospital setting would also not be eligible to receive EP incentive payments. If these EPs were eligible to receive incentive payments, some might reassign them to the hospital, and the hospital could then use the EP's incentive payments for additional integrated outpatient EHR systems.
- As will be explained in the next section of this proposed rule, the hospital's total incentive payment is based on total inpatient services. As result, a hospital with a large outpatient department will not receive a higher incentive payment as a result of their outpatient services.
- Finally, as previously discussed, we are proposing that the Stage 1 meaningful use criteria for eligible hospitals apply only to a hospital's inpatient setting.

Because of these factors, we are concerned that hospital investment in their outpatient primary care sites is likely to lag behind their investment in their inpatient EHR systems. To address these concerns, as part of future rulemaking, we plan to consider ways to realign the meaningful use objectives and criteria to include a broader definition of hospital care to include outpatient services. We believe this could provide an important incentive for hospital investment in EHRs for their outpatient primary care sites. We welcome comments on these issues including other ways that CMS, under the current statute, could help meet the objective that nearly all primary care providers are meaningful users of EHR technology by 2014.

We also seek comment on the extent to which hospitals install EHRs in their outpatient clinics as part of their adoption of EHRs. In addition, we seek comment on the way that hospitals with provider-based entities meet the provider-based requirements at 42 CFR 413.65(d) if they have EHRs in any or all parts of the hospital.

Finally, we seek comment on whether we should use another method for defining hospital-based EPs than what we have proposed here. Any comments should address implementation based on the specific POS codes identified, and/or any complexities that would result from not including all outpatient settings owned and operated by and integrated with the hospital in the determination of whether an EP is hospital-based.

7. Interaction With Other Programs

The HITECH Act addresses interactions between the Medicare EHR incentive program and the E-prescribing Incentive Program authorized by MIPPA. Under section 1848(m)(2)(D) of the Act, as added by section 4101(f)(2)(B) of the HITECH Act, if a Medicare FFS or MA EP receives an incentive payment from the Medicare EHR incentive program, the EP (or group practice) is not eligible to also receive the incentive payment under the E-prescribing Incentive Program created by MIPPA. Given the payment timelines proposed in this rule for the Medicare EHR incentive program and the existing payment timeline for the E-prescribing Incentive Program, we will know whether an EP received a Medicare EHR incentive payment before the E-Prescribing Incentive Program payment is calculated. Thus we will exclude those EPs (or group practices) who accept a Medicare EHR incentive payment for a given year from being eligible for the E-Prescribing Incentive Program payment for that same year. EPs receiving a Medicaid EHR incentive payment would remain eligible for the Medicare MIPAA E-Prescribing Incentive Program payment.

As the HITECH Act does not specify any other restrictions on participation in other programs and participation in the Medicare and Medicaid EHR incentive programs, we do not propose any other restrictions. There may be opportunities to avoid duplication of reporting requirements among our various programs. In section II.A.3. of this proposed rule, we discuss how we will avoid duplication of reporting requirements for clinical quality measures.

B. Medicare Fee-for-Service Incentives

1. Incentive Payments for Eligible Professionals (EP)

Section 1848(o)(1)(A) of the Act, as amended by section 4101(a) of the HITECH Act, provides for incentive payments to EPs who are meaningful users of certified EHR technology during the relevant EHR reporting periods. Section 1848(o)(1)(A)(i) of the Act provides that EPs who are meaningful EHR users during the relevant EHR reporting period are entitled to an incentive payment amount, subject to an annual limit, equal to 75 percent of the Secretary's estimate of the Medicare allowed charges for covered professional services furnished by the EP during the relevant payment year. Under section 1848(o)(1)(B)(ii)(VI) of the Act, an EP is entitled to an incentive payment for up to 5 years. In addition, in accordance with section 1848(o)(1)(A)(ii) of the Act, there shall be no incentive payments made with respect to a year after 2016. The incentive payments would be disbursed from the Federal Supplementary Medical Insurance Trust Fund, as provided for under section 1848(o)(1)(A)(i) of the Act. As noted in section II.A. of this proposed rule, EPs who qualify for both the Medicare and Medicaid incentive payments must elect to receive payments from one program or the other.

a. Definitions

In accordance with section 1848(o)(5)(C) of the Act, we propose to add a definition of the term "eligible professional" in our regulations at § 495.100 to mean a physician as defined under section 1861(r) of the Act. Section 1861(r) of the Act defines the term "physician" to mean the following five types of professionals, each of which must be legally authorized to practice their profession under state law: A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. As discussed in section II.B.1.a of this proposed rule, in accordance with section 1848(o)(1)(C) of the Act, hospital-based EPs are not eligible for an incentive payment.

Section 1848(o)(5)(A) of the Act defines covered professional services as having the same meaning as in section 1848(k)(3) of the Act, that is, services furnished by an eligible professional for which payment is made under, or is based on, the Medicare physician fee schedule.

In accordance with section 1848(a)(1) of the Act, the Medicare allowed charge for covered professional services is the lesser of the actual charge or the Medicare physician fee schedule amount established in section 1848 of the Act. As specified under section 1848(o)(1)(A)(i), the Secretary's estimate of allowed charges is based on claims submitted to Medicare no later than 2 months following the end of the relevant payment year. We propose to codify these specifications and definitions in our regulations at [cite proposed regulation range].

b. Incentive Payment Limits

Section 1848(o)(1)(B)(i) of the Act sets forth the annual limits on the EHR-related incentive payments to EPs. Specifically, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given payment year shall not exceed the following amounts:

- For the EP's first payment year, for such professional, $15,000 (or, $18,000 if the EP's first payment year is 2011 or 2012).
- For the EP's second payment year, $12,000.
- For the EP's third payment year, $8,000.
- For the EP's fourth payment year, $4,000.
- For the EP's fifth payment year, $2,000.
- For any succeeding year, $0.

Under section 1848(o)(1)(B)(iv) of the Act, for EPs who predominantly furnish services in a geographic HPSA (as designated by the Secretary under section 332(a)(1)(A) of the Public Health Service (PHS) Act), the incentive payment limitation amounts for each payment year are increased by 10 percent. Section 1848(o)(1)(B)(iii) of the Act also provides for a phased reduction in payment limits for EPs who first demonstrate meaningful use of certified EHR technology after 2013. Specifically, if the EP's first payment year is after 2013, then the annual limit on the incentive payment equals the annual limit applicable to an EP whose first payment year is 2013. Accordingly, if the EP's first payment year is 2014, the EP's maximum incentive payment will be $12,000 in 2014, $8,000 in 2015, and $4,000 in 2016. Section 1848(o)(1)(B)(v) of the Act provides that if the EP's first payment year is after 2014, then the applicable incentive payment limit for such year and any subsequent year shall be $0. In other words, an EP who does not qualify to receive an EHR-related incentive payment prior to 2015 will not receive any of these incentive payments. Table 22 shows the maximum incentive payment amounts available to EPs under Medicare FFS. (As noted above and discussed further below, these limits are increased by 10 percent for EPs who predominantly furnish services in an HPSA.)

TABLE 22—MAXIMUM TOTAL AMOUNT OF EHR INCENTIVE PAYMENTS FOR A MEDICARE EP WHO DOES NOT PREDOMINANTLY FURNISH SERVICES IN A HPSA

Calendar year	First CY in which the EP receives an incentive payment				
	2011	2012	2013	2014	2015–subsequent years
2011	$18,000				
2012	12,000	$18,000			
2013	8,000	12,000	$15,000		
2014	4,000	8,000	12,000	$12,000	
2015	2,000	4,000	8,000	8,000	$0
2016		2,000	4,000	4,000	0
Total	44,000	44,000	39,000	24,000	0

The following examples illustrate how the payment amount would be determined:

- *Example 1:* EP that receives the maximum payment. For payment year 2011, the incentive payment for an EP would be, subject to a payment limit of $18,000, equal to 75 percent of the EP's Medicare physician fee schedule allowed charges for CY 2011 (in this case, the maximum allowed charges recognized for the purposes of the incentive, or $24,000 × .75 = $18,000), estimated based on claims for covered professional services furnished by the EP from January 1, 2011 through December 31, 2011, and submitted to the appropriate Medicare administrative contractor (MAC/carrier) on or before February 29, 2012.
- *Example 2:* EP that receives less than the maximum payment. Assume for this example that the EP's estimated total allowed charges for covered professional services are $10,000 which is less than the $24,000 maximum allowed charges that could be recognized for purposes of this incentive. Therefore, for payment year 2011, the incentive payment in this case would be, $10,000 × .75 = $7,500, based on claims for covered professional services furnished by the EP from January 1, 2011 through December 31, 2011, and submitted to the appropriate Medicare administrative contractor (MAC) or carrier on or before February 29, 2012.

We propose, for each subsequent payment year, to use the annual allowed charges and claims in a similar manner to calculate the Secretary's estimate of allowed charges for purposes of computing the incentive payment.

- *Example:* For payment year 2012, the incentive payment issued to an EP would be, subject to a payment limit (that is, $18,000 if it is the first payment year, $12,000 if it is the second payment year), equal to 75 percent of the EP's Medicare physician fee schedule allowed charges for CY 2012, based on claims for covered professional services performed by the EP from January 1, 2012 through December 31, 2012, and submitted to the appropriate Medicare administrative contractor (MAC/carrier) on or before February 28, 2013.

c. Increase in Incentive Payment for EPs Who Predominantly Furnish Services in a Geographic Health Professional Shortage Area (HPSA)

Section 1848(o)(1)(B)(iv) of the Act provides that the amount of the annual incentive payment limit for each payment year be increased by 10 percent for EPs who predominantly furnish services in an area that is designated by the Secretary (under section 332(a)(1)(A) of the PHS Act) as a geographic health professional shortage area (HPSA). Section 332(a)(1)(A) of the PHS Act refers to geographic HPSAs, or areas that have been determined to have a shortage of

health professionals, based on the population-to-provider ratio and other factors. HPSAs are located in every State, and in both rural and urban areas.

Geographic HPSAs are defined in 42 CFR Part 5 and include primary medical care, dental, and mental health HPSAs. In accordance with the statute, we will increase the limits per payment year by 10 percent for EHR-related incentive payments to EPs who predominantly furnish covered professional services in a geographic primary medical care, dental, or mental health HPSA.

We propose that an EP be considered as "predominantly" furnishing covered professional services in a geographic HPSA if more than 50 percent of the EP's Medicare covered professional services are furnished in a geographic HPSA. Using "more than 50 percent" as the criterion to define "predominantly" is consistent with how the term is defined in general parlance as well as how the definition is used for purposes of other aspects of the Medicare program.

To determine whether an EP has furnished more than 50 percent of his/her covered professional services in a geographic HPSA, we propose to utilize frequency of services provided over a 1-year period from January 1 to December 31, rather than basing it on the percentage of allowed charges. Our data indicates that most physicians either provide all or none of their services in a geographic HPSA, so we believe that our proposal to base eligibility for the 10 percent EHR HPSA payment limit increase on frequency, rather than allowed charges, will have little or no impact on the determination of whether an EP is eligible for the EHR HPSA payment limit increase. To apply the payment limit increase, we will first need to determine whether more than 50 percent of an EP's covered professional services were furnished in a geographic HPSA during a particular payment year. We propose to first make the generally applicable incentive payment to the EP based on an EP's estimated allowed charges for the relevant payment year.

Once we compile a full year of data, we would determine eligibility for the EHR HPSA payment limit increase for the payment year based on whether the EP provided more than 50 percent of his/her services in a geographic HPSA during the payment year. The determination would be made based on claims submitted not later than 2 months after the end of the year. If we determine that the EP provided more than 50 percent of his/her services in a geographic HPSA and is therefore eligible for the EHR HPSA payment limit increase, we would then make an additional lump sum payment to reflect that increased limit amount based on the estimated allowable charges for that EP for the prior year. We propose that the additional amount would be paid no later than 120 days after the end of the prior year for which the EP was eligible for the 10 percent EHR HPSA payment limit increase.

Most physicians furnishing services in a HPSA furnish 100 percent of their covered services in a HPSA. Based on our data, we found very few physicians provide even a modest percentage of their services across HPSA and non-HPSA areas. We estimate that about 17 percent of EPs would qualify for the 10 percent EHR HPSA payment limit increase, provided they satisfy the other requirements for the incentive payment. Section 1848(o)(1)(B)(iv) of the Act also authorizes us to apply the provisions of sections 1833(m) and (u) of the Act in implementing this 10 percent EHR HPSA payment limit increase, as the Secretary determines appropriate. Section 1833(m) of the Act establishes the HPSA bonus program, which provides a 10 percent bonus to physicians who furnish Medicare covered professional services in a geographic HPSA. Section 1833(u) of the Act establishes the Physician Scarcity Area bonus program, which provided a 5 percent bonus to physicians who furnish Medicare covered professional services in areas that are determined to physician scarcity areas. (Note: The authority for the Physician Scarcity Area program ended on June 31, 2008.)

Section 1833(m)(1) of the Act provides that physicians who furnish covered professional services in a year in an area that is designated as a geographic HPSA prior to the beginning of the year are eligible to receive the HPSA bonus for services furnished during the current year. We have interpreted this to mean that bonus payments should continue throughout the current year, even if the area loses its designation as a geographic HPSA during the current year. Physicians furnishing covered professional services in an area that is not designated as a geographic HPSA by December 31 of the prior year are not eligible to receive the HPSA bonus for the current year, even if the area is subsequently designated as a geographic HPSA during the current year. We propose to apply these same rules for the 10 percent EHR HPSA payment limit increase provided under section 1848(o)(1)(B)(iv) of the Act. Specifically, we propose that EPs who predominately furnish covered professional services in an area that is designated as a geographic HPSA as of December 31 of the prior year would be eligible to receive the 10 percent EHR HPSA payment limit increase during the current year, provided the EP qualifies for the EHR HPSA payment limit for the current year. For example, an EP furnishing a covered professional service in an area that was designated as a geographic HPSA as of December 31, 2010, and who qualifies to receive the EHR HPSA payment in 2011, also would receive a 10 percent EHR incentive payment limit increase for 2011.

Section 1833(m)(2) of the Act also provides that geographic HPSAs that consist of an entire county be identified and the bonus paid automatically. We publish a list annually of the zip codes that are in these areas on our Web site at *http://www.cms.hhs.gov/HPSAPSAPhysicianBonuses/01_Overview.asp#TopOfPage.* Physicians furnishing Medicare covered professional services in a zip code that is on this list automatically receive the HPSA bonus payment. Physicians furnishing Medicare covered professional services in a zip code that is not on this list but that was designated as a geographic HPSA as of December 31 of the prior year must use a modifier when submitting a Medicare claim in order to receive the HPSA bonus.

We note that we would only list a zip code on our Web site if the entire geographic area encompassed by the zip code is designated as a geographic HPSA. If a zip code encompasses both areas designated as a geographic HPSA and areas that are not a geographic HPSA, we will not list the zip code on our Web site. Our list also will not include zip codes for areas designated as geographic HPSAs after we create the zip code list (but before December 31). EPs furnishing Medicare covered professional services in an area eligible for the EHR HPSA payment limit increase that is not included in the list of zip codes for automatic payment would need to use a modifier when submitting a claim to identify their eligibility for the HPSA EHR payment limit increase.

Table 23 shows the maximum total EHR HPSA payment limit for an EP who predominantly furnishes covered professional services in a HPSA as described previously above for CYs 2011 through 2016. Table 24 shows the maximum additional amount of incentive payments for a Medicare EP who predominantly furnishes services in a HPSA. (That is, Table 24 shows the difference between Tables 22 and 23.)

TABLE 23—MAXIMUM TOTAL AMOUNT OF INCENTIVE PAYMENTS FOR A MEDICARE EP WHO PREDOMINANTLY PERFORMS SERVICES IN A HPSA

Calendar year	Year that EP becomes EHR user in a HPSA				2015 and subsequent years
	2011	2012	2013	2014	
2011	$19,800				
2012	13,200	$19,800			
2013	8,800	13,200	$16,500		
2014	4,400	8,800	13,200	$13,200	
2015	2,200	4,400	8,800	8,800	$0
2016		2,200	4,400	4,400	0
Total	48,400	48,400	42,900	26,400	0

TABLE 24—MAXIMUM ADDITIONAL AMOUNT OF INCENTIVE PAYMENTS FOR A MEDICARE EP WHO PREDOMINANTLY PERFORMS SERVICES IN A HPSA

Calendar year	Year that an EP first receives the incentive payment for Medicare covered professional services furnished in a geographic HPSA				2015 and subsequent years
	2011	2012	2013	2014	
2011	$1,800				
2012	1,200	$1,800			
2013	800	1,200	$1,500		
2014	400	800	1,200	$1,200	
2015	200	400	800	800	$0
2016		200	400	400	0
Total	4,400	4,400	3,900	2,400	0

d. Form and Timing of Payment

Section 1848(o)(1)(D)(i) of the Act, as amended by section 4101(a) of the HITECH Act, provides that the incentive payments may be disbursed as a single consolidated payment or in periodic installments as the Secretary may specify. We propose to make a single, consolidated, annual incentive payment to EPs. We believe that making a single, consolidated payment would be the least administratively burdensome for both CMS and most EPs. We expect that many EPs who demonstrate meaningful use of certified EHR technology will receive the maximum incentive payments. We propose that payments would be made on a rolling basis, as soon as we ascertain that an EP has demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year for subsequent years), and reached the threshold for maximum payment.

Section 1848(o)(1)(A) of the Act provides that "with respect to covered professional services provided by an eligible professional," the incentive payment "shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6))." Section 1842(b)(6)(A) of the Act allows for reassignment to an employer or entity with which the physician has a valid contractual arrangement allowing the entity to bill for the physician's services. Therefore, EPs are allowed to reassign their incentive payment to their employer or an entity which they have a valid employment agreement or contract providing for such reassignment, consistent with all rules governing reassignments. The statute does not address the case where the EP has multiple employers/contractual arrangements, and it would be difficult operationally for CMS to allocate the incentive payment among two or more individuals/entities. Therefore, in § 495.10(e) we are proposing to preclude an EP from reassigning the incentive payment to more than one employer or entity. We believe that the question of whether the EP has reassigned the incentive payment to the employer/entity under his or her contract with the employer/entity, including any pre-existing contract between the parties, is a matter of contract interpretation that should be resolved by the parties themselves. We note that nothing in the statute or our existing regulations would prohibit an EP from assigning to the employer/entity only the allowable charges for his or her professional services, with the EP retaining any incentive payment, or vice versa. If an EP will reassign his or her incentive payment to an employer/entity with which the EP has a contractual arrangement, the parties will need to review their existing contract to determine whether it currently provides for reassignment of the incentive payment to the employer/entity or needs to be revised.

The statute provides that the incentive payment shall be paid to the employer or facility in the cases described in clause (A) of section 1842(b)(6) of the Act. This clause provides that payment for a service provided to an individual may not be paid to anyone other than the individual or the practitioner who provided the service, except that the practitioner may reassign his or her right to payment to his or her employer or an entity with whom he or she has a contractual arrangement if certain conditions are met. Any such authorization must be in accordance with our regulations at 42 CFR 424.73 and 42 CFR 424.80.

Section 1848(o)(1)(D)(ii) of the Act requires the Secretary to establish rules to coordinate the incentive payments made among practices for an EP furnishing covered professional services in more than one practice, including the application of the limits on the amounts of the incentive payments. To implement this requirement, we propose to use the EP's Medicare enrollment information to determine whether an EP belongs to more than one practice (that is, whether the EP's National Provider Identifier (NPI) is

associated with more than one practice). In cases where the EP is associated with more than one practice, we propose that EPs select one tax identification number to receive any applicable EHR incentive payment.

Although it would not be impossible for Medicare contractors to make proportional EHR incentive payments to each TIN associated with a provider, we believe this option would entail the creation of highly complex and potentially unwieldy administrative systems. Therefore, we believe our proposal to permit the EP to select one TIN to which we will make any EHR incentive payment is the most efficient alternative. We have proposed that payments would be made on a rolling basis, as soon as we ascertain that an EP has demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year for subsequent years), and reached the threshold for maximum payment. If we were to adopt an alternative policy, permitting EHR incentive payments to be made to multiple TINs, we would need to calculate the percentage of covered professional services billed by each TIN for that EP, and the total of any incentive payment amount would be divided and paid accordingly. Thus, a policy permitting payment to multiple TINs would conflict with our proposal to make payment on a rolling basis as EPs meet the criteria to receive the maximum EHR incentive payment. An additional confounding factor is the possibility that an EP might change group affiliations during the year. Therefore, we believe the most judicious policy would be to permit the EP to designate one TIN to which payment will be made.

e. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs Who Are Not Meaningful Users of Certified EHR Technology

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 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 any EHR reporting period for the year, then the Medicare physician fee schedule amount for covered professional services furnished by the EP during the year (including the fee schedule amount for purposes of determining a payment based on the fee schedule amount) is adjusted to equal the 'applicable percent' of the fee schedule amount (defined below) that would otherwise apply. The HITECH Act includes a significant hardship exception, discussed below, which, if applicable, could exempt certain EPs from this payment adjustment. The payment adjustments will not apply to hospital-based EPs, as defined elsewhere.

The term 'applicable percent' means: "(I) for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment if the EP is not a successful electronic prescriber under section 1848(a)(5) 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 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 from the applicable percent in the preceding year, but in no case shall the applicable percent be less than 95 percent.

Significant Hardship Exception—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 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 exemption is subject to annual renewal, but in no case may an EP be granted a hardship exemption for more than 5 years.

We will include specific proposals to implement these payment adjustments for EPs who are not meaningful EHR users in future rulemaking prior to the 2015 effective date. We welcome comments on these payment adjustments and any comments received will be considered in developing future proposals to implement these provisions, including comments on the possible circumstances for which we should allow an EP to qualify for the significant hardship exception.

2. Incentive Payments for Hospitals

a. Definition of Eligible Hospital for Medicare

Section 1886(n) of the Act, as amended by section 4102(a)(1) of the HITECH Act, provides for incentive payments, beginning in FY 2011 (that is, October 1, 2010 through September 30, 2011) for eligible hospitals that are meaningful users of certified EHR technology during the EHR reporting period for the payment year. We are proposing a new § 495.104 to implement this provision. For purposes of this provision, section 1886(n)(6)(B) of the Act defines "eligible hospitals" as "subsection (d) hospitals," as that term is defined in section 1886(d)(1)(B) of the Act. Section 1886(d)(1)(B) of the Act generally defines a "subsection (d) hospital" as a "hospital located in one of the fifty States or the District of Columbia." The term therefore does not include hospitals located in the territories or hospitals located in Puerto Rico. Section 1886(d)(9)(A) of the Act separately defines a "subsection (d) Puerto Rico hospital" as a hospital that is located in Puerto Rico and that "would be a subsection (d) hospital * * * if it were located in one of the 50 states." Therefore, because section 4102(a)(1) of the HITECH Act does not refer to "subsection (d) Puerto Rico hospitals," incentive payments for meaningful users of certified EHR technology are not available under this provision to hospitals located in Puerto Rico. The provision does apply to inpatient, acute care hospitals located in the State of Maryland. These hospitals are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. Despite this waiver, the Maryland hospitals continue to meet the definition of a "subsection (d) hospital" because they are located in the 50 states. The statutory definition of a subsection (d) hospital also does not apply to hospitals and hospital units excluded under section 1886(d)(1)(B) from the IPPS, such as psychiatric, rehabilitation, long term care, children's, and cancer hospitals. For purposes of this provision, we will provide incentive payments to hospitals as they are distinguished by provider number in hospital cost reports. Incentive payments for eligible hospitals will be calculated based on the provider number used for cost reporting purposes, which is the CCN of the main provider (also referred to as OSCAR number). Payments to eligible hospitals are made to each provider of record. The criteria for being a meaningful EHR user, and the manner for demonstrating meaningful use, are discussed in section B.2. of this proposed rule.

b. Incentive Payment Calculation for Eligible Hospitals

Section 1886(n)(2) of the Act, as amended by 4102(a) of HITECH, describes the methodology for determining the incentive payment amount for eligible hospitals that are meaningful users of certified EHR technology during the EHR reporting period for a payment year. In general,

that section requires the incentive payment for each payment year to be calculated as the product of: (1) An initial amount; (2) the Medicare share; and (3) a transition factor applicable to that payment year.

As amended by section 4201(a) of the HITECH Act, section 1886(n)(2)(A)(i) of the Act defines the initial amount as the sum of a "base amount," as defined in section 1886(n)(2)(B) of the Act, and a "discharge related amount," as defined in section 1886(n)(2)(C) of the Act. The base amount is $2,000,000, as defined in section 1886(n)(2)(B) of the Act. The term "discharge related amount" is defined in section 1886(n)(2)(C) of the Act as "the sum of the amount, estimated based upon total discharges for the eligible hospital (regardless of any source of payment) for the period, for each discharge up to the 23,000th discharge as follows:

(i) For the first through the 1,149th discharge, $0.

(ii) For the 1,150th through the 23,000th discharge, $200.

(iii) For any discharge greater than the 23,000th, $0.

In addition to the base amount, the discharge related amount provides an additional $200 for each hospital discharge during a payment year, beginning with a hospital's 1,150th discharge of the payment year, and ending with a hospital's 23,000th discharge of the payment year. No additional payment is made for discharges prior to the 1,150th discharge, or for those discharges subsequent to the 23,000th discharge.

Section 1886(n)(2)(C) of the Act, as amended by section 4102(a) of the HITECH Act, specifies that a "12-month period selected by the Secretary" may be employed for purposes of determining the discharge related amount. While the statute specifies that the payment year is determined based on a Federal fiscal year (FY), section 1886(n)(2)(C) of the Act provides the Secretary with authority to determine the discharge related amount on the basis of discharge data from a relevant hospital cost reporting period, for use in determining the incentive payment during a FY. FYs begin on October 1 of each calendar year, and end on September 30 of the subsequent calendar year. Hospital cost reporting periods can begin with any month of a calendar year, and end on the last day of the 12th subsequent month. For purposes of administrative simplicity and timeliness, we propose, for each eligible hospital during each incentive payment year, to use data on the hospital discharges from the hospital fiscal year that ends during the FY prior to the FY that serves as the payment year as the basis for making preliminary incentive payments. Final payments would be determined at the time of settling the cost report for the hospital fiscal year that ends during the payment year, and settled on the basis of the hospital discharge data from that cost reporting period.

Example: FY 2011 begins on October 1, 2010 and ends on September 30, 2011. For an eligible hospital with a cost reporting period running from July 1, 2010 through June 30, 2011, we would employ the relevant data from the hospital's cost reporting period ending June 30, 2010 in order to determine the incentive payment for the hospital during FY 2011. This timeline would allow us to have the relevant data available for determining payments in a timely manner for the first and subsequent payment years. This timeline would also render it unnecessary to develop a cumbersome process to extract and employ discharge data across more than one hospital cost reporting period in order to determine the discharge related amount for a FY-based payment period. However, final payments would be based on hospital discharge data from the cost report ending June 30, 2011, and determined at the time of settlement for that cost reporting period.

c. Medicare Share

As previously discussed, the initial amount must be multiplied by the Medicare share and an applicable transition factor to determine the incentive payment to an eligible hospital for an incentive payment year. As added by section 4102(a) of the HITECH Act, section 1886(n)(2)(D) of the Act defines the Medicare share for purposes of calculating incentive payments as a fraction based on estimated Medicare FFS and managed care inpatient bed days, divided by estimated total inpatient bed-days, modified by charges for charity care. This section specifies that the Medicare share fraction is determined for the incentive payment year "for an eligible hospital for a period selected by the Secretary." As in the case of the discharge data discussed above, this clause provides the Secretary with authority to determine the Medicare share fraction on the basis of data from a relevant hospital cost reporting period, for use in determining the incentive payment during a FY. For purposes of administrative simplicity and timeliness equivalent to those discussed above with regard to discharge data, we propose, for each eligible hospital during each incentive payment year, to employ data on the hospital's Medicare fee-for-service and managed care inpatient bed days, total inpatient bed-days, and charges for charity care from the hospital fiscal year that ends during the FY prior to the FY that serves as the payment year as the basis for preliminary payment. Final payment would be made on the basis of the data from the hospital fiscal year that ends during the FY that serves as the payment year at the time of the settlement of the cost report for the latter period.

Section 1886(n)(2)(D) of the Act, as amended by section 4102 of the HITECH Act, defines the numerator and denominator of this fraction in terms of estimated Medicare FFS and managed care inpatient bed days, estimated total inpatient bed-days, and charges for charity care. Specifically, section 1886(n)(2)(D)(i) of the Act defines the numerator of the Medicare share fraction as the sum of—

- The estimated number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals with respect to whom payment may be made under part A; and
- The estimated number of inpatient-bed-days (as so established) that are attributable to individuals who are enrolled with a MA organization under Part C.

We propose to determine the numbers of Medicare Part A and Part C inpatient-bed-days using the same data sources and methods for counting those days that we employ in determining Medicare's share for purposes of making payments for direct graduate medical education costs, as provided under section 1886(h) of the Act and § 413.75 of our regulations. Specifically, we propose to derive "the estimated number of inpatient-bed-days * * * attributable to individuals with respect to whom payment may be made under part A" from lines 1, 6 through 9, 10 and 14 in column 4 on Worksheet S–3, Part I of the Medicare cost report. The data entered on these lines in the cost report include all patient days attributable to Medicare inpatients, excluding those in units not paid under the IPPS and excluding nursery days. Similarly, we propose to derive the "estimated number of inpatient-bed-days attributable * * * to individuals who are enrolled with a MA organization under Part C" from line 2 in column 4 on Worksheet S–3, Part I of the Medicare cost report. The methodology and data sources for making these bed day determinations are not only well established, but also well known and understood within the hospital community. We therefore see no reason to develop or propose any alternative approach for determining the "subsection (d) hospital" numbers of Medicare Part A and Part C inpatient-bed-days for purposes of calculating these incentive payments.

Section 1886(n)(2)(D)(ii) of the Act defines the denominator of the Medicare share fraction as the product of—

- The estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and
- The estimated total amount of the eligible hospital's charges during such period, not including any charges that are attributable to charity care (as such term is used for purposes of hospital cost reporting under Title XVIII), divided by the estimated total amount of the hospitals charges during such period.

As in the case of Medicare Part A and Part C inpatient-bed days, for purposes of determining total inpatient-bed days in the denominator of the Medicare share fraction, we propose to use the same data sources, and the same methods, that we employ in determining Medicare's share for purposes of making payments for direct graduate medical education costs. Specifically, we will derive the relevant data from lines 1, 6 through 9, 10 and 14 in column 6 on Worksheet S–3, Part I of the Medicare cost report. The data entered on these lines in the cost report include all patient days attributable to inpatients, excluding those in units not paid under the IPPS.

d. Charity Care

In determining the denominator of the Medicare share fraction, we also must determine any charges that are attributable to charity care furnished by an eligible hospital or CAH. The exclusion of charges attributable to charity care has the effect of decreasing the denominator of the Medicare share fraction as the proportion of charity care (charity care charge ratio) provided by a hospital increases. This is because the ratio of estimated total hospital charges, not including charges attributable to charity care, to estimated total hospital charges during a period decreases, relatively speaking, as a hospital provides a greater proportion of charity care. The effect of this factor on the denominator of the Medicare share fraction is therefore to decrease the denominator (as the total number of inpatient-bed days is multiplied by a relatively lower charity care charge ratio), as a hospital provides a greater proportion of charity care. A smaller denominator increases the Medicare share factor, providing for higher incentive payments, to a hospital that provides a greater proportion of charity care. Conversely, as a hospital provides a lower proportion of charity care, the ratio of estimated total hospital charges, not including charges attributable to charity care, to estimated total hospital charges during a period increases. In this case, the effect of this factor on the denominator of the Medicare share fraction is therefore to increase the denominator (as the total number of inpatient-bed days is multiplied by a relatively higher charity care charge ratio), as a hospital provides a smaller proportion of charity care. A larger denominator in turn decreases the Medicare share factor, providing for lower incentive payments, as a hospital provides a lower proportion of charity care.

The data and methods for determining this charity factor for purposes of the Medicare share fraction warrants more extensive discussion. Section 112 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) directs the Secretary to require prospective payment system hospitals to submit data on the costs incurred by the hospitals for providing inpatient and outpatient hospital services for which the hospitals are not compensated, including non-Medicare bad debt, charity care, and charges for medical and indigent care as part of the Medicare cost report.

In the August 1, 2000 **Federal Register** (65 FR 47054), we published a final rule that set forth changes to the IPPS and FY 2001 rates. In that final rule we responded to comments on implementing section 112 of Public Law 106–113. We informed the public that the hospital Medicare cost report and instructions would be revised to collect uncompensated care data. As a result of meeting with, and receiving input from, various hospital industry groups, "Worksheet S–10; Hospital Uncompensated and Indigent Care Data", was added to the Medicare cost reporting forms to implement section 112 of Public Law 106–113. The Worksheet S–10 was placed in effect for cost reporting periods beginning on or after April 30, 2002.

In May 2005, the Medicare Payment Advisory Commission (MedPAC) convened an expert panel to address concerns on the usefulness of the Worksheet S–10 data. Based on the panel discussion, MedPAC issued a list of recommended changes to the Worksheet S–10. In addition, in its March 2007 report to Congress, MedPAC recommended that the Secretary should improve the form and accompanying instructions for collecting data on uncompensated care in the Medicare cost report; and require hospitals to report using the revised form as soon as possible. (Recommendation 2A–3)

In the August 22, 2007 **Federal Register** (72 FR 47406), we published a final rule responding to the MedPAC recommendation. We stated in that final rule that we were undertaking a major update to the Worksheet S–10 form and accompanying instructions based on the panel's discussions with MedPAC.

In the July 2, 2009 **Federal Register** (74 FR 31738), we accordingly published a proposed collection to revise the Hospital and Hospital Health Care Complex Cost Report, Form CMS–2552–10, which included a revised Worksheet S–10 form. This worksheet may change based on public comments. The revised cost report and accompanying instructions that include the definition of charity care based on MedPAC's recommendations are currently in the Paperwork Reduction Act clearance process. We anticipate that the revised hospital cost report will be effective for cost reporting periods beginning on or after February 1, 2010.

For the purposes of this proposed rule, we propose to define charity care as part of uncompensated and indigent care described for Medicare cost reporting purposes in the Medicare cost report instructions at section 4012 of the Provider Reimbursement Manual (PRM), Part 2; Worksheet S–10; Hospital Uncompensated and Indigent Care Data. Subsection (d) hospitals and CAHs are required to complete the Worksheet S–10.

As part of the Form CMS–2552–10 described above, the revised Worksheet S–10 instructions define uncompensated care as follows: "* * * charity care and bad debt which includes non-Medicare bad debt and non-reimbursable Medicare bad debt. Uncompensated care does not include courtesy allowances or discounts given to patients." These instructions further define charity care to include health services for which a hospital demonstrates that the patient is unable to pay. Charity care results from a hospital's policy to provide all or a portion of services free of charge to patients who meet certain financial criteria. For Medicare purposes, charity care is not reimbursable, and unpaid amounts associated with charity care are not considered as an allowable Medicare bad debt. Therefore, we are proposing to use the charity care charges that are reported on line 19 of the revised Worksheet S–10 in the computation of the Medicare share of the incentive payments. The revised instructions for line 19 of Worksheet S–10 state the following:

Enter the total initial payment obligation of patients who are given a full or partial discount, based on the hospital's charity care criteria (measured at full charges), for care delivered during this cost reporting period for the entire facility. For uninsured patients, including patients with coverage from an entity that does not have a contractual relationship with the provider (column 1), this is the patient's total charges. For patients covered by a public program or private insurer with which the provider has a contractual relationship (column 2), this is the deductible and coinsurance payments required by the payer. Include charity care for all services except physician and other professional services. Do not include charges for either uninsured patients given discounts without meeting the hospital's charity care criteria or patients given courtesy discounts. Charges for non-covered services provided to patients eligible for Medicaid or other indigent care program (including charges for days exceeding a length of stay limit) can be included, if such inclusion is specified in the hospital's charity care policy and the patient meets the hospital's charity care criteria.

Under section 1886(n)(2)(D) of the Act, if the Secretary determines that data are not available on charity care necessary to calculate the portion of the formula specified in clause (ii)(II) of section 1886(n)(2)(D) of the Act, the Secretary shall use data on uncompensated care and may adjust such data so as to be an appropriate proxy for charity care including a downward adjustment to eliminate bad debt data from uncompensated care data. In the absence of the data necessary for the Secretary to compute the amount described in clause (ii)(II) of section 1886(n)(2)(D) of the Act, the amount under such clause shall be deemed to be 1.

We believe that the charity care charges reported on line 19 of the Worksheet S–10 represent the most accurate measure of charity care charges as part of the hospital's overall reporting of uncompensated and indigent care for Medicare purposes. Therefore, since eligible hospitals and CAHs are required to complete the Worksheet S–10, if a hospital has not properly reported any charity care charges on line 19, we may question the accuracy of the charges used for computing the Medicare share of the incentive payments. With appropriate resources, we believe the charity care data can be obtained by the MAC. This data would be used to determine if the hospital's charity care criteria are appropriate, if a hospital should have reported charity care charges, and if the reported charges are proper. If we determine, as based on the determination of the MAC, that the hospital did not properly report charity care charges on the Worksheet S–10, then we propose to deem the denominator in section 1886(n)(2)(D)(ii)(II) of the Act to be 1.

In this proposed rule, we are specifically soliciting public comments on the charity care financial criteria established by each hospital and reviewed by the MACs, the collection of charity care data on the Worksheet S–10, and whether proxies for charity care may be developed with other data available to us.

e. Transition Factor

As we have previously discussed, the initial amount must be multiplied not only by the Medicare share fraction, but also by an applicable transition factor in order to determine the incentive payment to an eligible hospital for an incentive payment year. Section 1886(n)(2)(E)(i) of the Act designates that the applicable transition factor equals 1 for the first payment year, three-fourths for the second payment year, one-half for the third payment year, one-fourth for the fourth payment year, and zero thereafter. However, section 1886(n)(2)(E)(ii) of the Act provides that if "the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013." Accordingly, if a hospital's first payment year is FY 2014, the applicable transition factor equals three-fourths for the first payment year (FY 2014), one-half for the second payment year (FY 2015), one-fourth for the third payment year (FY 2015, and zero thereafter.) If a hospital's first payment year is FY 2015, the applicable transition factor equals one-half for the first payment year (FY 2015), one-fourth for the second payment year (FY 2016), and zero thereafter. As discussed in more detail below, under section 1886(n)(2)(E)(ii) of the Act, the transition factor for a hospital for which the first payment year is after 2015 equals zero for all years. In other words, 2015 is the last year for which eligible hospitals may begin participation in the Medicare EHR Incentive Program.

Figure 1—Incentive Payment Calculation for Subsection D Hospitals

Incentive Amount = [Initial Amount] × [Medicare Share] × [Transition Factor]

Initial Amount = $2,000,000 + [$200 per discharge for the 1,150th – 23,000th discharge]

Medicare Share = *Medicare/(Total*Charity Care)* = *[M/(T*C)]*

M = [# of Inpatient Bed Days for Part A Beneficiaries] + [# of Inpatient Bed Days for MA Beneficiaries]

T = [# of Total Inpatient Bed Days]

C = [Total Charges − Charges for Charity Care*]/[Total Charges]

*If data on charity care is not available, then the Secretary would use data on uncompensated care as a proxy. If the proxy data is not also available, then "*C*" would be equal to 1.

TRANSITION FACTOR

Consecutive payment year	Transition factor
1	1
2	¾
3	½
4	¼

f. Duration and Timing of Incentive Payments

Section 1886(n)(2)(E)(i) of the Act establishes that an eligible hospital that is a meaningful user of certified EHR technology could receive up to 4 years of financial incentive payments. The transition factor phases down the incentive payments over the 4-year period. Therefore, an eligible hospital that is a meaningful user of certified EHR technology during the relevant EHR reporting period, in payment year FY 2011, could receive incentive payments beginning with FY 2011 (transition factor equals 1), and for FY 2012 (transition factor equals three-fourths), 2013 (transition factor equals one-half), and 2014 (transition factor equals one-fourth) if they continue to be a meaningful user of certified EHR technology during the relevant EHR reporting periods.

Section 1886(n)(2)(E)(ii) of the Act establishes the range of time during which a hospital may begin to receive incentive payments, and the applicable transition periods for hospitals that are permitted to begin receiving incentive payments after FY 2011. Specifically, that section provides that if the "first payment year for an eligible hospital is after 2015, then the transition factor * * * for such hospital and for such year and subsequent year shall be 0." This clause in effect provides that no incentive payments will be available to a hospital that would begin to receive such payments after FY 2015. In other words, FY 2015 is the last FY in which a hospital can begin to receive incentive payments. Taken together, sections 1886(n)(2)(G)(i) and 1886(n)(2)(E)(ii) of the Act allow hospitals to begin receiving incentive payments during FYs 2011 through 2015. Section 1886(n)(2)(E)(ii) of the Act also establishes the transition periods and

factors that will be in effect for hospitals that begin to receive transition payments during FY 2014 and 2015. As discussed previously, that section states that if "the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013." Section 1886(n)(2)(E)(ii) of the Act also establishes the transition periods that will be in effect for hospitals that begin to receive transition payments during FYs 2014 through 2015. That section states that if "the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013." By implication, this clause establishes that, for hospitals that begin to receive incentive payments in FYs 2012 and 2013, the transition periods are equivalent to those for hospitals that begin to receive such payments in FY 2011. An eligible hospital that is a meaningful user of certified EHR technology could receive incentive payments beginning with FY 2012 (transition factor equals 1), and for FY 2013 (transition factor equals three-fourths), FY 2014 (transition factor equals one-half), and FY 2015 (transition factor equals one-fourth). Similarly, an eligible hospital that is a meaningful EHR user could receive incentive payments beginning with FY 2013 (transition factor equals 1), and for FYs 2014 (transition factor equals ¾), 2015 (transition factor equals ½), and 2016 (transition factor equals ¼).

However, this section also specifically provides that the transition factor is modified for those eligible hospitals that first become meaningful users of certified EHR technology beginning in 2014 or 2015. Such hospitals would receive payments as if they became meaningful EHR users beginning in 2013. In other words, if a hospital were to begin to demonstrate meaningful use of EHR certified technology in 2014, the transition factor used for that year (2014) would be ¾ instead of 1, ½ for the second year (2015), ¼ for the third year (2016), and zero thereafter. Similarly, if a hospital were to begin meaningful use of certified EHR technology in 2015, the transition factor used for that year would be ½ instead of 1, ¼ for the second year (2016), and zero thereafter.

Table 25 shows the possible years an eligible hospital could receive an incentive payment and the transition factor applicable to each year.

TABLE 25—TRANSACTION FACTOR FOR MEDICARE FFS ELIGIBLE HOSPITALS

Fiscal year	Fiscal year that eligible hospital first receives the incentive payment				
	2011	2012	2013	2014	2015
2011	1.00				
2012	0.75	1.00			
2013	0.50	0.75	1.00		
2014	0.25	0.50	0.75	0.75	
2015		0.25	0.50	0.50	0.50
2016			0.25	0.25	0.25

We welcome comments from the public on our discussion of these statutory requirements regarding the computation of the incentive payment amounts, and the issues regarding the sources and timing of data for use in these computations.

g. Incentive Payment Adjustment Effective in FY 2015 and Subsequent Years for Eligible Hospitals Who Are Not Meaningful EHR Users

In addition to providing for incentive payments for meaningful use of EHRs during a transition period, section 1886(b)(3)(B) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides for an adjustment to the market basket 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, section 1886(b)(3)(B) 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." For FY 2015 and each subsequent FY, 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, the Secretary is required to subject eligible hospitals who are not meaningful users to one-quarter, one-half, and three-quarters reductions of their market basket updates in FY 2015, FY 2016, and FY 2017 and subsequent years respectively. 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." This provision establishes a continuing incentive for hospitals to become meaningful EHR users, because a hospital that does become a meaningful EHR user in any year after the effective date of the update reduction will receive the same, fully updated standardized amount for that year, and subsequent years, as those hospitals that were already meaningful EHR users at the time when the update reduction went into effect (although hospitals would remain subject to a separate reduction for failure to report quality data under RHQDAPU). In order to conform with this new update reduction, section 4102(b)(1)(A) of the HITECH Act revises section 1886(b)(3)(B)(viii)(1) of the Act 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 market basket update. In this way, even the combined reductions for 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 market basket remains a positive number.

The following example illustrates how this payment reduction would work. Suppose that the market basket "percentage increase otherwise applicable" to the IPPS standardized

amount is 2.0 percent. Of this 2.0 percent, one-quarter (0.5 percent) of the market basket update would be subject to a reduction for any hospital that fails to submit data on quality measures, and up to three-quarters (1.5 percent) would be subject to a reduction for any hospital that is not a meaningful EHR user. For FY 2015, hospitals could receive one of four different updates, depending upon their reporting of quality data and their use of EHRs:

- A hospital that reports quality data and qualifies as a meaningful EHR user would receive the full update of 2.0 percent.
- A hospital that fails to report quality data but is a meaningful EHR user would receive an update of 1.5 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data.
- A hospital that reports quality data but does not qualify as a meaningful EHR user would receive an update of 1.5 percent, which represents the full 2.0 percent update minus 0.5 percentage point (33⅓ percent of three-quarters of the full update: ⅓ times 1.5 equals 0.5).
- A hospital that fails to report quality data and does not qualify as a meaningful EHR user would receive an update of 1.0 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data, and a further reduction of 0.5 percentage point (33⅓ percent of three-quarters of the full update: ⅓ times 1.5 equals 0.5).

For FY 2016, hospitals could receive one of four different updates (assuming a 2 percent update that is otherwise applicable), depending upon their reporting of quality data and their use of EHRs:

- A hospital that reports quality data and qualifies as a meaningful EHR user would receive the full update of 2.0 percent.
- A hospital that fails to report quality data, but is a meaningful EHR user would receive an update of 1.5 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data.
- A hospital that reports quality data, but does not qualify as a meaningful EHR user would receive an update of 1.0 percent, which represents the full 2.0 percent update minus 1.0 percentage point (66⅔ percent of three-quarters of the full update: ⅔ times 1.5 equals 1.0).
- A hospital that fails to report quality data, and does not qualify as a meaningful EHR user would receive an update of 0.5 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data, and a further reduction of 1.0 percentage point (66⅔ percent of three-quarters of the full update: ⅔ times 1.5 equals 1.0).

For FYs 2017 and subsequent FYs, the possibilities (assuming a 2 percent update that is otherwise applicable) are as follows:

- A hospital that reports quality data and qualifies as a meaningful EHR user would receive the full update of 2.0 percent.
- A hospital that fails to report quality data, but is a meaningful EHR user would receive an update of 1.5 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data.
- A hospital that reports quality data, but does not qualify as a meaningful EHR user would receive an update of 0.5 percent, which represents the full 2.0 percent update minus 1.5 percentage points (100 percent of three-quarters of the full update, which equals 1.5) for failing to be a meaningful EHR user.
- A hospital that fails to report quality data, and does not qualify as a meaningful EHR user would receive an update of 0.0 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data, and a further reduction of 1.5 percentage points (100 percent of three-quarters of the full update, which equals 1.5) for failing to be a meaningful EHR user.

These examples are illustrative of current law. Specific proposals to implement these payment adjustments for subsection (d) hospitals that are not meaningful EHR users are not being made at this time but will be subject to future rule-making prior to the 2015 implementation date. We welcome comments on these payment adjustments and any comments received will be considered in developing future proposals to implement these provisions.

3. Incentive Payments for Critical Access Hospitals (CAHs)

Section 1814(l)(3)(A) of the Act, as amended by section 4102(a)(2) of the HITECH Act, also provides for incentive payments for CAHs that are meaningful users of certified EHR technology during an EHR reporting period for a cost reporting period beginning during a payment year after FY 2010 but before FY 2016. The criteria for being a meaningful EHR user, and the manner for demonstrating meaningful use, are discussed in section II.A.2. of this proposed rule.

a. Definition of CAHs for Medicare

Section 1861(mm)(1) of the Act defines a CAH as a facility that has been certified as a critical access hospital under section 1820(c). CAHs are reimbursed for services furnished to Medicare beneficiaries under section 1814(l) of the Act for inpatient services and section 1834(g) of the Act for outpatient services. Incentive payments for CAHs under section 1814(l)(3)(A) of the Act will be calculated based on the provider number used for cost reporting purposes, which is the CCN of the main provider. The process for making incentive payments to CAHs is discussed in section II.B.4.c. of this proposed rule.

b. Current Medicare Payment of Reasonable Cost for CAHs

For Medicare purposes, CAHs are paid for most inpatient and outpatient services to Medicare beneficiaries on the basis of reasonable cost under section 1814(l) and section 1834(g) of the Act, respectively. Thus, CAHs are not subject to the IPPS and Hospital Outpatient Prospective Payment System (OPPS).

Section 1861(v)(1)(A) of the Act is the statutory basis for reasonable cost reimbursement in Medicare. Under the reasonable cost reimbursement methodology, payments to providers are based on the reasonable cost of furnishing Medicare-covered services to beneficiaries. Reasonable cost includes all necessary and proper costs in furnishing the services, subject to the principles of reasonable cost reimbursement relating to certain specific items of revenue and cost. Reasonable cost takes into account both direct and indirect costs of providers of services, including normal standby costs. The objective of the reasonable cost methodology is to ensure that the costs for individuals covered by the program are not borne by others not so covered, and the costs for individuals not so covered are not borne by the program. The reasonable costs of services and the items to be included are determined in accordance with the regulations at 42 CFR part 413, manual guidance, and other CMS instructions.

Currently, under section 1814(l)(1) of the Act and § 413.70(a) of the regulations, effective for cost reporting periods beginning on or after January 1, 2004, payment for inpatient services of a CAH, other than services of a distinct part unit of a CAH, is 101 percent of the reasonable costs of the CAH in providing CAH services to its inpatients, as determined in accordance with

section 1861(v)(1)(A) of the Act and with the applicable principles of cost reimbursement in Parts 413 and 415 of the regulations. However, payment for inpatient CAH services is not subject to the reasonable cost principles of the lesser of cost or charges, the reasonable compensation equivalent limits for physician services to providers, the ceilings on hospital operating costs, and the payment window provisions for preadmission services, specified in § 412.2(c)(5) and § 413.40(c)(2). Section 1834(g) of the Act and § 413.70(b) of the regulations describe the payment methodology for outpatient services furnished by a CAH.

Currently, reasonable cost reimbursement for CAHs includes payment for depreciation of depreciable assets used in providing covered services to beneficiaries, as described under Part 413 subpart G of our regulations and § 104 of the Medicare Provider Reimbursement Manual (PRM). In general, the depreciation expense of an asset, representing a portion of the depreciable asset's costs which is allocable to a period of operation, is determined by distributing the acquisition costs of the depreciable asset, less any salvage costs, over the estimated useful life of the asset.

c. Changes Made by the HITECH Act

Sections 4102(a)(2) and 4102(b)(2) of the HITECH Act amended section 1814(l) of the Act, which governs payment for inpatient CAH services. The HITECH Act did not amend section 1834(g) of the Act, which governs payment for outpatient CAH services.

Sections 4102(a)(2) and 4102(b)(2) of the HITECH Act amended section 1814(l) of the Act by adding new paragraphs (3), (4), and (5) as follows:

Section 1814(l)(3)(A) of the Act provides the following:

The following rules shall apply in determining payment and reasonable costs * * * for a critical access hospital that would be a meaningful EHR user (as would be determined under paragraph (3) of section 1886(n)) for an EHR reporting period for a cost reporting period beginning during a payment year if such critical access hospital was treated as an eligible hospital under such section:

(i) The Secretary shall compute reasonable costs by expensing such costs in a single payment year and not depreciating these costs over a period of years (and shall include as costs with respect to cost reporting periods beginning during a payment year costs from previous cost reporting periods to the extent they have not been fully depreciated as of the period involved).

(ii) There shall be substituted for the Medicare share that would otherwise be applied [to CAHs under section 1814(l)(1)] a percent (not to exceed 100 percent) equal to the sum of—

(I) the Medicare share (as would be specified under paragraph (2)(D) of section 1886(n)) for such critical access hospital if such critical access hospital was treated as an eligible hospital under such section; and

(II) 20 percentage points.

Section 1814(l)(3)(B) of the Act provides that the incentive payment for CAHs will be paid "through a prompt interim payment (subject to reconciliation) after submission and review of such information (as specified by the Secretary) necessary to make such payment." The provision also states that "[i]n no case may payment under this paragraph be made with respect to a cost reporting period beginning during a payment year after 2015 and in no case may a critical access hospital receive payment under this paragraph with respect to more than 4 consecutive payment years."

Section 1814(l)(3)(C) of the Act provides that the reasonable costs for which a CAH may receive an incentive payment are costs for the purchase of certified EHR technology to which purchase depreciation (excluding interest) would otherwise apply under section 1814(l)(1) of the Act.

Section 1814(l)(4)(A) of the Act provides for an adjustment, subject to the hardship exemption in section 1814(l)(4)(C) of the Act, to a CAH's reimbursement at 101 percent of its reasonable costs if the CAH has not met the meaningful EHR user definition for an EHR reporting period that begins in FY 2015 or a subsequent fiscal year. Section 1814(l)(4)(B) of the Act specifies that if a CAH is not a meaningful EHR user during the cost reporting period beginning in FY 2015, its reimbursement will be reduced from 101 percent of its reasonable costs to 100.66 percent. For FY 2016, the percentage of reimbursement for a CAH that is not a meaningful EHR user is reduced to 100.33 percent of its reasonable costs. For FY 2017 and each subsequent FY, the percentage of reimbursement is reduced to 100 percent of reasonable costs. Section 1814(l)(4)(C) of the Act states that, as provided for eligible subsection (d) hospitals, the Secretary may, on a case-by-case basis, exempt a CAH from this adjustment if the Secretary determines, subject to annual renewal, that requiring the CAH to be a meaningful EHR user during a cost reporting period beginning in FY 2015 or a subsequent fiscal year would result in a significant hardship, 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 exemption under this provision for more than 5 years.

Section 1814(l)(5) provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of: (1) The methodology and standards for determining the amount of payment under section 1813(l)(3) and payment adjustments under section 1814(l)(4); (2) the methodology and standards for determining a CAH to be a meaningful EHR user; (3) the methodology and standards for determining if the hardship exemption applies to a CAH; (4) the specification of EHR reporting periods; and (5) the identification of reasonable costs used to compute CAH incentive payments.

d. Incentive Payment Calculation for CAHs

Consistent with section 1814(l)(3)(A) of the Act, we are proposing to amend § 413.70(a) to add a new paragraph (5) to provide for an incentive payment to a qualifying CAH for the reasonable costs incurred for the purchase of certified EHR technology in a cost reporting period beginning during a payment year after FY 2010 but before FY 2016. We are proposing to include a cross-reference to § 495.106 which defines the terms associated with the CAH incentive payment, including the definition of a "qualifying CAH" that is eligible to receive the CAH incentive payment, and the methodology for determining the amount of that incentive payment. In addition, we are proposing to amend § 413.70(a) to add a new paragraph (6) to provide for the adjustment of a CAH's reasonable costs of providing inpatient services starting in FY 2015 if the CAH is not a qualifying CAH.

In computing the CAH incentive payment and applying the adjustments to a CAH's payment if the CAH is not a qualifying CAH, we propose to apply the definitions of certified EHR technology, EHR reporting period, meaningful EHR user and qualified EHR in proposed § 495.4 that are discussed elsewhere in this proposed rule.

In proposed § 495.106(a), we are proposing to define a qualifying CAH as a CAH that meets the meaningful EHR user definition for eligible hospitals in § 495.4, which is discussed in section II A.1. of this proposed rule. Also in proposed § 495.106(a), for the purposes of computing the CAH incentive payment, we are proposing that the reasonable costs for the purchase of certified EHR technology mean the reasonable acquisition costs, excluding any depreciation and interest expenses associated with the acquisition,

incurred for the purchase of depreciable assets as described at part 413 subpart G, such as computers and associated hardware and software, necessary to administer certified EHR technology as defined in § 495.4 of this proposed rule. We also propose to define payment year for CAHs to mean a fiscal year beginning after FY 2010 but before FY 2016.

Under proposed § 495.106(b), we specify that a qualifying CAH shall receive an incentive payment for its reasonable costs incurred for the purchase of certified EHR technology. The CAH incentive payment will be for a cost reporting period that begins during a payment year after FY 2010 but before FY 2016.

Consistent with section 1814(l)(3)(A) of the Act, under proposed § 495.106(c), the proposed payment methodology for computing the incentive payment for a qualifying CAH for a cost reporting period during a payment year is equal to the product of—(1) the reasonable costs incurred for the purchase of certified EHR technology in that cost reporting period and any similarly incurred costs from previous cost reporting periods to the extent they have not been fully depreciated as of the cost reporting period involved and (2) the CAH's Medicare share which equals the Medicare share as computed for eligible hospitals including the adjustment for charity care (described in sections II.A.2.b. and A.3. of this proposed rule) plus 20 percentage points. However, in no case will the resulting Medicare share for a CAH exceed 100 percent. This percentage adjustment will be used in place of the 101 percent typically applied to a CAH's reasonable costs under section 1814(l)(1) of the Act and § 413.70(a) of the regulations.

For example, a CAH first requests an incentive payment for its cost reporting period beginning on January 1, 2012 which is in FY 2012. The CAH incurred reasonable costs of $500,000 for the purchase of certified EHR technology in its previous cost reporting period beginning on January 1, 2011. This CAH is a meaningful user of certified EHR technology during the relevant EHR reporting period and thus qualifies for an incentive payment for FY 2012. (For illustrative purposes this example assumes no salvage value of the assets acquired.) The CAH depreciated $100,000 of the costs of these items in the cost reporting period beginning on January 1, 2011. As a result, the amount used to compute the incentive payment will be the remaining $400,000 of undepreciated costs. The CAH's Medicare share is 90 percent (its Medicare share of 70 percent using the methodology described in section II.A.2.b. of this proposed rule plus 20 percentage points). Therefore, the CAH's incentive payment for FY 2012 is $360,000 ($400,000 times 90 percent). This CAH's first payment year is FY 2012, and it can receive incentive payments through 4 consecutive payment years which, in this example, would be FYs 2012 through 2015.

If, in the above example, the CAH also incurred reasonable costs of $300,000 for the purchase of certified EHR technology in its cost reporting period beginning in FY 2012 that will not be depreciated, then the incentive payment for FY 2012 is $630,000 ($700,000 ($400,000 in FY 2011 plus $300,000 in FY 2012) times 90 percent).

(The preceding examples are offered for illustrative purposes only and are not intended to encompass all possible computations of the CAH incentive payment.)

Under proposed § 495.106(d)(1), the amount of the incentive payment made to a qualifying CAH under this section represents the expensing and payment of the reasonable costs of certified EHR technology computed as described above in a single payment year and, as specified in § 413.70(a)(5), such payment is made in lieu of any payment that would have been made under § 413.70(a)(1) for the reasonable costs of the purchase of certified EHR technology including depreciation and interest expenses associated with the acquisition. The Medicare contractor will review the CAH's current year and each subsequent year's cost report to ensure that the assets associated with the acquisition of certified EHR technology are expensed in a single period and that depreciation and interest expenses associated with the acquisition are not allowed.

Under proposed § 495.106(d)(2), the amount of the incentive payment made to a qualifying CAH under this section is paid through a prompt interim payment for the applicable payment year after—(1) The CAH submits the necessary documentation, as specified by CMS or its Medicare contractor, to support the computation of the incentive payment amount; and (2) CMS or its Medicare contractor reviews such documentation and determines the interim amount of the incentive payment.

Under § 495.106(d)(3), the interim incentive payment is subject to a reconciliation process as specified by CMS and the final incentive payment as determined by CMS or its Medicare contractor is considered payment in full for the reasonable costs incurred for the purchase of certified EHR technology in a payment year.

Under § 495.106(d)(4), we propose that an incentive payment may be made with respect to a cost reporting period beginning during a payment year beginning with FY 2011 (October 1, 2010 through September 30, 2011) through FY 2015 (October 1, 2014 through September 30, 2015), but in no case may a CAH receive an incentive payment with respect to more than four consecutive payment years. Therefore, a CAH, that is a meaningful EHR user, may begin receiving an incentive payment for its cost reporting period beginning in FY 2011 for the incurred reasonable costs for the purchase of certified EHR technology during that cost reporting period and in previous cost reporting periods to the extent that the item or items have not been fully depreciated. These incentive payments will continue for no more than 4 consecutive payment years and will not be made for a cost reporting period beginning during a payment year after 2015. As discussed in section II.B.4. of this proposed rule, the CAH must submit supporting documentation for its incurred costs of purchasing certified EHR technology to its Medicare contractor (Fiscal Intermediary (FI)/MAC).

CAHs cannot receive an incentive payment for a cost reporting period that begins in a payment year after FY 2015. If the first payment year for a CAH is FY 2013 then the fourth consecutive payment year would be 2016. However, the CAH cannot be paid an incentive payment for FYs 2016 and beyond. For FY 2016 and beyond, payment to CAHs for the purchase of additional EHR technology will be made under § 413.70(a)(1) in accordance with the reasonable cost principles, as described above, which would include the depreciation and interest cost associated with such purchase.

e. Reduction of Reasonable Cost Payment 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) to include an adjustment to a CAH's reimbursement at 101 percent of its reasonable costs if the CAH has not met the meaningful EHR user definition for an EHR reporting period that begins in FY 2015, FY 2016, FY 2017, and each subsequent FY thereafter. Consistent with this provision, under proposed § 495.106(e) and § 413.70(a)(6), if a CAH has not demonstrated meaningful use of certified EHR technology for FY 2015, its reimbursement will be reduced from

101 percent of its reasonable costs to 100.66 percent. For FY 2016, its reimbursement will be reduced to 100.33 percent of its reasonable costs. For 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 exempted from this adjustment if CMS or its Medicare contractor determines, on an annual basis, that requiring the CAH to be a meaningful EHR user would result in a significant hardship, 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 exemption under this provision for more than 5 years.

Section 1814(l)(5) of the Act exempts the determinations made under paragraphs (l)(3) and (l)(4) from administrative and judicial review. Accordingly, under proposed § 413.70(a)(6)(iv) and § 495.106(f), we are proposing that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following:

- The methodology and standards for determining the amount of payment under section 1814(l)(3) of the Act and payment adjustments under section 1814(l)(4) of the Act for CAHs, including selection of periods under section 1886(n)(2) of the Act for determining, and making estimates or using proxies of, inpatient-bed-days, hospital charges, charity charges, and the Medicare share under subparagraph (D) of section 1886(n)(2) of the Act;
- The methodology and standards for determining a CAH to be a meaningful EHR user under section 1886(n)(3) of the Act as would apply if the CAH was treated as an eligible hospital under section 1886(n) of the Act;
- The methodology and standards for determining if the hardship exemption under section 1814(l)(4)(C) of the Act applies to a CAH;
- The specification of EHR reporting periods under section 1886(n)(6)(B) of the Act as applied under section 1814(l)(3) and (4) of the Act for CAHs; and
- The identification of reasonable costs used to compute the CAH incentive payment under section 1814(l)(3)(C) of the Act.

4. Process for Making Incentive Payments Under the Medicare FFS Program

As previously discussed in section II.B.1. and 2. of this proposed rule and sections 1848(o)(1) and 1886(n)(1) of the Act, the statute provides for incentive payments to eligible professionals, eligible hospitals, and CAHS who are meaningful users of certified EHR technology as early as FY 2011 for qualifying eligible hospitals and CAHs and CY 2011 for qualifying EPs. The statute does not specify the process for making these payments to qualifying EPs and qualifying eligible hospitals and CAHs participating in the FFS Medicare incentive payment program, but instead leaves the payment process to the Secretary's discretion.

We propose that FIs, carriers, and MACs, as appropriate, would be responsible for determining the incentive payment amounts for qualifying EPs and qualifying eligible hospitals and CAHs in accordance with the proposed methodology set forth in section II.B.1.b. and B.2.b. of this proposed rule based on the previously discussed meaningful use criteria, disbursing the incentive payments to qualifying EPs and qualifying eligible hospitals and CAHs, and resolving any reconciliation issues.

a. Incentive Payments to EPs

We propose that the carriers/MACs calculate incentive payment amounts for qualifying EPs. Incentive payments will be disbursed on a rolling basis, as soon as they ascertain that an EP has demonstrated meaningful use for the applicable reporting period (i.e., 90 days for the first year or a calendar year for subsequent years), and reached the threshold for maximum payment. As discussed previously in section II.A.1.b. of this proposed rule, once a qualifying EP's allowed charges reach the minimum threshold of allowed charges for the payment year, the qualifying EP is eligible to receive the maximum incentive payment; the carrier/MAC would be authorized to disburse the full incentive payment to that qualifying EP. If a qualifying EP's allowed charges do not reach the minimum threshold during the payment year (including subsequent claims submitted not later than 2 months after the end of the payment year per statute) and if the qualifying EP is also a qualifying MA EP, the qualifying MA organization with which the EP is affiliated will receive the incentive payment for the EP from the MA. If the qualifying EP does not also qualify as a MA EP, then the carriers/MAC will calculate the amount of the qualifying EP's incentive payment an amount determined by statute as 75 percent of the accumulated allowed charges based on claims submitted not later than 2 months after the end of the payment year), and disburse the incentive payment to the qualifying EP in the year following payment year. The carriers/MACs will issue incentive payments to qualifying EPs after ensuring payment has not already been made under the Medicaid program for the relevant payment year. As required by section 1848(m)(2) of the Act as amended by section 4101(f) of the HITECH Act, qualifying EPs receiving incentive payments from the Medicare EHR incentive payment program may not also receive an e-prescribing incentive payment. The carriers/MACs will also track the incentive payment at the qualifying EP's TIN level, and disburse the electronic payment to the TIN provided by the qualifying EP indicated during the registration process; qualifying EPs who do not have individual TINs (that is, a qualifying EP who works solely in a group practice) will be paid at the group practice level's TIN. Since some EPs work in multiple group practices, we considered allowing these EPs to direct that their incentive payment be allocated among the multiple practices based on individual and/or group TINs. However, as discussed more fully in section II.B.1.d of this proposed rule, we determined that this would create a significant administrative burden for us and therefore are proposing that qualifying EPs select one TIN for disbursement of their Medicare EHR incentive payment. Of course, after the payment is disbursed to their designated TIN, qualifying EPs may decide to allocate their incentive payment among the multiple practices in which they furnish covered professional services. subject to applicable laws, regulations and rules, including, without limitation, those related to fraud, waste, and abuse.

In addition, we recognize that financial relationships between physicians and their employers/entities with which they have contractual arrangements may implicate certain fraud, waste, and abuse laws, regulations, and rules. Therefore, we are considering including specific safeguards to limit the risk that the allocation/reassignment of incentive payments could raise under those and other applicable laws, regulations and rules; we appreciate public comments on this consideration.

b. Incentive Payments to Eligible Hospitals

The FIs/MACs will calculate incentive payments for qualifying eligible hospitals, and will disburse such payments on an interim basis once the hospital has demonstrated it is a meaningful EHR user for the EHR reporting period for the payment year. As discussed above in section B.2.b. of the proposed rule, the formula for

calculating a qualifying eligible hospital's incentive payment requires the following data: (1) An initial amount; (2) the Medicare share; and (3) a transition factor applicable to that payment year. FIs/MACs will use the prior-year cost report, Provider Statistical and Reimbursement (PS&R) System data, and other estimates to calculate the interim incentive payment. As discussed in section II.B.2.c. of this proposed rule, beginning in 2010, cost reports will capture charity care data which will be used in calculating the Medicare share of the payment. As discussed in section II.B.2.b. of this proposed rule, we are proposing to calculate a qualifying hospital's final incentive payment using data from the cost report for the hospital's fiscal year that ends during the FY prior to the FY that serves as the payment year. We therefore are proposing that the FIs/MACs calculate the final incentive payment using actual cost report data report for the hospital's fiscal year that ends during the FY prior to the fiscal year that serves as the payment year, and will reconcile the incentive payment as necessary at settlement of the cost report. Incentive payments for qualifying eligible hospitals will be calculated based on the provider number used for cost reporting purposes, which is the CCN of the main provider. Therefore, the FIs/MACs would disburse incentive payments to qualifying hospitals based on the CCN rather than the TIN.

c. Incentive Payments to CAHs

CAHs are paid on a cost reimbursement basis; once a CAH incurs actual EHR costs, it can submit supporting documentation to the FI/MAC for review. The FIs/MACs will determine an incentive payment amount, as previously discussed in section II.A.3. of this proposed rule by substituting for the Medicare share amount that would otherwise be applied under the formula used for computing payments for eligible hospitals, a percent (not to exceed 100 percent) equal to the sum of—(1) The Medicare share for such CAH, and (2) 20 percentage points.

The FIs/MACs will reconcile the cost report and ensure the EHR expenses are adjusted on the cost report to avoid duplicate payments. Incentive payments for qualifying CAHs will be calculated based on the provider number used for cost reporting purposes, which is the CCN number of the main provider. Therefore, the FIs/MACs will disburse incentive payments to qualifying CAHs based on the CCN number rather than the TIN.

d. Payment Accounting Under Medicare

We will conduct selected compliance reviews of EPs, eligible hospitals, and qualified CAHs who register for the incentive programs and of recipients of incentive payments for the meaningful use of certified EHR technology. The reviews will validate provider eligibility and their meaningful use attestations including verification of meaningful use and would also review components of the payment formulas.

We will identify and recoup overpayments made under the incentive payment programs that result from incorrect or fraudulent attestations, quality measures, cost data, patient data, or any other submission required to establish eligibility or to qualify for a payment. The overpayment will be recouped by CMS or its agents from the EP, eligible hospital, MA organization, CAH, other entities to whom the right to payment has been assigned/reassigned, or, in the case of Medicaid, from the State Medicaid agencies. Medicare FFS EPs and eligible hospitals will need to maintain evidence of qualification to receive incentive payments for 10 years after the date they register for the incentive program.

C. Medicare Advantage (MA) Organization Incentive Payments

1. Definitions

a. Qualifying MA Organization

Section 1853(l)(1) of the Act, as added by section 4101(c) of the HITECH Act, provides for incentive payments to qualifying MA organizations for certain of their affiliated EPs who are meaningful users of certified EHR technology during the relevant EHR reporting period for a payment year. Section 1853(l)(5) of the Act defines the term "qualifying MA organization" as an MA organization that is organized as a health maintenance organization (HMO) as defined in section 2791(b)(3) of the PHS Act. Section 2791(b)(3) of the PHS Act in turn defines a health maintenance organization as a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as an HMO. Since there are few federally qualified HMOs, we expect MA organizations to primarily qualify for incentive payments as State-licensed HMOs, or as organizations regulated for solvency under State law in the same manner and to the same extent as HMOs. Therefore, in § 495.200 we propose to define "qualifying MA organization."

In § 495.202(a)(2), we propose to deem MA organizations offering MA HMO plans that are not federally-qualified HMOs to meet the definition of HMO in section 2791(b)(3) of the PHS Act, as HMOs recognized under State law, or as entities subject to State solvency rules in the same manner as HMOs. We believe this is reasonable because under the MA application process, State regulators are required to certify that MA organizations operating in their State are authorized to offer the type of MA plan they propose to offer, and meet solvency standards that are adequate for these purposes. For each MA organization offering MA HMO plans, the State has thus recognized that the organization is able to assume risk as an HMO. Therefore, we have determined that absent evidence to the contrary, an MA organization offering HMO plans is recognized by the State as a health maintenance organization, or that it is subject to State solvency standards in the same manner and to the same extent as an HMO and therefore provides sufficient assurance that the section 2791(b)(3) of the PHS Act definition is met.

In proposed § 495.202(a)(3), for MA organizations that offer other coordinated care MA plans (Preferred Provider Organization (PPO) plans, Provider Sponsored Organization (PSO) plans, and Regional Preferred Provider Organization (RPPO) plans) and for other MA organizations offering other MA plan types (private fee-for-service (PFFS) plans, Medical Savings Account (MSA) plans), we would require the sponsoring MA organization to attest that the MA organization is recognized under State law as an HMO, or that it is a similar organization regulated under State law for solvency in the same manner and to the same extent as an HMO before we would make a determination that the MA organization is a qualifying MA organization for purposes of incentive payments.

b. Qualifying MA Eligible Professional (EP)

A qualifying MA organization may receive an incentive payment only for those EPs described under section 1853(l)(2) of the Act, as added by section 4101(c) of the HITECH Act. Section 1853(l)(2) of the Act provides that these EPs must be "eligible professionals" as defined under section 1848(o) of the Act as added by section 4101(a) of the HITECH Act, and must either—

- Be employed by the qualifying MA organization; or
- Be employed by, or be a partner of, an entity that through contract with the

qualifying MA organization furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of the qualifying MA organization.

Further, the EP must furnish at least 80 percent of his or her professional services covered under Title XVIII (Medicare) to enrollees of the qualifying MA organization and must furnish, on average, at least 20 hours per week of patient care services.

As discussed in section II.A.1. of this proposed rule, an EP is defined as a physician (under section 1861(r) of the Act).

We interpret "employed by" to mean that the EP is considered an employee of a qualifying MA organization or qualifying entity under the usual common law rules applicable in determining the employer-employee relationship under section 3121(d)(2) of the Internal Revenue Code of 1986.

We interpret "to be a partner of" to mean that the qualifying MA EP has an ownership stake in the entity. Under this proposed interpretation, a professional that contracts with an entity, but has no ownership stake in the entity, would not be considered a qualifying MA EP.

We interpret "furnishing at least 80 percent" of the entity's "patient care services" to mean at least 80 percent of the qualifying MA EP's total Medicare revenue in a year (that is, total revenue from Medicare FFS as well as from all MA organizations) must be from a single qualifying MA organization.

We propose to interpret the requirement that a qualifying MA EP furnish at least 80 percent of their professional services covered under Title XVIII means that at least 80 percent of the professional's total Medicare revenue in a year (that is, total revenue from Medicare FFS as well as from all MA organizations) must be from a single qualifying MA organization. We believe that in establishing the rule that qualifying MA EPs need to furnish at least 80 percent of the EP's Title XVIII covered services "to enrollees of the organization," the statute limits payment related to any specific qualifying MA EP to a single qualifying MA organization. Thus, if a qualifying MA EP provided an average of 20 hours per week of patient care services to two distinct qualifying MA organizations, we would pay the qualifying MA organization for the MA EP only if such a qualifying EP provided at least 80 percent of his or her professional services covered under Title XVIII to enrollees of that organization.

For purposes of determining whether a qualifying MA EP furnishes, on average, at least 20 hours per week of patient care services, we interpret the requirement to include both Medicare and non-Medicare patient care services. Moreover, we propose that the relevant time period for determining whether an MA EP furnishes at least 20 hours per week of patient care services should be the EHR reporting period. (We discuss the proposed definition of EHR reporting period in section II.A. 1. e. of this proposed rule.) Therefore, over the EHR reporting period, the qualifying EP must provide on average 20 hours per week of patient care services. Finally, we interpret "patient care services" to mean services that would be considered "covered professional services" under sections 1848(o)(5)(A) and (k)(3) of the Act. That is, health care services for which payment would be made under, or for which payment would be based on, the fee schedule established under Medicare Part B if they were furnished by an eligible professional.

We considered various methods of determining when at least 20 hours per week, on average, of patient care services will be considered to be provided by MA EPs. We considered methods such as defining a dollar or service threshold, or the number of hours of direct patient care services actually provided. After due consideration we propose to require qualifying MA organizations to attest to the fact that MA EPs for whom they are requesting EHR incentive payments have provided, on average, 20 hours of patient care services during the EHR reporting period.

As discussed in section II.B. of this proposed rule relating to Medicare FFS EPs, a qualifying MA EP is also defined as a physician under section 1861(r) of the Act. Section 1853(l)(1) of the Act, as added by section 4101(c) of the HITECH Act, provides that the provisions of sections 1848(o) and 1848(a)(7) of the Act, as amended and added by sections 4101(a) and (b) of the HITECH Act, respectively, which establish the incentive payments for EPs under Medicare FFS, apply to a qualifying MA organization's qualifying MA EPs "in a similar manner" as they apply to EPs under Medicare FFS. As discussed above in section II.A.6. of this proposed rule, section 1848(o)(1)(C)(i) of the Act, as added by section 4101(a) of the HITECH Act, states that hospital-based EPs are not eligible for incentive payments. Therefore, we propose that, similar to the Medicare FFS incentive program, MA incentive payments would also not be available for hospital-based EPs. We note that the hospital where a hospital-based EP provides his or her Medicare covered services would be potentially entitled to an incentive payment either through the Medicare FFS incentive program, or through the MA-affiliated hospital EHR incentive program. Therefore, for such a hospital-based MA EP, a qualifying MA organization would be no more entitled to an MA EP incentive payment under the MA EHR incentive program than a similarly situated EP would be entitled to an incentive payment under the Medicare FFS EHR incentive program.

As discussed previously, an MA EP must either be employed by the qualifying MA organization, or be employed by, or be a partner of, an entity that through contract with the qualifying MA organization furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of the qualifying MA organization. With respect to the later criteria, we do not propose to define the term "entity," but instead recognize that there exist a range of entities with which MA organizations contract for patient care services, including a physician group, an Independent Practice Association (IPA), an Exclusive Provider Organization (EPO), a Physician Hospital Organization (PHO), or Preferred Provider Organization (PPO).

Moreover, we recognize that an EP may contract with more than one such entity, and that these entities often contract with a number of MA organizations and other health care insurers. An EP also may directly contract with more than one MA organization. In general it is only when an EP is employed by a single qualifying MA organization, or is employed by or in partnership with an entity that contracts with a single qualifying MA organization that an EP can satisfy the criteria to be an MA EP.

Finally, the qualifying MA organization must attest to the fact that each MA EP is a meaningful user of certified EHR technology in accordance with proposed § 495.4. If all of these conditions are met, such an individual is identified as an MA EP. We propose to define the term "MA eligible professional (EP)" at § 495.200 as an EP who satisfies these conditions.

Section 4101(d) of the HITECH Act directs the Secretary to study and report on "nearly exclusive" physicians that primarily treat MA enrollees and that would not otherwise qualify for incentive payments under current law. This proposed rule does not address such individuals, as it is limited to codifying in regulation existing statutory language as discussed herein.

c. Qualifying MA-Affiliated Eligible Hospital

We propose to define "qualifying MA-affiliated eligible hospital" in § 495.200. A qualifying MA organization may receive an incentive payment only for a qualifying MA-affiliated eligible hospital described under section 1853(m)(2) of the Act, as added by section 4102(c) of the HITECH Act, that is a meaningful user of certified EHR technology as defined in proposed § 495.4 . Section 1853(m)(2) of the Act provides that such MA-affiliated eligible hospitals are "eligible hospitals" as defined under section 1886(n)(6) of the Act and must be under common corporate governance with a qualifying MA organization that serves individuals enrolled under MA plans offered by such organization where more than two-thirds are Medicare individuals enrolled under MA plans offered by such organization. As discussed in section II.A.1. of this proposed rule, section 1886(n)(6) of the Act, defines an "eligible hospital" as a subsection (d) hospital (as defined under section 1886(d)(1)(B) of the Act). In § 495.200, we also propose to define "under common corporate governance", as a qualifying MA organization and a qualifying MA-affiliated eligible hospital that have a common parent corporation, that one is a subsidiary of the other, or that the organization and the hospital have a common board of directors.

Section 1853(m)(3)(B)(i) of the Act, as added by section 4101(c) of the HITECH Act, provides that if for a payment year at least one-third (33 percent) of a MA eligible hospital's discharges (or bed-days) of Medicare patients are covered under Part A (rather than under Part C), the hospital may only receive an incentive payment under section 1886(n) of the Act—the Medicare FFS incentive program.

In § 495.200 we propose to define "inpatient-bed-days" in the same manner as that term is defined for purposes of implementing section 4201(a) of the HITECH Act in the preamble of this proposed rule. The term will be used in the same way in computing incentive payments due qualifying MA organization under the qualifying MA-affiliated eligible hospital incentive payment program.

We note that, as discussed in section II.B.2.b. of this proposed rule, under section 1886(n)(2)(D)(i)(II) of the Act, the portion of the Medicare FFS hospital incentive payment comprising the discharge related amount, or Medicare share, is based in part on the estimated number of inpatient-bed-days attributable to individuals enrolled in MA plans under Part C. This means that hospitals that treat individuals enrolled in MA plans will receive a Medicare FFS hospital incentive payment partially based on the number of MA-enrollee bed-days. To the extent a hospital does not meet the 33 percent threshold requiring payment through the FFS Medicare EHR hospital incentive program, incentive payments can be made to a qualifying MA organization under common corporate governance to the extent other requirements of the MA EHR hospital incentive program are met. (See section II.C.3 of this proposed rule for the computation of incentive payments to qualifying MA organizations.)

Therefore, we propose to make EHR incentive payments to qualifying MA-affiliated eligible hospitals under the FFS EHR incentive program. Finally, to the extent that such data necessary to estimate the inpatient-bed-days-related incentive payment amount are not already available to us through the normal submission of hospital cost reports, we propose to require that qualifying MA organizations seeking reimbursement for qualifying MA-affiliated eligible hospitals submit similar data.

2. Identification of Qualifying MA Organizations, MA EPs, and MA-Affiliated Eligible Hospitals

In § 495.202 we propose to require MA organizations that intend to ask for reimbursement under the MA EHR incentive payment program to so indicate as part of submissions of their initial bid under section 1854(a)(1)(A) of the Act, and to attest, in some cases, that they meet the requirements of a qualifying MA organization. For MA organizations offering an MA HMO plan type, we will deem such organizations to meet the definition of HMO in 42 U.S.C. 300–gg(b)(3), (that is, section 2791(b)(3) of the PHS Act). As noted previously, for MA organizations offering plan types other than HMOs, we propose to require an attestation by the organization that the MA organization is recognized under State law as an HMO, or that it is a similar organization regulated under State law for solvency in the same manner and to the same extent as an HMO before we would make a determination that the MA organization is a qualifying MA organization for purposes of incentive payments. We propose to require this beginning with bids due in June 2010 (for plan year 2011) for MA organizations seeking reimbursement for MA EPs and MA-affiliated eligible hospitals.

We also propose requiring qualifying MA organizations, as part of their initial bids starting with plan year 2011, to make a preliminary identification of potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals for which the organizations will seek EHR incentive payments.

In developing the preliminary and final lists of potentially qualifying MA EPs, qualifying MA organizations must exclude hospital-based MA EPs. We propose that qualifying MA organizations identify hospital-based MA EPs using the same criteria outlined in section II.A.6 of this proposed rule for identifying hospital-based EPs in the Medicare FFS EHR incentive program.

Along with both the preliminary and final lists of potentially qualifying MA EPs and hospitals, qualifying MA organizations must submit an attestation that these professionals and hospitals meet the criteria to be considered eligible. For example, for hospitals, the qualifying MA organization must attest that they are under common corporate governance with the qualifying MA organization. For example, for EPs, the qualifying MA organization must attest that the list does not include any hospital-based EPs.

We propose requiring qualifying MA organizations to provide final identification of potentially qualifying MA EPs by the end of the MA EP payment year (December 31), and final identification of potentially qualifying MA-affiliated eligible hospitals by the end of the MA-affiliated hospital payment year (the FFY ending on September 30), for which MA EHR incentive payments will be sought. We also propose requiring qualifying MA organizations to report the name, practice address, and other identifying information, like NPI, for all physicians that meet the requirements of a qualifying MA EP for which the qualifying MA organization will be requesting payment under the MA EHR incentive payment program.

Once a qualifying MA organization identifies potential EPs, we are required to ensure that such EPs did not receive the maximum EHR incentive payment for the relevant payment year under the Medicare FFS program under section 1848(o)(1)(A) of the Act, as added by section 4101(a) of the HITECH Act, before releasing an incentive payment to a qualifying MA organization related to such EP. (See section 1853(l)(3)(B)(i) of the Act, as added by section 4101(c) of the HITECH Act). Therefore, in order to allow us time to determine whether an MA EP received the maximum EHR incentive payment under the Medicare

FFS program, we propose not to make incentive payments to qualifying MA organizations for the MA EPs for a payment year until after the final computation of EP incentive payments for that year under the Medicare FFS program. Additionally, we propose to require qualifying MA organization to ensure that all MA EPs are enumerated through the NPI system, in order to detect and prevent duplicate payment for EPs under both the FFS and MA EHR incentive payment programs.

We also propose to require all qualifying MA organizations to self-report and identify themselves, regardless of whether they have qualifying MA EPs or MA-affiliated eligible hospitals for whom or which the organization plans to claim incentive payments at the time the initial bid is due (the first Monday of June, see section 1854(a)(1)(A) of the Act) beginning in 2014 for bids related to plan year 2015. We propose to require this reporting by all qualifying MA organizations in years beginning with 2014 in anticipation of the statutory requirement in sections 1853(l)(4) and 1853(m)(4) of the Act, to negatively adjust our capitation payments to qualifying MA organizations for MA EPs and MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology for years beginning with 2015.

3. Computation of Incentives to Qualifying MA Organizations for MA EPs and Hospitals

In § 495.204, we propose a methodology under which payments to qualifying MA organizations for qualifying MA EPs will be computed. Section 1853(l)(3)(A) of the Act provides that in applying section 1848(o), instead of the additional payment amount specified under section 1848(o)(1)(A) of the Act, the Secretary may substitute an amount determined by the Secretary, to the extent feasible and practical, to be similar to the estimated amount in the aggregate that would be payable under, or would be based on, the Medicare physician fee schedule under Part B instead of Part C. Section II.B.1. of this proposed rule discusses these provisions.

Section 1853(m)(3)(A) of the Act provides that in providing an incentive payment to qualifying MA organizations for MA-affiliated hospitals, we substitute for the amount specified under section 1886(n)(2) of the Act—the incentive payment amount under Medicare FFS for qualifying eligible hospitals—an amount determined by the Secretary to be similar to the estimated amount in the aggregate that would be payable if payment for services furnished by such hospitals was payable under Part A instead of Part C. (For more detailed information see section II.B.2. of this proposed rule.)

Section 1848(o) of the Act permits us to make the incentive payments for a year in installments, although we are proposing to make a single lump sum payment under the Medicare FFS EHR incentive program. We read the term "aggregate" to mean the aggregate installment payments made by us under the FFS EHR incentive program to a qualifying EP over the course of the relevant payment year.

The duplicate payment provisions in section 1853(l)(3)(B)(i)(II) of the Act direct us to make payment for EPs "only under" the MA EHR incentive program "and not under" the Medicare FFS EHR incentive program to the extent any EP has earned "less than [the] maximum incentive payment for the same period" under the Medicare FFS EHR incentive program. We note that section 1853(l)(1) of the Act, provides that section 1848(o) of the Act applies in a "similar," but not the same, manner to qualifying MA organizations as it applies to EPs under Part B. The Medicare FFS incentive payment program under section 1848(o) does not include payment for professional services provided to MA enrollees, but only for services paid under Part B. In a similar manner we propose to limit payment to an MA organization to only payment for their EPs' services to MA enrollees of plans offered by the MA organization. We do not believe it would be appropriate to provide an incentive payment to an MA organization for services provided to individuals covered under Part B. Therefore, we propose, that in calculating qualifying MA EP incentive payments, we will only consider covered professional services provided to enrollees of MA plans offered by qualifying MA organizations and will not include in the calculation any services reimbursed by Medicare FFS.

Under the Medicare FFS EHR incentive program, an EP's incentive payment may not exceed the annual limits specified under section 1848(o)(1)(B)(i) of the Act. We propose that similar payment limits apply to qualifying MA organizations for their qualifying MA EPs. Specifically, the incentive payment to a qualifying MA organization for each of its qualifying MA EPs may not exceed certain limits. Specifically, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given year shall not exceed the following amounts:

- For the EP's first payment year, $15,000 (or, if the first payment year is 2011 or 2012, $18,000).
- For the EP's second payment year, $12,000.
- For the EP's third payment year, $8,000.
- For the EP's fourth payment year, $4,000.
- For the EP's fifth payment year, $2,000.
- For any succeeding year, $0.

Note that, similar to the Medicare FFS EHR incentive program, there will be no incentive payments made with respect to a year after 2016. We propose similar restrictions related to qualifying MA organizations. So, the maximum cumulative incentive payment over 5 years to a qualifying MA organization for each of its qualifying MA EPs that meaningfully use certified EHRs beginning on or before 2012 would be $44,000 per qualifying MA EP. For qualifying MA organizations first reporting the meaningful use of certified EHRs by qualifying MA EPs after 2014, there is no incentive payment amount available. Subject to an exception discussed below, for MA organizations first reporting the meaningful use of certified EHRs by qualifying MA EPs in 2013 or 2014, the maximum potential incentive payment per qualifying EP is, respectively, $39,000 over 4 years, and $24,000 over 3 years.

As we discuss in more detail in the section II.C.4. of this proposed rule, we propose to make MA EP incentive payments to qualifying MA organizations on the same payment cycle for all employed/partnering qualifying EPs of the organization. In other words, all MA EPs of a specific qualifying MA organization will be in the same payment year with respect to the amount of the incentive payment per qualifying EP that we will make. So, for instance, if a qualifying MA organization is in its second payment year in 2013 and it hires a new EP for which the qualifying MA organization had not previously received an EHR incentive payment, we will nevertheless make a second year incentive payment (up to $12,000 in 2013) with respect to such an MA EP—assuming all other conditions are met. Thus, the limits on MA EP incentive payments discussed above are applied to the qualifying MA organization's entire MA EP population in any specific payment year relative to that MA organization, regardless of the length of employment/partnership of/between that specific MA EP and that specific qualifying MA organization.

Under section 1848(o)(1)(B)(iv) of the Act, the annual incentive payment limit for EPs who predominantly furnish Part

B services in a geographic health professional shortage area (HPSA) is increased by 10 percent. While we do not anticipate that MA EPs would generally practice in a HPSA area, to the extent that an MA EP practices in an area where he or she would be entitled to the 10 percent increase, that amount would apply to MA EPs as well. We explored various ways of computing the EP-level incentive payments due qualifying MA organizations whose qualifying MA EPs meaningfully use certified EHR technology.

One option that we considered was using MA plan bidding and MA payment data to estimate average annual MA revenue for qualifying MA EPs with respect to a qualifying MA organization. So, for instance, a qualifying MA organization that estimated MA Part B service-related physician costs of $3 million/year in its bid for a year, and that employed 100 qualifying MA eligible physicians, would be assumed to have an average physician Part B charge per physician per year factor of $30,000 ($3,000,000/100). However, we did not pursue this option because the approach results in an average revenue amount across all potentially qualifying MA EPs with respect to a qualifying MA organization and, therefore, would include revenue amounts that exceed the annual per-professional ceiling on incentive payments under FFS for *all* EPs. We believe such a result is contrary to the legal requirement that qualifying MA organizations are to incentive payments only for qualifying MA EPs that actually provide at least 20 hours per week of patient care services. Under this method there would also be no way to know if the EP provided 80 percent of his/her professional Medicare services to enrollees of the organization.

We also considered a reporting system for which qualifying MA organizations would be required to report eligible-professional-specific information along with MA patient encounters for nonhospital-based office visits. Specifically, we examined requiring qualifying MA organizations to report qualifying MA EP encounters with MA plan enrollees based on the five levels of office visit codes recognized by Medicare FFS.

We would use such reports to estimate the amount of compensation that a qualifying MA EP working primarily for a qualifying MA organization would be eligible to receive under Medicare FFS. For example, a qualifying MA EP with a primary care specialty might have an average of 10 MA patient low/moderate intensity office visits with members of a qualifying MA organization per day. Such an EP would potentially qualify for the maximum Medicare FFS EP incentive payment in the first year based on a calculation of $63 * 10 * 52 = $32,760—which is more than the Medicare FFS EHR incentive program threshold of $24,000 necessary to qualify for the maximum incentive payment of $18,000 if the fist payment year were 2011 or 2012.

We estimated the national average FFS allowed amounts for the 5 levels of office visit codes (CPT codes 99211–99215) in 2009 to be: $20, $39, $63, $95, $129, respectively. We contemplated allowing, but not requiring, qualifying MA organizations to report consultation codes for specialist physicians (CPT codes 99241–99245) estimated to have national average FFS allowed amounts of $50, $94, $129, $190, and $234, respectively.

However, we now believe that such a process would be administratively burdensome and difficult to operationalize. Therefore, we are proposing an alternative approach, but seek input from interested parties as to which of these approaches, or perhaps others, would best address the statutory requirement to compensate qualifying MA organizations for qualifying MA EPs the amount that would be payable if payment for services furnished by such professionals were made under Part B instead of Part C.

We propose an approach in which the revenue received by the qualifying MA EP for services provided to enrollees of the qualifying MA organization would serve as a proxy for the amount that would have been paid if the services were payable under Part B. Under this approach, the qualifying MA organization would report to us the aggregate annual amount of revenue received by each qualifying MA EP for MA plan enrollees of the MA organization. We would calculate the incentive payment amount due the qualifying MA organization for each qualifying MA EP as an amount equal to 75 percent of the reported annual MA revenue of the qualifying MA EP, up to the maximum amounts specified under section 1848(o)(1)(B) of the Act.

For qualifying MA EPs who are compensated on a salaried basis, we propose requiring the qualifying MA organization to develop a methodology for estimating the portion of the qualifying MA EP's salary attributable to providing services that would otherwise be covered as professional services under Part B of Medicare to MA plan enrollees of the MA organization. The methodology, which would require review and approval by us, could be based on the relative share of patient care hours spent with MA enrollees of the organization or another reasonable method. So, for instance, if a qualifying MA EP spends 30 percent of his or her time providing covered Part B physician office services to MA plan enrollees, then the qualifying MA organization would report 30 percent of the qualifying MA EP's salary as annual revenue, which would be used to compute the amount of the MA incentive payment due to the qualifying MA organization for the qualifying MA EP. Thus, if the qualifying MA EP had a base salary of $150,000, 30 percent would be $45,000—which is well over the threshold of $24,000 needed by the MA organization to qualify for a maximum incentive payment of up to $18,000 (70 percent of $24,000) for such a qualifying MA EP in any year. We also propose to require that salaries be prorated to ensure that the amount reported reflects the salary paid for the applicable year.

Salaried physicians' compensation typically does not include an allowance for administrative practice costs. Given that Part B allowed amounts do include practice expense costs, we propose allowing qualifying MA organizations to identify, where appropriate, an additional amount related to overhead that would be added to the qualifying MA EP's estimated Part B compensation. To the extent Medicare FFS compensation to physicians includes an amount for office space rental, office staffing, and equipment, we believe that qualifying MA organizations should also be permitted to include an amount for overhead related to such costs not directly experienced by salaried qualifying MA EPs. In § 495.204(b)(4)(ii), we propose requiring qualifying MA organizations to develop a methodology for estimating the additional amount related to overhead attributable to providing services that would otherwise be covered under Part B of Medicare. The methodology would require review and approval by us.

For qualifying MA EPs who are not salaried (that is, who are paid on a capitated or fee-for-service basis), we propose in § 495.204(b)(5) to require qualifying MA organizations to obtain attestations from such EPs and to submit to CMS information from the attestations as to the amount of compensation received by the EPs for MA plan enrollees of the MA organization. We are proposing such attestations because many EPs are not paid directly by MA organizations, but rather by intermediary contracting entities, such as physician groups, and as a result the qualifying MA

organization may not otherwise know how much compensation is received by each qualifying MA EP. In reporting compensation, we are proposing that the EPs include only those amounts for professional services that would otherwise be payable under Part B and for which payment would be made under, or would be based on, the Medicare physician fee schedule.

As mentioned previously, in applying the instruction in section 1853(m)(3)(A) of the Act to substitute for the amount specified under section 1886(n)(2) of the Act an amount similar to the estimated amount in the aggregate that would be payable if payment for the hospitals' services were made under Part A instead of Part C, we read the term "aggregate" to mean the aggregate installment payments made by us if EHR incentive payments were made under Part A instead of Part C.

Incentive payments to eligible hospitals under the Medicare FFS EHR incentive program are comprised of three components: (1) An initial amount composed of a base incentive payment of $2,000,000 and a second incentive payment amount of $200 per discharge for discharges 1,150–23,000 during a 12-month period selected by the Secretary; (2) the Medicare share; and (3) a transition factor. As discussed in the preamble related to proposed § 495.104(c), for purposes of calculating incentive payments to eligible hospitals under the Medicare FFS EHR incentive program, we are proposing that the 12-month period be based on the FFY. For the purpose of calculating incentive payments for qualifying MA-affiliated eligible hospitals, we similarly are proposing that the 12-month period be based on the FFY.

Section II.B. of this proposed rule discusses our proposed methodology for calculating the incentive payment for qualifying eligible hospitals under the Medicare FFS EHR program. As set forth in proposed § 495.204(c)(2), we propose to use the FFS EHR hospital incentive program for purposes of calculating and making the incentive payment for qualifying MA-affiliated hospitals. To the extent data are not available to reimburse MA-affiliated hospitals through the FFS hospital incentive program, we propose to require submission of such data to us and adopt the same definition of "inpatient-bed-days" and other terms proposed under the Medicare FFS EHR hospital incentive program specified in § 495.104 of this proposed rule. In such a case we propose in § 495.204(c)(1) to make payment for such MA-affiliated eligible hospitals to the qualifying MA organization.

The formula for calculating the hospital incentive payment under the Medicare FFS hospital incentive program is an initial amount of the sum of the base amount of $2,000,000 per hospital plus an additional $200 per discharge for discharges 1,150 through 23,000 for that hospital in that payment year. This initial amount is then multiplied by a transition factor and then again by the Medicare share. These last two numbers are fractions and will tend to reduce the initial amount computed in the first step.

Similar to the Medicare FFS EHR hospital incentive program, we propose to use inpatient-bed-day data, discharges, and other components of the FFS calculation for each qualifying MA-affiliated eligible hospital from the hospital-specific fiscal year that ends during the FFY prior to the FFY that serves as the payment year. To the extent such data are not already available to us through the normal submission of hospital cost reporting data, we propose requiring qualifying MA organizations seeking reimbursement for their qualifying MA-affiliated eligible hospitals to submit similar data.

We can only pay for qualifying MA-affiliated eligible hospitals under common corporate governance based on inpatient-bed-days computed on a fiscal year basis where less than one-third of the inpatient-bed-days of Medicare patients are covered under Medicare FFS—Part A. However, it does not appear that reimbursement *only* under the MA EHR incentive program is required for qualifying MA-affiliated eligible hospitals that are under common corporate governance. Rather, section 1853(m)(3)(B), of the Act only prohibits payment under the MA EHR incentive program when Medicare hospital inpatient-bed-days covered under Part A exceed 33 percent of all Medicare inpatient-bed-days. Although eligibility under the MA EHR hospital incentive program is not available to qualifying MA organizations for any specific hospital when FFS inpatient-bed-days exceed 33 percent of the Medicare total, a qualifying MA organization could be reimbursed through the Medicare FFS EHR hospital incentive payment program for qualifying hospitals under common corporate governance even for hospitals with very low ratios of FFS to MA inpatient-bed days.

Given that the hospital incentive payment methodology and payment amount will be identical under the Medicare FFS EHR incentive program and the MA EHR incentive program, and given that there is no statutory prohibition on reimbursing a qualifying MA-affiliated eligible hospital through the Medicare FFS EHR incentive program, for purposes of administrative efficiency, and pursuant to our authority under section 1857(e) of the Act to add new "appropriate" contract terms (incorporated for Part D by section 1860D–12(b)(3)(D) of the Act), we propose requiring that qualifying MA organizations receive incentive payments for qualifying MA-affiliated eligible hospitals through their affiliated hospitals under the Medicare FFS EHR incentive program if they are eligible for such payments, rather than through the MA EHR incentive program. We believe this is the most efficient way in which to administer the MA EHR hospital incentive program in light of the expected low volume of MA-affiliated eligible hospitals (approximately 50 hospitals), and in light of preliminary data which indicates that MA-affiliated eligible hospitals already submit Medicare cost reporting data to us from which we can compute hospital incentive payments due. To the extent sufficient data do not exist to make such payments under the Medicare FFS EHR incentive program, qualifying MA organizations will be required to submit additional data to us.

Finally, to the extent payments are made to qualifying MA organizations for qualifying MA EPs or qualifying MA-affiliated eligible hospitals, we propose to conduct selected compliance reviews to ensure that EPs and eligible hospitals for which such organizations received incentive payments were actually meaningful users of certified EHR technology, in accordance with our existing authority in section 1857(d) of the Act and 42 CFR 422.504 of the regulations related to protections against fraud. The reviews would include validation of meaningful user attestations, the status of the organization as a qualifying MA organization, and verification of both meaningful use and data used to calculate incentive payments. We propose requiring MA organizations to maintain evidence of compliance with all aspects of the MA EHR incentive payment program for 10 years after the date payment is made with respect to a given payment year. Payments that result from incorrect or fraudulent attestations, cost data, or any other submission required to establish eligibility or to qualify for a payment, will be recouped by CMS from the MA organization.

4. Timeframe for Payment

For payments to qualifying MA EPs, in § 495.206 we propose the time frame

for payment to be after the Medicare FFS program computes incentive payments due under the Medicare FFS EHR incentive program—so the first possible incentive payments would be made sometime in early 2012. We propose that payments for qualifying MA-affiliated eligible hospitals under common corporate governance occur in the same manner and in the same time frame as payments made under the Medicare FFS EHR incentive program to "subsection (d)" hospitals as discussed in section II.B.2.d. of this proposed rule.

We propose to define "payment year" with respect to qualifying MA EPs in § 495.200. Section 1853(l)(3)(C) of the Act directs us to establish the same first payment year for all EPs with respect to any specific qualifying MA organization. Consistent with the statute, we propose to pay a qualifying MA organization on the same schedule for all of its qualifying MA EPs. In other words, the first year during which the qualifying MA organization receives an incentive payment for its qualifying EPs will be considered the first payment year for all of its qualifying EPs. Accordingly, for purposes of determining the applicable incentive payment limits, the second, third, fourth, and fifth years during which the qualifying MA organization receives an incentive payment for its qualifying EPs will be considered the second, third, fourth, and fifth payments years for each of its qualifying EPs, regardless of whether the MA organization claimed an incentive payment for a particular EP for a prior payment year. Such a consistent payment cycle relative to qualifying MA organizations and qualifying MA EPs obviates the need to track payment years and payment adjustment years based on prior payments or adjustments with respect to any individual qualifying MA EP. Rather, for purposes of payment years and payment adjustment years, any EP employed by or partnering with any specific MA organization will be on the same cycle with respect to that organization.

Similar to the Medicare FFS EHR incentive program, payment to qualifying MA organizations for qualifying MA EPs and payment for qualifying MA-affiliated eligible hospitals is available only for a finite number of years. As previously discussed in the section on the calculation of MA incentive payments, above, a qualifying MA organization can receive an incentive payment of up to $18,000 for each of its qualifying MA EPs for its first payment year if its first payment year is 2011 or 2012, or up to $15,000, if its first payment year is 2013, or up to $12,000, if its first payment year is 2014. Note that, similar to the Medicare FFS EHR incentive program, there would be no incentive payments made with respect to a year after 2016.

We propose to define "payment year" with respect to qualifying MA-affiliated eligible hospitals in § 495.200. For incentive payments for qualifying MA-affiliated eligible hospitals, the first year for which an MA organization may claim payment is FY 2011. Similar to the Medicare FFS EHR hospital incentive program, we propose to use the hospital inpatient-bed-days data from the hospital fiscal year that ends during the FFY prior to the fiscal year that serves as the payment year. For qualifying MA-affiliated eligible hospitals, we propose to compute hospital EHR incentive payments due in the same manner as they are being computed in the Medicare FFS hospital incentive payment program. For qualifying MA-affiliated eligible hospitals for which the first payment year is 2011 through 2013, up to 3 additional years of incentive payments are available. For qualifying MA-affiliated eligible hospitals for which the first payment year is after 2015, no EHR payment incentive can be made for that year or any subsequent year. Finally, for qualifying MA-affiliated eligible hospitals for which the first payment year is 2014 or 2015, only 2 (or 1) more year(s) of hospital incentive payments will be available.

Unlike the fixed schedule for application of limitation on incentive payments for MA EPs discussed previously in this section of the proposed rule in which all employed/partnering MA EPs will be paid on the same schedule (first payment year, second payment year, etc.) with respect to any specific qualifying MA organization, we propose to make payments to MA organizations for MA-affiliated eligible hospitals on a hospital-specific basis. In other words, if a qualifying MA organization has some MA-affiliated eligible hospitals with a first payment year of FY 2011, it may have other MA-affiliated eligible hospitals with a first payment year of FYs 2012 through 2015.

5. Avoiding Duplicate Payment

We propose duplicate payment avoidance provisions in § 495.208. Section 1853(l)(3)(B) of the Act, as added by the HITECH Act, is entitled "Avoiding Duplication of Payments." Subclause (I) of the Act states that to the extent an MA EP is entitled to the maximum incentive payment under section 1848(o)(1)(A) of the Act, the Medicare FFS EHR incentive payment program—such incentive payment will only be made under the Medicare FFS EHR incentive program. Therefore, before payments can be made to qualifying MA organizations for MA EPs, we must first determine if a maximum incentive payment under the Medicare FFS program has been previously earned by potential MA EPs. Under the Medicare FFS incentive payment program, incentive payment calculations will not be completed for the first payment year, 2011, until the early part of 2012. Therefore, we would not be able to make payments to qualifying MA organizations for MA EPs until claims submissions counted for Medicare FFS incentive payments for CY 2011 have been closed, and payment calculations for participating EP under the Medicare FFS EHR incentive program have been completed in the early part of CY 2012. We will follow the same practice—first computing Medicare FFS incentive payments for EPs and then computing and paying MA incentive payments, where appropriate—in all subsequent payment years.

Subclause (II) of section 1853(l)(3)(B)(i) of the Act further states that to the extent an MA EP is entitled to less than the maximum incentive payment under the Medicare FFS EHR incentive program, that payment is to be made solely under the MA provision. In other words, we will need to withhold Medicare FFS incentive payments from EPs of less than the maximum to the extent such professionals are also identified as MA EPs under section 1853(l)(2) of the Act. Again, we would need to await the computation of payments due EPs under the Medicare FFS EHR incentive program before we can determine whether the EP is entitled to less than the maximum payment amount under the Medicare FFS EHR program, in which case any incentive payment for the EP will only be made to the qualifying MA organization under the MA EHR program, and not to the EP under the Medicare FFS EHR program.

Section 1853(m)(3)(B) of the Act, states that incentive payments for qualifying MA-affiliated eligible hospitals are to be made under either the Medicare FFS hospital incentive payment program, or under the MA hospital incentive payment program. If more than 33 percent of discharges or bed-days of all Medicare patients for a year are covered under Part A, then payment for that year is to only be made under section 1886(n) of the Act—the Medicare FFS EHR incentive program—and no payment is to be made under the MA hospital incentive payment

program. Otherwise, to the extent less than 33 percent of bed days of all Medicare patients for an incentive payment year are covered under Part A, then payment for that incentive payment year may be made under the MA EHR incentive payment program.

Unlike the process we propose to follow related to qualifying EPs (where we will wait for the Medicare FFS incentive payment program to compute eligible physician incentive payments due under that program before determining the amount due under the MA EHR incentive program), we would not need to rely on Medicare FFS EHR incentive payment program calculations before determining eligibility for MA-affiliated hospital incentive payments. We would reimburse all hospitals, including MA-affiliated eligible hospitals, under the Medicare FFS hospital incentive program. We believe that by doing so, we will prevent duplicate payments being made for the same hospitals by Medicare FFS and the MA incentive payment programs. To the extent that qualifying MA organizations are to receive incentive payments through the MA program rather than through their hospitals under the Medicare FFS EHR incentive program due to a lack of sufficient data to make payments under the FFS program, we would identify and reimburse only appropriate qualifying MA organizations for qualifying MA-affiliated eligible hospitals. Such reimbursement will be in a manner similar to the manner in which the Medicare FFS EHR incentive program will reimburse eligible hospitals due an incentive payment under the Medicare FFS EHR incentive program.

In order to avoid duplicate payments and in accordance with section 1853(m)(3)(B)(ii)(II) of the Act, we will not make MA EHR hospital incentive payments to qualifying MA organizations for MA-affiliated eligible hospitals other than through the Medicare FFS EHR hospital incentive payment program without first ensuring that no such payments under the Medicare FFS EHR hospital incentive payments were made.

We invite industry and public comment on our proposed process to eliminate duplicate payments to EPs and MA-affiliated eligible hospitals under the Medicare FFS and MA incentive payment programs.

6. Meaningful User Attestation

We propose meaningful user attestation requirements in § 495.210. For each MA EP and MA-affiliated hospital for which a qualified MA organization seeks an incentive payment, the organization must attest, in a form and manner specified by us, that its MA EPs and MA-affiliated eligible hospitals are meaningful EHR users, as required by sections 1853(l)(6) and 1853(m)(1) of the Act. We further propose to adopt the definitions of meaningful user proposed under the Medicare FFS program related to EPs and hospitals in proposed § 495.4. We propose to require qualifying MA organizations to attest each payment year whether each of its MA EPs and MA-affiliated eligible hospitals for which it is seeking an incentive payment was a meaningful EHR user for the EHR reporting period for a payment year. A qualifying MA organization must make this attestation for each payment year for which it is seeking an incentive payment for MA EPs and MA-affiliated eligible hospitals. We believe attestations should occur toward the end of a year with respect to that year, since qualifying MA organizations will need to attest to, based on our proposed rule, meaningful use for the appropriate duration and during the appropriate period related to MA EPs and MA-affiliated eligible hospitals before claiming incentive payments for them.

Note that unlike the Medicare FFS EHR incentive program, where we will require the reporting of clinical quality measures—see § 495.8—we will not require qualifying MA organizations to submit clinical quality measures per section 1848(o)(2)(B) of the Act, with respect to EPs, and section 1886(n)(3)(B) of the Act, with respect to eligible hospitals. Consistent with sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) of the Act, we note that qualifying MA organizations sponsoring coordinated care MA plans are already required to submit Healthcare Effectiveness Data and Information Set (HEDIS), Health Outcomes Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures per § 422.152 and § 422.516. Coordinated care MA plans include HMO, PPO and RPPO (Regional PPO) plans. Beginning with CY 2010, PFFS and MSA plans will also be required to begin collecting and submitting administrative HEDIS measures.

We believe that all qualifying MA organizations will be organizations offering MA coordinated care plans, and therefore; those MA organizations from which we routinely receive complete HEDIS dataset reporting. Pursuant to sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) of the Act, for clinical quality measures which overlap between the existing MA quality reporting program and under the HITECH program, we propose to allow qualifying MA organizations to continue reporting under the existing MA quality reporting program. For those HITECH clinical quality measures that do not overlap and that are appropriate for the MA program, we are considering requiring that qualifying MA organizations that receive an incentive payment report those measures to CMS. This would ensure that clinical quality measure reporting under HITECH is consistent between the FFS program and MA. An alternative approach would be to require that qualifying MA organizations that receive an incentive payment report all of the HITECH clinical quality measures under section II.A.2 of this proposed rule that are appropriate for the MA program directly to CMS, while also reporting those HEDIS, HOS, and CAHPS measures under the existing MA quality program. This may result in duplicative reporting under the HITECH program and current MA quality reporting, but may provide us with more direct access to quality data under the HITECH program. We invite public comment on these approaches, including alternative methods to consistently treat MA-affiliated providers and FFS providers under the HITECH Medicare incentive program.

Therefore, we propose requiring qualifying MA organizations to submit attestations to us related to meaningful use by MA-affiliated hospitals within 30 days of the close of the FFY—which is the payment year for MA-affiliated hospitals—by October 30. We also propose requiring qualifying MA organization to submit attestations to us related to meaningful use by MA EPs within 30 days of the close of the MA EP payment year—which is a CY—by January 30.

7. Posting Information on the CMS Web Site

Sections 1853(l)(7) and 1853(m)(5) of the Act, require us to post information on an Internet Web site related to the receipt of incentive payments under the MA EHR incentive program. Information would include the names, business addresses, and business phone numbers of each qualifying MA organization receiving an incentive payment under this section for qualifying MA EPs and hospitals. A list of the names of each qualifying MA EP and qualifying MA-affiliated eligible hospital for which an incentive payment has been made would also be posted. Since this requirement is applicable to other Medicare EPs and eligible hospitals, we have included this requirement in proposed § 495.108.

8. Limitation on Review

Section 1853(l)(8) of the Act states that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR EP incentive program. This includes provisions related to duplication of payment avoidance and rules developed related to the fixed schedule for application of limitation on incentive payments for all qualifying MA EPs related to a specific qualifying MA organization. This also includes the methodology and standards developed for determining qualifying MA EPs and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures. We propose to codify these requirements in § 495.212(b).

Section 1853(m)(6) of the Act, as added by the HITECH Act, states that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR hospital incentive program. This includes provisions related to duplication of payment. This also includes the methodology and standards developed for determining qualifying MA hospitals and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures. We propose to codify these requirements in § 495.212(c).

9. Conforming Changes

Sections 4101(e) and 4201(d)(2) and (3) of the HITECH Act provide conforming amendments to Part C of the Social Security Act. Therefore, we are proposing the following conforming changes to the regulations text:

- Revising § 422.304 by adding a new paragraph (f) to account for the amendment to section 1853(a)(1)(A) of the Act referencing the additional EHR incentive payments that may be made to qualifying MA organizations in the section of the statute that provides for monthly capitation payments to MA organizations. (This addition would also act as a cross-reference to MA EHR incentive payment rules in proposed subpart C of part 495 of this chapter.)
- Revising § 422.306(b)(2) by adding a new paragraph (iv) to address the amendments to section 1853(c)(1)(D)(i) of the Act which exclude the EHR incentive payments made to EPs and hospitals under the Medicare FFS program from the computation of FFS costs in a year for the purpose of computing MA monthly capitation amounts.
- Revising § 422.308 by adding a new paragraph (a)(1) to address the amendments to section 1853(c)(1)(D)(1) and (c)(6)(A) of the Act regarding the exclusion of FFS Medicare EHR incentive payments and adjustments from the calculation of the national per capita growth percentage.
- Revising § 422.322 by adding a new paragraph (a)(3) to account for the amendments to section 1853(c)(6)(A) and (f) of the Act specifying that the source of EHR incentive payments to qualifying MA organizations are from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund.
- Revising § 422.322(b) by adding a reference to § 495.204 to address the amendment to section 1851(i)(1) of the Act that indicates that EHR incentive payments are instead of incentive payments that would otherwise be payable under original Medicare.

10. Payment Adjustment and Future Rulemaking

In future rulemaking we will develop standards related to payment adjustments to qualifying MA organizations related to MA EPs and MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology. We solicit comment on how we can most effectively and efficiently apply payment adjustments to qualifying MA organizations whose MA eligible EPs and hospitals have not successfully meaningfully used certified EHR technology.

The statutory requirement related to imposition of payment adjustments with respect to MA EPs is set forth in section 1853(l) of the Act. Specifically, section 1853(l)(4) of the Act requires that instead of applying the payment adjustment in section 1848(a)(7) of the Act, we apply the payment adjustment to the Medicare physician expenditure proportion. This is our estimate of the proportion of the expenditures under Parts A and B paid to the qualifying MA organization in the form of capitation payments under section 1853 of the Act that are not attributable to the EHR incentive payment program, that are attributable to expenditures for physician services. In the case of a qualifying MA organization that attests that not all MA EPs of the organization are meaningful EHR users with respect to years beginning with 2015, we are directed to apply the payment adjustment on the proportion of the capitation payment with respect to all such EPs of the organization that are not meaningful users for such year. The adjustment amount is 1 percent for 2015, 2 percent in 2016, and 3 percent in 2017 and subsequent years.

The statutory requirement related to imposition of payment adjustments with respect to MA-affiliated eligible hospitals is provided in section 1853(m) of the Act. Specifically, section 1853(m)(4) of the Act requires us to apply the adjustment to the hospital expenditure proportion, which is our estimate of the proportion of the expenditures under Parts A and B paid to the qualifying MA organization in the form of capitation payments under section 1853 of the Act that are not attributable to the EHR incentive payment program, that are attributable to expenditures for inpatient hospital services. In the case of a qualifying MA organization that attests that not all MA-affiliated eligible hospitals of the organization are meaningful EHR users with respect to years beginning with 2015, we are directed to apply the payment adjustment on the proportion of all such MA-affiliated eligible hospitals of the organization that are not meaningful users for such year. The adjustment amount is of three-fourths of the market basket increase related to a hospital by a 33⅓ percent reduction in 2015, by a 66⅔ percent reduction in 2016, and by a 100 percent reduction in 2017 and all subsequent years. Effectively, the reduction is of all but 25 percent of the market basket increase for a specific hospital in years after 2016.

We welcome comments on these incentive payment adjustments and on how we can most effectively and efficiently apply payment adjustments to qualifying MA organizations whose EPs and MA-affiliated hospitals have not successfully meaningfully used certified EHR technology. Any comments received will be considered in developing future rulemaking.

D. Medicaid Incentives

1. Overview of Health Information Technology in Medicaid

Under the HITECH Act, State Medicaid programs, at their option, may receive Federal financial participation (FFP) for expenditures for incentive payments to certain Medicaid providers to adopt, implement, upgrade, and meaningfully use certified EHR technology. Additionally, FFP is available to States for administrative expenses related to administration of those incentive payments as long as the

State meets certain conditions. Section 1903(a)(3)(F)(i) of the Act, as amended by section 4201 of the HITECH Act, establishes 100 percent FFP to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade, and meaningfully use certified EHR technology. The incentive payments are not direct reimbursement for the purchase and acquisition of such technology, but rather are intended to serve as incentives for EPs and eligible hospitals to adopt and meaningfully use certified EHR technology.

Section 1903(a)(3)(F)(ii) of the Act, as amended by section 4201 of the HITECH Act, also establishes 90 percent FFP to States for administrative expenses related to carrying out the substantive requirements associated with the incentive payments. As discussed later in this proposed rule, we interpret these administrative expenses as including approvable expenses related to oversight activities and promotion of health information exchange.

It is important to note that we do not believe that the Medicaid incentive and administrative payments authorized under section 4201 of the HITECH Act should be viewed in isolation. Rather, we encourage States, providers, and other stakeholders to view these new programs in concert with the numerous other initiatives recently undertaken and currently being promoted by both CMS and the Department to encourage advancements in health care technology and health information exchange. These initiatives include the following:

- The establishment of the Office of the National Coordinator (first through executive order in 2004 and then as legislatively mandated in the HITECH Act);
- The Medicaid Transformation Grant program authorized by section 6081 of the Deficit Reduction Act of 2005 (Pub. L. 109–171). This program provided $150 million in grants in FY 2007 through FY 2008 to States to support innovative methods for transforming Medicaid programs. Twenty-two States focused on HIT, with initiatives ranging from the use of statewide EHRs for beneficiaries, to mechanized clinical decision support, to e-prescribing, to electronic health information exchange. For more information on the program, we refer readers to: *http://www.cms.hhs.gov/MedicaidTransGrants.*
- The Medicaid Information Technology Architecture (MITA) initiative and framework. MITA is a plan to promote improvements in the Medicaid enterprise and the systems that support it through collaboration between CMS and the States. The MITA framework consists of models, guidelines, and principles for States to use as they plan and implement business and technology enterprise solutions. Integral to the MITA is the State's Medicaid Management Information System (MMIS). The MMIS contains a great deal of claims data and other Medicaid programmatic information that we believe should be used by States in analyzing their current HIT environments. Once States establish a baseline assessment, they can then plan the steps necessary to transition towards achieving some of the objectives of the HITECH Act, such as improving both quality of care and health care outcomes. In addition, the MITA framework is CMS's initiative that will allow States to modernize and transform their MMIS to improve the administration of the Medicaid program, while supporting the States' need for flexibility, adaptability, and rapid response to changes in the unique aspects of their individual Medicaid programs. The ultimate goal of MITA is to develop seamless and integrated systems that communicate effectively and that are interoperable, both within and across States as well as with other health care entities and payers, such as public health departments and non-Medicaid payers. For more information on MITA, we refer readers to: *http://www.cms.hhs.gov/MedicaidInfoTechArch/.*

We believe that the HITECH Act incentives create a unique opportunity for States and Medicaid providers to build upon prior and current efforts in HIT in order to help achieve interoperable health information exchange in health care. We believe that States should build upon the lessons learned from these initiatives in order to ensure that the incentive and administrative payments are leveraged in a way that maximizes the role of HIT in enhancing quality and access, reducing costs, and improving health care outcomes.

We also plan to ensure public involvement as the HIT environment evolves, both as a result of the HITECH Act incentives, as well as a result of other Departmental HIT initiatives. We have already convened several State calls on the HITECH Act, including discussing the definition of meaningful use of certified EHR technology, and the impact the definition would have on specific provider groups. More information on the content of these calls can be found in section II.A.2.a of this proposed rule. We convened additional calls with State staffs on the Medicaid EHR incentives leading up to our development of this proposed rule. Issues addressed include policies such as State oversight of adopting, implementing, and upgrading certified EHR technology; alternative fiscal agents under consideration; and validating data to establish program eligibility.

We also released a State Medicaid Director's letter on September 1, 2009. This letter outlines steps State Medicaid agencies can take to assess the current status of their HIT efforts; develop a roadmap for achieving their HIT objectives in support of the Medicaid EHR incentive program; set Medicaid-specific performance goals and incentives for provider adoption of HIT; and partner with a broad range of stakeholders. Furthermore, we conducted a follow-up technical assistance call with State Medicaid Directors and their staffs to provide an overview and answer questions.

Finally, as required by section 1903(t)(10) of the Act, we will be reporting to Congress on the status, progress, and oversight of the overall EHR incentive program. These reports will discuss steps taken to avoid duplicate Medicare and Medicaid incentive payments to EPs, the extent to which Medicaid EPs and hospitals have adopted certified EHR technology as a result of the incentive payments, and any improvements in health outcomes, clinical quality, or efficiency resulting from the adoption of such technology.

- 2. General Medicaid Provisions

In the proposed § 495.342 and § 495.344 we provide the general rule that States, at their option, may receive: (1) 90 percent FFP for State expenditures related to the administration of an EHR incentive program for certain Medicaid providers that are adopting, implementing, or upgrading and meaningfully using certified EHR technology; and (2) 100 percent FFP for State expenditures for those incentive payments.

- 3. Identification of Qualifying Medicaid EPs and Eligible Hospitals

a. Overview

As specified in section 1903(t)(2) of the Act, only certain Medicaid providers will be eligible for incentive payments. This section of the preamble discusses some of these eligibility requirements, including requirements relating to patient volume, whether a provider is hospital-based, and whether an EP is practicing predominantly in a federally-qualified health center (FQHC) or a rural health clinic (RHC). Proposed

regulations relating to these requirements may be found at § 495.304 through § 495.306.

• b. Program Participation

As specified under section 1903(t)(2)(A) of the Act, Medicaid participating providers who wish to receive a Medicaid incentive payment must meet the definition of a "Medicaid EP." This definition (1903(t)(3)(B) of the Act) lists five types of Medicaid professionals: Physicians, dentists, certified nurse-midwives, nurse practitioners, and physician assistants practicing in an FQHC or RHC that is so led by a physician assistant.

Additionally, to qualify for incentives, most Medicaid EPs cannot be "hospital-based." We propose to use the same definition of "hospital-based" as used in the Medicare EHR incentive program, as sections 1848(o)(1)(C) and 1903(t)(3)(D) of the Act use almost identical definitions of the term. We refer readers to section II.A. of this preamble for a proposed definition of "hospital-based," and for a thorough discussion of our proposed methodology.

The only exception to this rule is that Medicaid EPs practicing predominantly in an FQHC or RHC are not subject to the hospital-based exclusion.

Medicaid EPs must also meet the other criteria for Medicaid incentive payment eligibility, such as the patient volume thresholds or practicing predominantly in an FQHC or RHC, as described in this subpart. Since the statute at 1903(t)(2)(iii) of the Act does not define "practices predominantly," we propose that an eligible professional practices predominantly at an FQHC or an RHC when the clinical location for over 50 percent of his or her total patient encounters over a period of 6 months occurs at an FQHC or RHC.

Acute care and children's hospitals are listed in section 1903(t)(2) of the Act as the only two types of institutional providers potentially eligible for Medicaid incentive payments. These terms are specific to the Medicaid EHR incentive program and are not currently defined in the Medicaid regulations. Consequently, we propose to define these terms in § 495.302.

As specified under section 1903(t)(2)(B) of the Act, to qualify for incentive payments acute care hospitals also must meet patient volume threshold requirements, as specified in proposed § 495.306. Children's hospitals do not have patient volume requirements for Medicaid incentive program participation.

(1) Acute Care Hospitals

"Acute care" is defined as the necessary treatment of a disease or injury for only a short period of time in which a patient is treated for a brief but severe episode of illness.[1] Many hospitals can be considered acute care facilities if they provide both inpatient and outpatient services with the goal of discharging the patient as soon as the patient is deemed stable, with appropriate discharge instructions. We are proposing that for purposes of Medicaid incentive payments, an "acute care hospital" is defined as: A health care facility where the average length of patient stay is 25 days or fewer. For purposes of participation in the Medicaid EHR incentive program, this proposed definition ensures that hospitals are designated as acute care hospitals based on the level and nature of care they provide. This definition also includes some specialty hospitals where the average length of stay is 25 days or fewer. This definition of acute care hospitals will exclude specialty providers and long-term care facilities where the average patients' length of stay exceeds 25 days. To further refine the definition, we reviewed the Medicare-issued CCN. CCNs are issued to categories of providers who meet Federal requirements (known as conditions of participation) to participate in the Medicare program. State Medicaid agencies look to Medicare's conditions of participation when deciding whether to issue provider agreements to many categories of providers. In the case of inpatient hospital services § 440.10(a)(3)(iii) requires that for inpatient hospital services provided to Medicaid beneficiaries to be eligible for FFP, those services must be provided in an institution that meets the requirements for participation in Medicare as a hospital, and such hospitals receive CCNs.

Hospital CCNs are structured such that the first two digits represent the State in which the hospital is located, and the next four digits identify the type of facility and are assigned sequentially from the appropriate block of numbers. Short-stay general hospitals receive CCNs whose number range is 0001 through 0879. The 11 cancer hospitals in the United States also are issued CCNs within that number range. To allow some flexibility for hospital participation in the Medicaid EHR incentive program, we are proposing to define acute care hospitals for purposes of this Medicaid EHR incentive program as those with an average patient length of stay of 25 days or fewer and with a CCN that has the last four digits in the series 0001 through 0879 (that is, short-term general hospitals and the 11 cancer hospitals in the United States).

We also recognize a category of long-term care hospitals, which we are planning to exclude from the definition. Long term acute care hospitals are defined for Medicare purposes in regulations at 42 CFR 412.23(e). Specifically § 412.23(e)(2)(i) states that the hospital must have an average Medicare inpatient length of stay of greater than 25 days (which includes all covered and non-covered days of stay of Medicare patients).

We considered allowing both short-term and long-term acute care hospitals to meet the definition of acute care hospital for purposes of the Medicaid incentive payments. However, we are not proposing a definition that encompasses both types of acute care hospitals because CMS' interpretation was that long-term acute care hospitals did not satisfy the intent of the statute, which we believe intends to include general acute care hospitals. In addition, CMS knew of at least one State that does not recognize long-term acute care hospitals as a Medicaid provider type. We therefore drew the line at 25 days, the cut-off between short-term general and specialty hospitals and long-term acute care hospitals. We used this cut-off in conjunction with the list of CMS CCNs (which also distinguish between short-term and long-term hospitals (see CMS State Operations Manual Section 2779A1, as revised on April 20, 2007 and effective on October 1, 2007) in order to be as inclusive as possible within statute. Since Congress specifically singled out children's hospitals in addition to acute care hospitals, we believe that if Congress intended to include long-term care hospitals, it would have similarly given them separate mention. In addition, Congress specifically did not include nursing facilities, another category of long-term care provider (and an important source of Medicaid care) as a provider type eligible for incentive payments. CMS read this as further evidence that the statute did not intend inclusion of long-term care facilities.

(2) Children's Hospitals

The statute also does not include a definition for "children's hospitals." To assist with the development of a definition of "children's hospitals" for purposes of the Medicaid EHR incentive program, we convened teleconferences with States to gather input on topics

[1] State of Connecticut, Office of Health Care Access, "The Health of Connecticut's Hospitals," report released January 16, 2001, page 17.

that should be defined in this proposed rule. Participants noted that one critical issue is whether a children's wing of a general hospital could be considered a children's hospital for purposes of qualifying for a Medicaid incentive payment.

As with the acute care hospital definition, we again looked to Medicare-issued CCNs and recognized that numbers whose last four digits are in the 3300 to 3399 series are assigned to children's hospitals. Currently in the United States there are 78 certified children's hospitals, including both freestanding and hospital-within-hospital facilities.

For purposes of the Medicaid EHR incentive program, we propose one definition to include only separately certified children's hospitals, with CCNs in the 3300–3399 series in the definition of eligible "children's hospital." By proposing to define "children's hospital" in this way, CMS would (1) prevent general acute care hospitals, which cannot themselves qualify for the incentive because they do not meet the 10 percent Medicaid patient volume, from using the fact that they have a pediatric wing as justification for requesting a Medicaid incentive payment; (2) exclude many of the facilities that are perceived by the public as children's hospitals, but do not meet the Medicare standards as either freestanding or hospital-within-hospital children's hospitals; and (3) exclude some pediatric specialty hospitals which have CCNs as psychiatric or rehabilitation hospitals.

An alternative proposed definition of a "children's hospital" would include those hospitals with Medicare provider numbers in the following series:

- 0001 through 0879—Short-term (General and Specialty) Hospitals.
- 3025 through 3099—Rehabilitation Hospitals (Excluded from Prospective Payment Systems).
- 3300 through 3399—Children's Hospitals (Excluded from Prospective Payment Systems).
- 4000 through 4499—Psychiatric Hospitals (Excluded from Prospective Payment Systems).

This definition, for the purposes of the Medicaid HIT Incentive payments, would apply only to those freestanding hospitals within the above mentioned series that exclusively furnish services to individuals under age 21.

This broader definition would (1) still prevent acute care hospitals that cannot independently qualify for the incentive because they do not meet the 10 percent Medicaid patient volume from using the fact that they have a pediatric wing as justification for requesting an HIT incentive payment; (2) allow for participation in the incentive program by the greatest number of children's hospitals, including rehabilitative and psychiatric specialty hospitals; and (3) align with Federal efforts aimed at improving healthcare quality for all children, including those with physical and mental diseases/disabilities.

We are soliciting comment on the proposed definitions of "children's hospital" as it applies to the Medicaid EHR incentive program recognizing that there may be additional alternative definitions that could have a positive impact on the health care received by children.

c. Medicaid Professionals Program Eligibility

For Medicaid EPs, the general rule (subject to the two exceptions listed below) is that the EP must have at least 30 percent patient volume attributable to those who are receiving Medicaid. Section 1903(t)(2)(A)(i) of the Act provides authority to the Secretary to establish the methodology by which such patient volume will be estimated. We propose that to establish such patient volume, the EP must have a minimum of 30 percent of all patient encounters attributable to Medicaid over any continuous 90-day period within the most recent calendar year prior to reporting. There are two exceptions to the general 30 percent rule discussed previously. The first exception is that a pediatrician may have at least 20 percent patient volume attributable to those who are receiving health care services under the Medicaid program, as estimated in accordance with a methodology established by the Secretary (section 1903(t)(2)(A)(ii) of the Act). Again, the method we propose to use is that the pediatrician must have a minimum 20 percent of all patient encounters attributable to Medicaid over any continuous 90-day period within the most recent calendar year prior to reporting.

The second exception is that Medicaid EPs practicing predominantly in an FQHC or RHC must have a minimum of 30 percent patient volume attributable to "needy individuals." Again, the method we propose to use is that 30 percent of all patient encounters be attributable to needy individuals over any continuous 90-day period within the most recent calendar year prior to reporting.

Section 1903(t)(3)(F) of the Act defines needy individuals as individuals meeting any of the following three criteria: (1) They are receiving medical assistance from Medicaid or the Children's Health Insurance Program (CHIP); (2) they are furnished uncompensated care by the provider; or (3) they are furnished services at either no cost or reduced cost based on a sliding scale determined by the individual's ability to pay. An explanation of how we propose to apply each of these criteria is described in detail in this section of the proposed rule.

We propose this flexible patient volume methodology in order to capture the highest number of true Medicaid practitioners potentially eligible for the EHR incentive program. We believe Congress set the high patient volume thresholds in order to offer these incentives to the practitioners whose practices are open and accessible to Medicaid beneficiaries. We noted that many Medicaid eligible individuals, such as children, may seek care at specified times of the year, such as the beginning of the school-year for required immunizations. Since there are five different types of providers, varying from specialty to primary care, we thought the flexibility would capture any seasonal encounter adjustments in the year, while still honoring Congress' intent to reward higher-volume Medicaid practitioners.

d. Calculating Patient Volume Requirements

As required by section 1903(t)(2) of the Act and discussed in the previous section, all EPs and the vast majority of hospitals will need to meet certain patient volume thresholds in order to be eligible for incentive payments. (The only exception to this rule is for children's hospitals, which have no patient volume threshold requirement).

In addition, where patient volume is a criterion, most providers will be evaluated according to their "Medicaid" patient volume, while some professionals (those practicing predominantly in an FQHC or RHC) will be evaluated according to their "needy individual" patient volume.

We propose to define "patient volume" in § 495.302 to be a minimum participation threshold for each individual Medicaid provider (with the exception of children's hospitals).

For the Medicaid patient volume, this threshold (represented below) is calculated using as the numerator the individual hospital's or EP's total number of Medicaid patient encounters in any representative continuous 90-day period in the preceding calendar year and the denominator is all patient encounters for the same individual professional or hospital over the same 90-day period. We are not prescribing standards for what is a "representative"

period, but we intend to apply a plain meaning test. In other words, if a reasonable person would not consider the selected period to be representative (for example, because the selected period included a short-term temporary Medicaid outreach program), then it would not support a threshold calculation.

[Total (Medicaid) patient encounters in any 90-day period in the preceding calendar year/Total patient encounters in that same 90-day period] * 100

For the needy individual patient volume, the threshold (represented below) is calculated in the same manner, but with the numerator equal to the EP's total number of needy individual patient encounters in any representative 90-day period in the preceding calendar year.

[Total (Needy Individuals) patient encounters in any continuous 90-day period in the preceding calendar year/Total patient encounters in that same 90-day period] * 100

Medicaid EPs and eligible hospitals would be required to annually re-attest to patient volume thresholds to continue to qualify for Medicaid incentive payments. Table 26 demonstrates the above-referenced patient volume thresholds per provider type.

TABLE 26—QUALIFYING PATIENT VOLUME THRESHOLD FOR MEDICAID EHR INCENTIVE PROGRAM

Entity	Minimum 90-day Medicaid patient volume threshold (percent)	
Physicians	30	Or the Medicaid EP practices predominantly in an FQHC or RHC—30% "needy individual" patient volume threshold.
Pediatricians	20	
Dentists	30	
Certified nurse midwives	30	
Physician Assistants when practicing at an FQHC/RHC led by a physician assistant.	30	
Nurse Practitioner	30	
Acute care hospital	10	
Children's hospital		

If a State has an alternative approach to the established timeframe for measuring patient volume, it may propose it to us for review through the State Medicaid HIT Plan (SMHP) (discussed later) and we would make a determination of whether it is an acceptable alternative. To be considered for approval, the alternative approach would require a verifiable data source and justification. In defining the way in which patient volume is established, we provide for a consistent methodology per the statute, but also allow for the possibility that States may propose acceptable alternatives that synchronize with existing data sources, which could decrease State data burdens. This alternative approach must provide an auditable record (that is, a record of how the professional demonstrated patient volume) for CMS to monitor the States' oversight of the Medicaid EHR incentive program implementation.

In determining the "needy individual" patient volume threshold that applies to EPs practicing predominantly in FQHCs or RHCs, section 1902(t)(2) of the Act authorizes the Secretary to make a downward adjustment to the uncompensated care figure to eliminate bad debt data. We interpret bad debt to be consistent with the Medicare definition, as specified at § 413.89(b)(1). Under Medicare, bad debts are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services. "Accounts receivable" and "notes receivable" are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future. Providers should be required to use cost reports (for FQHCs and clinics this would be the Medicare 222–92 cost report, or the most recent version of the 222), or other auditable records to identify bad debts. All information under attestation is subject to audit. Our proposed regulations on calculating the needy individual patient volume can be found at § 495.302 and § 495.306.

Further, in establishing the Medicaid patient volume thresholds for EPs and acute care hospitals, section 1902(t)(2) of the Act requires that individuals enrolled in Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), or prepaid ambulatory health plans (PAHPs), under 42 CFR Part 438 be included in the calculation. Therefore, in determining patient volume, providers and States should be aware that individuals enrolled in such plans will be included in the patient volume calculation. Acute care hospitals have to meet the 10 percent Medicaid volume threshold.

We also note that although § 438.60 of our regulations would generally prohibit a State from making a direct payment to a provider for services that are included under a contract with an MCO, PIHP, or PAHP, providers contracted with these managed care plans will nevertheless be eligible for Medicaid EHR incentive payments because those payments are not for services that are included in such a contract. The fact that Congress directed that individuals enrolled in managed care be included in the patient volume calculation demonstrates an intent to allow qualified providers to receive incentive payments, whether they provided their services through capitated care arrangements or fee-for-service. Over 70 percent of Medicaid beneficiaries receive care in a managed care delivery system, and we do not believe that the intent of Congress in creating the incentives program was to remove the providers treating these individuals from the incentives program.

e. Entities Promoting the Adoption of Certified EHR Technology

We are proposing to define "promoting the adoption of certified EHR technology" in § 495.302. Under section 1903(t)(6)(A)(i), incentive payments must generally be made directly to the EP. Section 1903(t)(6)(A)(ii) of the Act provides an exception to permit payment of incentive payments to "entities promoting the adoption of certified EHR technology," as designated by the State, if participation in the payment arrangement is voluntary for the EP involved. Additionally, the entity must not retain more than 5 percent of the payment for costs unrelated to certified

EHR technology (and support services including maintenance and training) that is for, or is necessary for, the operation of the technology. While the Act authorizes States to designate these entities, the Secretary nevertheless retains authority to define what it means to be "promoting the adoption of certified EHR technology," as specified in section 1903(t)(6)(A)(ii) of the Act. Section 1102 of the Act authorizes the Secretary to "make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which he or she is charged under this Act." Since one of our functions is to approve Title XIX plans under sections 1902(b) and 1116 of the Act, and States would need to submit plans as to how they would spend section 4201 of the HITECH Act funds, we have the authority to determine whether a State's plan for allowing EPs to assign their Medicaid incentive payments to these entities is in compliance with our interpretation of the Act.

We propose to define "promoting" certified EHR adoption to mean the enabling and oversight of the business, operational and legal issues involved in the adoption and implementation of EHR and/or exchange and use of electronic health information between participating providers, in a secure manner, including maintaining the physical and organizational relationship integral to the adoption of certified EHR technology by EPs. For example, health information exchanges have the potential to transform the healthcare system by facilitating timely, accurate, and portable health information on each patient at the point of service. Health Information Exchanges (HIEs), are one type of entity that we believe would meet the definition of an entity that is promoting the adoption of certified EHR technology. HIEs provide the capability to move clinical information electronically between disparate health care information systems while maintaining the meaning of the information being exchanged. HIEs also provide the infrastructure for secondary use of clinical data for purposes such as public health, clinical, biomedical, and consumer health informatics research as well as institution and provider quality assessment and improvement, where permissible under HIPAA and other requirements included in the HITECH Act. In addition, use of health information exchange models can reduce the need for costly point-to-point interfaces between different EHR tools, as used in laboratories and pharmacies, thus providing a more scalable model of interoperable health information exchange. HIEs promote adoption of certified EHR technology by providing the infrastructure for providers' EHRs to reach outside of their clinical practice sites and connect with other points of care. Providers report that having a more complete picture of their patients' healthcare data from other providers and care settings is one of the primary appeals to using EHRs. Without health information exchange, electronic health records are simply digitized filing cabinets and will not achieve their quality of care or cost containment potential. Furthermore, given the proposed definition of meaningful use, HIEs can significantly help Medicaid providers adopt and use EHR in such a way that the goals of the incentive program are met. The inclusion in HITECH of HIE grants to be awarded to States or State-designated Entities by ONC are an additional indication of the symbiotic relationship between health information exchanges and optimal use of EHRs.

Under 1903(t)(6)(A)(ii) of the Act and as proposed in § 495.354, States must establish verification procedures that enable Medicaid EPs to voluntarily assign payments to entities promoting EHR technology. States must guarantee that the assignment is voluntary and that the entity does not retain more than 5 percent of those assigned Medicaid incentive payments for costs unrelated to certified EHR technology. We propose requiring States to publish and make available to all Medicaid EPs the procedures they developed for assigning incentive payments to the third party entities before payments can be assigned. Such publication must also include information about the State's verification mechanism. The State's method must assure compliance with the requirement that no more than 5 percent of the Medicaid EP's annual incentive payment is retained by the entity for costs not related to certified EHR technology.

Although section 1903(t)(6)(A)(ii) of the Act allows assignment of payment to entities promoting the adoption of EHR technology, we wish to clarify that such assignment would not remove the responsibility of the Medicaid EP to individually demonstrate meaningful use of the EHR technology (as discussed in greater detail below). Therefore, entities promoting the adoption would not receive the assigned payments unless the Medicaid EP meets all eligibility criteria. Our proposed definition for promoting the adoption of certified EHR technology is in § 495.302.

4. Computation of Amount Payable to Qualifying Medicaid EPs and Eligible Hospitals

The statute, at sections 1903(t)(1), (t)(4), and (t)(5) of the Act, creates different payment formulas for Medicaid EPs versus hospitals. The payment methodology for Medicaid hospitals shares many aspects of the methodology used for Medicare hospitals.

a. Payment Methodology for EPs

(1) General Overview

Pursuant to section 1903(t)(1)(A) of the Act, payment for EPs equals 85 percent of "net average allowable costs." While the Secretary is directed to determine "average allowable costs" based upon studies of the average costs of both purchasing and using EHR technology, the net average allowable costs that set payment are capped by statute. As discussed in more detail further on, generally stated, these caps equal $25,000 in the first year, and $10,000 for each of 5 subsequent years (there is an exception for pediatricians with under 30 percent Medicaid patient volume, whose caps are two-thirds of these amounts). Thus, the maximum incentive payment an EP could receive from Medicaid equals 85 percent of $75,000, or $63,750, over a period of 6 years. EPs must begin receiving incentive payments no later than CY 2016.

(2) Average Allowable Costs

Section 1903(t)(4)(C) of the Act gives the Secretary the authority to determine average allowable costs. Specifically, the Secretary is directed to study the average costs associated with the purchase, initial implementation, and upgrade of certified EHR technology, including support services, and integral related training. The Secretary also is directed to study the average costs of operating, maintaining, and using certified EHR technology. The statute permits the Secretary to use studies submitted by the States.

We conducted a literature review of recent studies on EHR technology to determine the average allowable cost of implementing and using such technology. We reviewed the results from four recent, comprehensive studies. Specifically, HHS' Office of the Assistant Secretary for Planning and Evaluation commissioned a study by Moshman Associates, Inc., Booz Allen Hamilton, in September 2006—Assessing the Economics of EMR Adoption and Successful Implementation in Physical Small Practice Settings. In this study, EHRs

consisted of a core group of functions that, in various permutations, are often associated with an electronic medical record and frequently include the capacity to: Capture and display clinical notes, display laboratory results, display diagnostic imaging results or reports, order drugs or diagnostic tests, and generate reports.[2]

The study found that EHR adoption is influenced by a variety of factors, including hardware costs, software costs, the costs of implementation and training, and costs associated with productivity that occur in the early stages of implementation. While there are challenges in making cost comparisons across different studies and across different functionalities (that is, EMRs versus EHRs), the costs per physician ranged between $33,000 and $50,000.[3]

In reviewing Market Watch, The Value of Electronic Health Records in Community Health Centers: Policy Implications by Robert H. Miller and Christopher E. West, the cost and benefits of electronic health records is reported in six community health centers (CHCs) that serve disadvantaged patients.[4] Robert Miller and Christopher West report that initial EHR costs per full-time-equivalent (FTE) billing provider averaged almost $54,000, with much variation across CHCs and within each cost category, including hardware, software, installation, training, etc. and ongoing costs per FTE provider, per year, averaged $20,610.[5]

A Congressional Budget Office (CBO) Paper: Evidence on the Costs and Benefits of Health Information Technology from May 2008 indicates that estimating the total cost of implementing HIT systems in office-based medical practices is complicated by differences in the types and available features of the systems now being sold, as well as differences in characteristics of the practices that adopt them. The CBO paper goes further to say that few detailed studies available report that total costs for office-based EHRs are about $25,000—$45,000 per physician[6] and estimates for annual costs for operating and maintaining the system, which include software licensing fees, technical support, and updating and replacing used equipment range between $3,000 to $9,000 per physician per year.[7]

An article written by the Agency for Healthcare Research and Quality (AHRQ), Research Activities, September 2005, Health Information Technology, adoption rates of electronic health records are low among physician groups—indicates that the average purchase and implementation cost of an EHR was $32,606 per FTE physician. The article indicates that maintenance costs were an additional $1,500 per physician, per month and smaller practices had the highest implementation costs per physician at $37,204.[8]

In conducting a review of the data, we determined that the studies demonstrate a cross-sectional view of small and large practices and community health centers. There was adequate data to support a depiction of costs across multiple provider types.

To summarize, we determined that the average costs of EHRs vary greatly because of the size and type of provider practices, the differences in available features of systems, and the additional costs associated with licensing, support, training, and maintenance. However, based on the information reviewed, we determined that the average costs for initial EHR systems currently can range from $25,000 to $54,000 in the implementation year, per professional. Since the average costs of EHR technology in the first year can be as much as $54,000 and no less than $25,000, and since we believe the costs of such technology will be increasing, we are proposing to set the average allowable cost at $54,000. We believe that to establish this average allowable cost at the high end of the range is reasonable since the data we reviewed is based on certification standards that may not be appropriate moving forward. Specifically, since the ONC will be establishing new certification standards for EHR technology in the coming months, we believe the average cost of certified EHR technology incorporating the new standards will be higher than the current costs of EHR technology. It is our assumption that making improvements to incorporate the new certification standards into current EHR technology will be costly. Thus, we believe that establishing the average allowable cost at $54,000 is reasonable.

Additionally, our analysis determined that the range for subsequent incentive payment year costs for most providers will fall into a large range, based on a number of factors. On one end of the range, costs related to maintenance could be as low as $3,000 to $9,000 per provider, where other studies state that maintenance will be as high as $18,000 to $20,610 per provider. Given the expectations in the ONC interim final rule for system performance, interoperability, and the health measures data discussed in this proposed rule that CMS and the States will need to collect from professionals, we believe that the costs for maintaining certified EHR technology will also be on the higher end of the range at $20,610.

(3) Net Average Allowable Costs

As required by section 1903(t)(3)(E) of the Act, in order to determine "net" average allowable costs, average allowable costs for each provider must be adjusted in order to subtract any payment that is made to Medicaid EPs and is directly attributable to payment for certified EHR technology or support services of such technology. The only exception to this requirement is that payments from State or local governments do not reduce the average allowable costs. The resulting figure is the "net" average allowable cost; that is, average allowable cost minus payments from other sources (other than State or local governments). The statute indicates that EPs may receive 85 percent of a maximum net average allowable cost in the first year of $25,000 and a maximum net average allowable cost of $10,000 in subsequent years. This would mean that, as required by the statute, the net average allowable costs are capped at these amounts.

Since we have proposed that the average allowable cost is $54,000 in the first year, EPs could receive as much as $29,000 in funding from sources (other than from State or local governments) as contributions to the certified EHR technology and the incentive payment would still be based on 85 percent of the maximum net average allowable cost of $25,000 (or $21,250). This is appropriate since $54,000 (the average allowable cost) minus $29,000 (contributing sources of funding from other than State or local governments) equals $25,000.

[2] Moshman Associates, Inc., Booz Allen Hamilton, in September 2006—Assessing the Economics of EMR Adoption and Successful Implementation in Physical Small Practice Settings, p. 40.

[3] Moshman Associates Inc., Booz, Allen, Hamilton, p. 50.

[4] Market Watch, The Value of Electronic Health Records in Community Health Centers: Policy Implications by Robert H. Miller and Christopher E. West, p. 206.

[5] Market Watch, The Value of Electronic Health Records in Community Health Centers: Policy Implications by Robert H. Miller and Christopher E. West, p. 208.

[6] A CBO Paper, Evidence on the Costs and Benefits of Health Information Technology, May 2008, p. 17.

[7] A CBO Paper, Evidence on the Costs and Benefits of Health Information Technology, May 2008, p. 18.

[8] Agency for Healthcare Research and Quality, Research Activities, September 2005, Health Information Technology, Adoption rates of electronic health records are low among physician groups.

Since $25,000 is equal to the level of the maximum net average allowable cost or capped amount discussed above, providers could receive 85 percent of $25,000 or $21,250 in year one as a Medicaid incentive payment.

The same logic would hold true for subsequent years. Specifically, if in the following years an eligible professional received as much as $10,610 in contributing funds from sources other than State or local governments, the maximum incentive payment of $8,500 would be unaffected in such subsequent years. This result is due to the fact that the average allowable costs of $20,610 for maintaining EHR technology minus the $10,610 received would still equal $10,000, the maximum net average allowable costs permitted under the statute.

In reviewing whether a reduction in the net average allowable cost was warranted based on other contributions to EHR technology, we considered the situation of EPs who may have been provided with the actual certified EHR technology, as well as training, support services, and other services that would promote the implementation and meaningful use of such technology. In some cases, we do not believe the contribution would reduce average allowable costs at all. For example, if an FQHC or RHC has provided technology to its staff EPs to use, we do not believe that such technology provision would be considered a "payment" from another source that would reduce average allowable costs. Moreover, we believe the situations in which an EP has been provided with the actual technology, support service, or training from another source are extremely limited in light of the statutory prohibitions on "kickbacks" at Section 1128B(b) of the Act.

(4) Payments for Medicaid Eligible Professionals

One important difference we propose between the payments to Medicaid EPs and hospitals is that States would disburse the payments to EPs in alignment with the calendar year, whereas hospitals will receive payments in alignment with the fiscal year, as described in section II.D.4.b. of this proposed rule. There are two primary reasons for this. The first is to align Medicaid incentive payment disbursements with that of the Medicare program, in order to support consistency between the two programs, as well as among the States. We will undertake national outreach activities to encourage provider EHR adoption and to align the annual payment periods. Since meaningful use of the certified EHR technology is the driver of the incentives, we believe that a cooperative approach between CMS, ONC, and the States would be realized with more providers participating in the program.

As previously discussed in this proposed rule, based on the 85 percent threshold applied to the net average allowable costs, we propose that most Medicaid EPs may receive up to a maximum incentive payment of $21,250 in the first payment year.

In subsequent years of payment, Medicaid EPs' incentive payments will be limited to 85 percent of the $10,000 cap on net average allowable cost, or up to a maximum of $8,500 annually for most Medicaid EPs.

Since pediatricians are qualified to participate in the Medicaid EHR incentive program as physicians, and therefore classified as Medicaid EPs, they may qualify to receive the full incentive (that is, the 85 percent threshold applied to the net average allowable cost) if the pediatrician is not hospital-based and can demonstrate that they meet the minimum 30 percent Medicaid patient volume requirements discussed in this subpart.

Pediatricians who are not hospital-based, and have a minimum of 20 percent of their patient encounters paid by Medicaid are also encouraged to participate in the Medicaid EHR incentive program. The maximum payment amount for these pediatricians, who meet the 20 percent Medicaid patient volume, but fall short of the 30 percent patient volume, is reduced to two-thirds of the net average allowable cost, subject to the 85 percent threshold. The reduction accounts for the reduced patient volume, but the intent is to offer an incentive to attract pediatricians to participate. This means pediatricians with a minimum 20 percent patient volume may qualify for up to a maximum of $14,167 in the first incentive payment year and up to a maximum of $5,667 in the 5 subsequent incentive payment years, or no more than $42,500 over the maximum 6 year period.

Table 27 demonstrates the various maximum incentive payment amounts for Medicaid professionals.

TABLE 27—MAXIMUM INCENTIVE PAYMENT AMOUNT FOR MEDICAID PROFESSIONALS

Cap on net average allowable costs, per the HITECH Act	85 percent allowed for eligible professionals	Maximum cumulative incentive over 6-year period
$25,000 in Year 1 for most professionals	$21,250	
$10,000 in Years 2–6 for most professionals	8,500	$63,750
$16,667 in Year 1 for pediatricians with a minimum 20 percent patient volume, but less than 30 percent patient volume, Medicaid patients	14,167	
$6,667 in Years 2–6 for pediatricians with a minimum 20 percent patient volume, but less than 30 percent patient volume, Medicaid patients	5,667	42,500

(5) Basis for Medicaid EHR Incentive Program First Payment Year and Subsequent Payment Years

(i) Medicaid EP Who Begins Adopting, Implementing or Upgrading Certified EHR Technology in the First Year

A Medicaid EP who begins by adopting, implementing, or upgrading certified EHR technology in the first year will be eligible for the incentive payments not in excess of the maximum amount. Under section 1903(t)(4) of the Act he or she is eligible to receive up to the maximum first year Medicaid incentive payments discussed in the previous sections, plus additional incentive payments for up to 5 years for demonstrating meaningful use of certified EHR technology. In other words, these providers may participate in the Medicaid EHR incentive program for up to 6 years.

Table 28 demonstrates the payment scenarios available to a Medicaid EP who begins in their first year by adopting, implementing, or upgrading certified EHR technology. As can be seen from the table, the EP can begin receiving payments as late as 2016, and still receive up to the maximum payments under the program.

TABLE 28—PAYMENT SCENARIOS FOR MEDICAID EPS WHO BEGIN ADOPTION IN THE FIRST YEAR

Calendar year	Medicaid EPs who begin adoption in					
	2011	2012	2013	2014	2015	2016
2011	$21,250					
2012	8,500	$21,250				
2013	8,500	8,500	$21,250			
2014	8,500	8,500	8,500	$21,250		
2015	8,500	8,500	8,500	8,500	$21,250	
2016	8,500	8,500	8,500	8,500	8,500	$21,250
2017		8,500	8,500	8,500	8,500	8,500
2018			8,500	8,500	8,500	8,500
2019				8,500	8,500	8,500
2020					8,500	8,500
2021						8,500
Total	63,750	63,750	63,750	63,750	63,750	63,750

(ii) Medicaid EP Who Has Already Adopted, Implemented or Upgraded Certified EHR Technology and Meaningfully Uses EHR Technology

For a Medicaid EP who has already adopted, implemented, or upgraded certified EHR technology and can meaningfully use this technology in the first incentive payment year, we propose that the Medicaid EP be permitted to receive the same maximum payments, for the same period of time, as the Medicaid EP who merely adopted, implemented or upgraded certified EHR technology in the first year. Section 1903(t)(6)(C)(ii) of the Act states that for a Medicaid EP or hospital who has completed "adopting, implementing, or upgrading" certified EHR technology "prior to the first year of payment. * * * clause (i)(I) shall not apply and clause (i)(II) [discussing the demonstration of meaningful use] shall apply to each year of payment to the Medicaid provider under this subsection, including the first year of payment." We believe this provision supports an interpretation that a Medicaid EP who has already adopted certified EHR technology, would still receive a "first year" of payment under section 1903(t)(4) of the Act, and like all other first years of payment, this payment could not exceed $21,250. Then, under section 1903(t)(4)(A)(ii) and (iii) of the Act, such Medicaid EPs could receive an additional 5 years of payment for subsequent years of payment, with payments not exceeding $8,500 in each of these 5 subsequent years. This approach allows early adopters of certified EHR to begin meaningfully using technology, without being at a competitive disadvantage, and without losing incentive payments for the previous costs associated with adopting, implementing, or upgrading certified EHR technology.

Thus, the maximum incentive payments for Medicaid EPs demonstrating that they are meaningful users in the first payment year, would be identical to the maximum payments available to those demonstrating adoption, implementation, or upgrading certified EHR technology in the first year, as depicted in Table 29.

TABLE 29—MAXIMUM INCENTIVE PAYMENTS FOR MEDICAID EPS WHO ARE MEANINGFUL USERS IN THE FIRST PAYMENT YEAR

Calendar year	Medicaid EPs who begin meaningful use of certified EHR technology in					
	2011	2012	2013	2014	2015	2016
2011	$21,250					
2012	8,500	$21,250				
2013	8,500	8,500	$21,250			
2014	8,500	8,500	8,500	$21,250		
2015	8,500	8,500	8,500	8,500	$21,250	
2016	8,500	8,500	8,500	8,500	8,500	$21,250
2017		8,500	8,500	8,500	8,500	8,500
2018			8,500	8,500	8,500	8,500
2019				8,500	8,500	8,500
2020					8,500	8,500
2021						8,500
Total	63,750	63,750	63,750	63,750	63,750	63,750

An alternative approach we request comment on would be to limit the incentive payment for Medicaid EPs who have already adopted, implemented, or upgraded certified EHR technology to 5 years of payment, at a maximum payment of $8,500 per year. This approach would interpret section 1903(t)(4)(A) of the Act, which states that the $25,000 cap on net average allowable costs is intended to cover the costs of implementing or adopting certified EHR technology, as limiting the $21,250 payment only to those actually adopting the technology in their first year of payment. While early adopters would still be eligible to receive incentive payments, the payment totals would be lower, because such adopters would not need an incentive payment in order to actually implement, adopt, or upgrade certified EHR technology. This alternative approach is depicted in Table 30.

TABLE 30—ALTERNATIVE INCENTIVE PAYMENT SCENARIO FOR MEDICAID EPS WHO HAVE ADOPTED EHR TECHNOLOGY BEFORE THE FIRST YEAR

Calendar year	Medicaid EPs who begin meaningful use in					
	2011	2012	2013	2014	2015	2016
2011	$8,500					
2012	8,500	$8,500				
2013	8,500	8,500	$8,500			
2014	8,500	8,500	8,500	$8,500		
2015	8,500	8,500	8,500	8,500	$8,500	
2016		8,500	8,500	8,500	8,500	$8,500
2017			8,500	8,500	8,500	8,500
2018				8,500	8,500	8,500
2019					8,500	8,500
2020						8,500
2021						
Total	42,500	42,500	42,500	42,500	42,500	42,500

Medicaid EPs are not required to participate on a consecutive annual basis. The tables in this section demonstrate how a Medicaid EP would maximize the aggregate incentive under different scenarios, considering that a Medicaid EP may initiate participation in 2011 through 2016. Additionally, these tables do not include the alternative Medicaid maximum incentive payment for pediatricians discussed in the previous section, which is two-thirds of the total amount listed in Tables 27 through 30. Finally, these tables do not represent EPs whose incentive payments may be reduced because net average allowable costs may actually be lower than $25,000 in the first year, or $10,000 in subsequent years, due to payments from other, non-State/local sources.

b. Payment Methodology for Eligible Hospitals

Statutory parameters placed on Medicaid incentive payments to hospitals are largely based on the methodology applied to Medicare incentive payments. The specifications described in this section are limits to which States must adhere when developing aggregate EHR hospital incentive amounts for Medicaid-eligible hospitals. States will calculate hospitals' aggregate EHR hospital incentive amounts on the FFY to align with hospitals participating in the Medicare EHR incentive program.

States may pay children's hospitals and acute care hospitals up to 100 percent of an aggregate EHR hospital incentive amount provided over a minimum of a 3-year period and a maximum of a 6-year period. The maximum incentive amounts for these providers are statutorily defined by a formula at section 1903(t)(5)(B) of the Act. The statute requires that Medicaid refer, with some adjustments, to the calculation for the Medicare hospital incentive payment described at sections 1886(n)(2)(A), 1886(n)(2)(C), and 1886(n)(2)(D) of the Act, to determine the aggregate EHR amount allowable for individual hospitals. The aggregate EHR hospital incentive amount is calculated using an overall EHR amount multiplied by the Medicaid share. The aggregate EHR hospital incentive amount is the total amount the hospital could receive in Medicaid payments over 4 years of the program.

States are responsible for using auditable data sources to calculate Medicaid EPs' aggregate EHR hospital incentive amounts, as well as determining Medicaid incentive payments to those providers. Auditable data sources include—

- Providers' Medicare cost reports;
- State-specific Medicaid cost reports;
- Payment and utilization information from the State's MMIS (or other automated claims processing systems or information retrieval systems); and
- Hospital financial statements and hospital accounting records.

All State Medicaid EHR incentive program calculations, payments, and limits under this section are subject to our review.

For purposes of the Medicaid EHR incentive program, the overall EHR amount is equal to the sum over 4 years of (I)(a) the base amount (defined by statute as $2,000,000); plus (b) the discharge related amount defined as $200 for the 1,150th through the 23,000th discharge for the first payment year (for subsequent payments years, States must assume discharges increase by the provider's average annual rate of growth for the most recent 3 years for which data are available per year): multiplied by (II) the transition factor for each year equals 1 in year 1, ¾ in year 2, ½ in year 3, and ¼ in year 4.

The statute specifies that the payment year is determined based on a Federal fiscal year. Section 1886(n)(2)(C) of the Act provides the Secretary with authority to determine the discharge related amount on the basis of discharge data from a relevant hospital cost reporting period, for use in determining the incentive payment during a Federal fiscal year. Federal fiscal years begin on October 1 of each calendar year, and end on September 30 of the subsequent calendar year. Hospital cost reporting periods can begin with any month of a calendar year, and end on the last day of the 12th subsequent month in the next calendar year. For purposes of administrative simplicity and timeliness, we propose that States, for each eligible hospital during each incentive payment year, use data on the hospital discharges from the hospital fiscal year that ends during the Federal fiscal year prior to the fiscal year that serves as the payment year.

Example: FY 2011 begins on October 1, 2010 and ends on September 30, 2011. For an eligible hospital with a cost reporting period running from July 1, 2010 through June 30, 2011, we would employ the relevant data from the hospital's cost reporting period ending June 30, 2010 in order to determine the incentive payment for the hospital during Federal fiscal year 2011. This timeline would allow States to have the relevant data available for determining the aggregate EHR hospital incentive amount in a timely manner for the first and subsequent payment years.

The discharge-related amount is $200 per discharge for discharges 1,150 through 23,000. To determine the discharge-related amount for the 3 subsequent payment years that are included in determining the overall EHR amount, States should assume discharges for an individual hospital have increased by the average annual growth rate for an individual hospital over the most

recent 3 years of available data from an auditable data source. Note that if a hospital's average annual rate of growth is negative over the 3 year period, it should be applied as such.

We have provided a sample calculation for review that assumes the following:

- An individual provider had 20,000 discharges in the first FY (2011).
- The most recent annual growth data available are as follows:
  - ++ FY 2005 (.028 annual growth rate)
  - ++ FY 2006 (.013 annual growth rate)
  - ++ FY 2007 (.027 annual growth rate)

The average annual growth rate over 3 years = (.028 × .013 × .027)/3 = .0227.

Year 1

2011 discharge related amount equals:
(20,000 − 1149) × $200 = $3,770,200

Year 2

2012 discharge related amount equals:
20,000 × 1.0227 = 20,454
(20,454 − 1149) × $200 = $3,861,000

Year 3

2013 discharge related amount equals:
20,454 × 1.0227 = 20,918
(20,918 − 1149) × $200 = $3,953,800

Year 4

2014 discharge related amount equals:
20,918 × 1.0227 = 21,393
(21,393 − 1149) × $200 = $4,048,800

The overall hospital EHR amount requires that a transition factor be applied to each year. This transition factor equals 1 for year 1, ¾ for year 2, ½ for year 3, and ¼ for year 4, as provided for in sections 1886(n)(2)(A) and 1886(n)(2)(E) of the Act, and as incorporated through section 1902(t)(5)(B) of the Act. We note that although, for purposes of the Medicare incentives, section 1886(n)(2)(E)(ii) of the Act requires a transition factor of 0, if the first payment year is after 2013, we do not believe this rule would apply in the context of the Medicaid incentive payments. Nothing in section 1903(t) of the Act specifically cross references this 0 transition factor, and, notably, section 1903(t) of the Act allows Medicaid incentive payments to begin as late as 2016.

The "Medicaid Share," against which the overall EHR amount is multiplied, is essentially the percentage of a hospital's inpatient, non-charity care days that are attributable to Medicaid inpatients. More specifically, the Medicaid share is a fraction expressed as—

- Estimated Medicaid inpatient-bed-days plus estimated Medicaid managed care inpatient-bed-days;
- Divided by;
- Estimated total inpatient-bed days multiplied by ((estimated total charges minus charity care charges) divided by estimated total charges).

As indicated in the above formula, the Medicaid share includes both Medicaid inpatient-bed-days and Medicaid managed care inpatient-bed-days. This is in keeping with section 1903(t)(5)(C) of the Act, which provides that in computing inpatient-bed-days, the Secretary shall take into account inpatient-bed-days that are paid for individuals enrolled in a Medicaid managed care plan under sections 1903(m) or 1932 of the Act. We interpret these managed care individuals to be individuals enrolled in a managed care organization (MCO), prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP) under 42 CFR part 438.

Some Medicaid managed care entities (that is, MCOs, PIHPs, and PAHPs with risk contracts) provide substitute services (or, "in-lieu-of services") in more cost effective or efficient settings than the State plan services in the managed care contract. For example, in a hospital inpatient setting, these services could be in a different unit, such as a subacute wing or skilled nursing wing, so long as States and contracting entities are in compliance with the actuarial soundness rules at 42 CFR 438.6(c), provision of substitute services is allowed. Although we understand that these substitute service days may be used to achieve efficiency and cost effectiveness, we do not believe such substitute service days should count as "inpatient-bed-days" in the hospital EHR incentive payment calculation. The statute requires us to calculate the Medicaid share "in the same manner" as the Medicare share under section 1886(n)(2)(D) of the Act and such substitute service days would not be considered "in the same manner." Thus, we propose that for purposes of the Medicaid formula, we would count only those days that would count as inpatient-bed-days for Medicare purposes under section 1886(n)(2)(D) of the Act.

In addition, because the formula for calculating the Medicaid share requires a determination of charity care charges, States should use the revised Medicare 2552–10, Worksheet S–10 or another auditable data source to determine the charity care portion of the formula. In the absence of sufficient charity care data to complete the calculation, section 1886(n)(2)(D) of the Act, requires the use of uncompensated care data to derive an appropriate estimate of charity care, including a downward adjustment for bad debts. We interpreted bad debt to be consistent with the Medicare definition of bad debt as promulgated at 42 CFR 413.89(b)(1).

Finally, per section 1886(n)(2)(D) of the Act, to the extent there is simply not sufficient data that would allow the State to estimate the inpatient bed-days attributable to Medicaid managed care patients, the statute directs that such figure is deemed to equal 0. Likewise, if there is simply not sufficient data for the State to estimate the percentage of inpatient bed days that are not charity care (that is, [estimated total charges—charity care charges]/estimated total charges), the statute directs that such figure is deemed to equal 1.

The aggregate EHR incentive calculation for Medicaid eligible hospitals is represented mathematically as follows:

(Overall EHR Amount) * (Medicaid Share) or
{Sum over 4 year of [(Base Amount + Discharge Related Amount Applicable for Each Year) * Transition Factor Applicable for Each Year]} *
{(Medicaid inpatient-bed-days + Medicaid managed care inpatient-bed-days)/[(total inpatient-bed days) * (estimated total charges − charity care charges)/(estimated total charges)]}

To achieve the aggregate EHR hospital incentive amount at 1903(t)(5)(a), the calculation must be aggregated over 4 years. For further clarification, we have provided a sample calculation of the aggregate EHR hospital amount.

Assume the following as constant over 4 years except where noted:

- 20,000 discharges (Note: This calculation assumes the same averaging data calculated in the average annual growth example above.)
- 34,000 inpatient Medicaid bed-days (including fee-for-service and managed care days)
- 100,000 total inpatient bed-days
- $1,000,000,000 in total charges
- $200,000,000 in charity care
- Overall EHR amount = Sum (Year 1, Year 2, Year 3, Year 4) = $14,655,050

Year 1: {$2,000,000 + ((20,000 − 1,149) × 200)} × 1 × 1 = $5,770,200
Year 2: {$2,000,000 + ((20,454 − 1,149) × 200)} × 1 × .75 = $4,395,750
Year 3: {$2,000,000 + ((20,918 − 1,149) × 200)} × 1 × .50 = $2,976,900
Year 4: {$2,000,000 + ((21,393 − 1,149) × 200)} × 1 × .25 = $1,512,200
Medicaid Share: 34,000/(100,000 × (($1,000,000,000—$200,000,000)/1,000,000,000) = 0.425
Overall EHR Amount × Medicaid Share = Medicaid aggregate EHR incentive amount $14,655,050 × 0.425 = $6,228,396

Unlike Medicaid EPs, who must waive rights to duplicative Medicare incentive payments, hospitals may receive incentive payments from both Medicare and Medicaid, contingent on successful demonstration of meaningful use and other requirements under both programs.

The last year that a hospital may begin receiving Medicaid incentive payments is FY 2016. States must make payments over a minimum of 3 years and a maximum of 6 years. Additionally, in any given payment year, no annual Medicaid incentive payment to a hospital may exceed 50 percent of the hospital's aggregate incentive payment. Likewise, over a 2-year period, no Medicaid payment to a hospital may exceed 90 percent of the aggregate incentive.

Table 31 demonstrates several scenarios for Medicaid hospitals. However, there are other scenarios not included here. For example, this table assumes that a hospital would participate on a consecutive annual basis until the incentive is exhausted. The purpose of Table 31 is to illustrate the general timeline for Medicaid hospital incentives.

TABLE 31: Hospital Incentives

States will monitor compliance of hospitals coming onto the program with different requirements depending on the year. Incentive determination will also be based on Y1 versus subsequent years. This chart is an example, noting that hospitals may collect the incentive over 3-6 years.								
	CY	**Demonstration of Compliance**						
←←Becomes more difficult to establish meaningful use.	2011	Y1	Y1 participants must demonstrate that they engaged in efforts to adopt, implement, or upgrade to certified EHR technology. However, if users already adopted, they may proceed to Y2 requirements in Y1.					
	2012	Y2	Y1	Y1, same as above. Y2 must become a meaningful EHR user. We expect to issue definition of meaningful use on a biannual basis beginning in 2011.				
	2013	Y3	Y2	Y1	Y1, same as above. Y2-3 will be the same.			
	2014	Y4	Y3	Y2	Y1	Y1, same as above. Y2-4, same as above.		
	2015	Y5	Y4	Y3	Y2	Y1	Y1, same as above. Y2-5, same as above.	
	2016	Y6	Y5	Y4	Y3	Y2	Y1	Y1, same as above. Y2-6, same as above.
	2017		Y6	Y5	Y4	Y3	Y2	
	2018			Y6	Y5	Y4	Y3	
	2019				Y6	Y5	Y4	
	2020					Y6	Y5	
	2021						Y6	

c. Alternative and Optional Early State Implementation to Make Incentive Payments for Adopting, Implementing, or Upgrading Certified EHR Technology

Unlike Medicare, Medicaid has no statutory implementation date for making EHR incentive payments. We believe that some States may be prepared to implement their program and make EHR incentive payments to Medicaid providers in 2010 for adopting, implementing, or upgrading certified EHR technology. We propose to allow States to initiate implementation of these payments to Medicaid EPs and hospitals after promulgation of the final rule if they successfully demonstrate to CMS that they are ready to make timely and accurate payments through the SMHP. States should include an additional attestation for providers assuring that they are not accepting payment in any other State.

In order for us to approve a State for early implementation, we are proposing that a State would have an electronic system for provider registration capable of collecting the relevant information identified in section II.A.5.c of this proposed rule, where we describe the data collection requirements. This includes the following:

- Name, National Provider Identifier (NPI), business address and business phone of each EP or eligible hospital;
- Taxpayer Identification Number to which the EP or eligible hospital wants the incentive payment made;
- For eligible hospitals, their CMS Certification Number (CCN);
- The remittance date and amount of any incentive payments made to an EP or eligible hospital.

Participating States would be responsible for transmitting this data to CMS so that CMS can ensure that no duplicate payments will be made to providers. We would use the single provider election repository described in section II.A.5.c. of this proposed rule to assure no duplicative payments were made between States.

We are not proposing that States would be able to make early payments to meaningful users. This opportunity is intended to offer Medicaid providers an early opportunity for capital so that they are more likely to have the certified EHR

technology required to demonstrate meaningful use in successive periods. Since hospitals may qualify under both programs, we hope that they will use the capital and qualify as a meaningful user under the Medicare program in the first year. We are requesting comments on this proposed approach.

d. Process for Making and Receiving Medicaid Incentive Payments

The process for making payments involves coordination between Medicare and State Medicaid agencies to avoid duplication of payments, prevent fraud and abuse, and create program efficiencies to encourage adoption. While we have responsibility regarding payments to Medicare EPs and hospitals, State Medicaid agencies (or their contractors) are fully responsible for administering and disbursing the incentive payments to Medicaid providers.

We will require that EPs make a selection between receiving incentive payments through either the Medicare or Medicaid EHR incentive programs. Medicaid EPs who practice in multiple states will be required to choose only one state from which to receive Medicaid incentive payments. The issues related to these decisions are discussed here, as well as in section II.A of this proposed rule.

In this section, we describe the steps Medicaid EPs will take to receive an incentive payment. Due to the inter-dependencies of multiple issues, we refer the reader to other sections of this proposed rule. Specifically, section II.A of this proposed rule solicits comments for a proposed reporting period in the first payment year of any continuous 90-day period that starts and ends within the calendar year. In addition, such 90-day period would apply in both the first and second payments years (that is, 2010 and 2011) for States approved for early implementation in 2010. Section II.A. also solicits comments on full annual reporting periods for all payment years other than the first payment year (except in the case of States approved for 2010 implementation, for which the full annual reporting period would begin in the third year). We also discuss the proposed single provider election repository and other issues impacting both programs.

It is important to note that there is a very clear intent in the statute that there is coordination between the EHR incentive programs to reduce or eliminate duplicate payments between Medicare and Medicaid. Additionally, Medicare requirements under section 1848(o)(1)(B) of the Act require that payments begin no earlier than 2011. While the Medicaid provisions have no statutory start date, before States may begin implementing the Medicaid EHR incentives, CMS, and ONC need to provide guidance to States in the form of rulemaking and other policy guidance. To that end, Medicaid will not begin to provide 100 percent FFP for incentive payments any earlier than FY 2011 for hospitals and CY 2011 for EPs, (except in the case of incentive payments for adopting, implementing, or upgrading, which could begin in 2010. See discussion in section II.D.4.b.(5).(c). of this proposed rule. This also gives CMS, ONC, and States an opportunity to coordinate between Medicare and Medicaid, which we hope will simplify administrative complexity in the EHR incentive program and facilitate provider adoption.

We believe that by aligning the EHR incentive programs where possible, Medicaid EHR incentive program administration could be more efficient for the States, and provider communication about the program could be less ambiguous. This will be of particular benefit to the providers who serve both Medicare and Medicaid program beneficiaries, and will be eligible for participation in both incentive programs. Also, we believe that the incidence of fraud and abuse could be curtailed, and the potential for duplication of payments could be decreased.

Under this proposed rule we are proposing that Medicaid EPs, as discussed in section II.D.5 and II.A.5.c of this proposed rule, will enroll in the program through the single provider election repository. Once an EP selects the Medicaid EHR incentive program, we propose that States must have a system for reporting and tracking necessary information to qualify an EP for an incentive payment. In addition, as detailed in § 495.316 States will be required to submit data to CMS including data for the number, type and practice location(s) of providers who qualified for an incentive payment on the basis of having adopted, implemented, or upgraded certified EHR technology or who qualified for an incentive payment on the basis of having meaningfully used such technology as well as aggregate de-identified data on meaningful use. States' systems and processes will be submitted by the States to CMS for prior approval, concurrent with the requirements described in section II.D.8 of this proposed rule for review and approval of the SMHP.

The specific timeframes for EPs and eligible hospitals to report and submit the required information in order to demonstrate they have adopted, implemented, or upgraded certified EHR technology, as well as meaningful use of such EHR technology are proposed for comment at section II.A.1.e of this preamble. As discussed in that section of this proposed rule, for the first payment year (as well as the second payment year for those hospitals that are able to begin receiving payments for FY 2010), the reporting periods for eligible hospitals will be on a continuous 90-day basis, in the sense that as long as the start and end dates occur within the payment year and as long as the period spans the proposed 90-day consecutive period, the period can begin at any time during the payment year. States will then be expected to process payments, also on a rolling basis. In the subsequent payment years, the reporting period will be a full annual period (that is, a full payment period).

e. Avoiding Duplicate Payment

At section 1903(t)(7) of the Act, the statute requires that the Medicare and Medicaid programs coordinate payments to avoid duplication. This section further specifies that CMS and the States should coordinate payments through a data matching process, utilizing NPIs to the extent practicable. Additionally, section 1903(t)(2) of the Act states that Medicaid EPs must waive rights to Medicare incentive payments under sections 1848(o) and 1853(l) of the Act. As previously noted, hospitals may qualify for incentives under both programs. We also propose requirements under the review and approval of SMHPs in proposed part 495 subpart D for States to verify that providers meet these requirements.

As discussed in section II.A of this proposed rule, we considered what information will be necessary to eliminate duplicative incentive payments to providers between the Medicare and Medicaid programs. In order to ensure against duplicate incentive payments, we believe three conditions are required: (1) Knowing which EHR incentive program a provider has selected, (2) uniquely identifying each provider participating in each incentive program; and (3) ensuring that each State has access to the information on which EPs or hospitals intend to receive incentive payments from another State, or from the Medicare program.

To achieve all three of these conditions, as discussed in section II.A.5.c of this proposed rule, we propose to collect this data in a single provider election repository. Next, in administering each State Medicaid EHR incentive program, we propose that

States would cross-check for potential duplicative payments through the data available to them through the single provider election repository, which is based on the NPIs. We believe that this coordinates with our proposed requirements that a State must have an approved SMHP which will include a mechanism for cross-checking this information prior to payment.

f. Flexibility To Alternate Between Medicare and Medicaid EHR Incentive Programs One Time

We refer readers to section II.A.5.b of this proposed rule, where we discuss our proposal to allow Medicare and Medicaid EPs to make one EHR incentive program election change prior to 2015, and not to permit any switching after the year 2014. Under such a proposal, even if an EP initially received incentive payments under the Medicare program, such an EP could still switch to the Medicaid program one time prior to 2015. Similarly, an EP who initially selected the Medicaid EHR incentive program could switch to the Medicare program one time prior to 2015.

g. One State Selection

We propose that for EPs and hospitals with multi-state Medicaid practice locations, that the provider may annually pick only one State from which to receive incentive payments. In other words, a provider would not be able to receive incentive payments from more than one State in the same year. For example, a provider may be licensed to practice in Illinois as well as in Iowa, particularly in the area known as the Quad Cities because of the multiple cities in proximity to the Illinois and Iowa borders. There are numerous situations like this throughout the country for States sharing borders. Medicaid EPs and hospitals may change the State that they select annually when they re-attest to the program requirements.

Since qualifying for the Medicaid incentive payments is not a claims accrual process, as it is in Medicare, allowing providers to include multiple practice sites across State boundaries would create enormous administrative complexity for both CMS and State Medicaid agencies. For example, States would have to collect and verify Medicaid patient volume across more than one State, then divide and administer payments based on a methodology suitable between the State Medicaid agencies and the providers. Given that the providers qualifying for the Medicaid incentive program will receive the same incentive payment dollar amount regardless of whether payments are made by one, or more than one, State, we believe it would not be worth the resulting administrative complexity to allow payments from multiple States.

We considered the possible impact of this proposed approach with respect to patient volume calculations on Medicaid EPs and hospitals in border State areas. While we addressed the administrative complexity of this issue here, we recommend that States consider these border State providers when developing their policies and attestation methodology. We afforded additional flexibility in the patient volume at proposed § 495.306 to account for unique circumstances and data collection.

5. Single Provider Election Repository and State Data Collection

We refer readers to section II.A.5.c of this proposed rule for a discussion of the single provider election repository. As discussed in that section, the repository will collect a minimum amount of information on all EPs and hospitals to prevent duplicative payments and coordinate technical assistance.

6. Collection of Information Related to the Eligible Professional's National Provider Identifier and the Tax Identification Number

Similar to the policy proposed where Medicaid EPs and hospitals must select one State, for those EPs in multiple group practices or multiple types of practice locations, we propose to require such professionals to select one TIN for Medicaid EHR payment disbursement. In other words, such EPs could not require a State to divide payments among different practices or practice locations based upon group TINs. Requiring EPs to use only one TIN would reduce administrative complexity, as it would ensure that States are not put in the position of dividing payments in any way an EP requests (such as by patient encounters or amount contributed to EHR technology). We also believe that requiring reimbursement to be made to one TIN would reduce opportunities for fraud or abuse, as States will be able to cross-check EP and TIN combinations more easily to verify EP attestations.

Although the State would not divide payments among the various TINs of an individual EP, Medicaid EPs could decide to divide payment themselves, and distribute funds among their respective group practices or practice locations after the initial disbursement from the State to their designated TIN.

7. Activities Required To Receive Incentive Payments

• a. General Overview.

As previously discussed, for Medicaid providers (including both EPs and eligible hospitals) to qualify to receive a first year Medicaid incentive payment, section 1903(t)(6)(C)(i) of the Act indicates that the provider must demonstrate that they are "engaged in efforts to adopt, implement, or upgrade certified EHR technology." For providers who meet this standard in their first year of participation in the Medicaid incentive program, in subsequent years of participation, they must then demonstrate "meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary," and that may be based upon the methods employed under the Medicare incentive payments to physicians and hospitals, per sections 1848(o) or 1886(n) of the Act.

• b. Definitions Related to Certified EHR Technology and Adopting, Implementing or Upgrading Such Technology.

(1) Certified EHR Technology

As noted previously, in order to receive a Medicaid incentive payment the EHR technology must be "certified." Section 1903(t)(3) of the Act defines "certified EHR technology" as a qualified electronic health record (as defined in section 3000(13) of the PHS Act) that is certified pursuant to section 3001(c)(5) of the PHS Act as meeting standards adopted under section 3004 of the PHS Act that are applicable to the type of record involved (as determined by the Secretary), such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals). In section I.A of this proposed rule, for both Medicare and Medicaid, we discussed incorporating ONC's definition of certified EHR technology.

(2) Adopting, Implementing or Upgrading

Unlike the Medicare incentive programs, the Medicaid program allows eligible providers to receive an incentive payment even before they have begun to meaningfully use certified EHR technology. These providers may receive a first year of payment if they are engaged in efforts to "adopt, implement, or upgrade" to certified EHR technology. In proposed § 495.302, we define adopting, implementing or upgrading certified EHR technology as the process by which providers have installed and commenced utilization of certified EHR

technology capable of meeting meaningful use requirements; or expanded the available functionality and commenced utilization of certified EHR technology capable of meeting meaningful use requirements at the practice site, including staffing, maintenance, and training.

For the purposes of demonstrating that providers adopted, implemented, or upgraded certified EHR technology, Medicaid EPs and hospitals would have to attest to having adopted, (that is, acquired and installed) or commenced utilization of (that is, implemented) certified EHR technology; or expanded (that is, upgraded) the available functionality of certified EHR technology and commenced utilization at their practice site. States would be responsible for ensuring that processes are in place to verify that providers have actually adopted, implemented or upgraded certified EHR technology, patient volume, as well as other requirements in this section, including verifying that attestations are consistent with methodologies to combat fraud and abuse (see proposed § 495.366 through 370, Financial Oversight, Program Integrity, and Provider Appeals). The State's SMHP must detail these processes.

The CMS Medicaid Transformation Grants have demonstrated the many challenges that exist to adopting EHR technology. EHR system availability is not the same as EHR system utilization. It is for that reason that we propose to include staff training and efforts to redesign provider workflow under the definition of implementing certified EHR technology. Success is not simply defined by the acquisition and installation of new or upgraded certified EHR technology, but more importantly by providers demonstrating progress towards the integration of EHRs into their routine health care practices to improve patient safety, care, and outcomes.

In establishing criteria for the "adoption" portion of the "adopt, implement, or upgrade" requirement, we propose that there be evidence that a provider demonstrate actual installation prior to the incentive, rather than "efforts" to install. This evidence will serve to differentiate between activities that may not result in installation (for example, researching EHRs or interviewing EHR vendors) and actual purchase/acquisition or installation. It is the States' responsibility to verify this evidence of EHR adoption. As these Medicaid incentive payments are intended to stimulate meaningful use of EHR technology, they need to result in tangible adoption, implementation, or upgrading of certified EHR technology.

In establishing criteria for the "implementation" portion of "adopt, implement or upgrade" requirement, we are proposing that "implementation" mean that the provider has installed certified EHR technology and has started using the certified EHR technology in his or her clinical practice. Implementation activities would include staff training in the certified EHR technology, the data entry of their patients' demographic and administrative data into the EHR, or establishing data exchange agreements and relationships between the provider's certified EHR technology and other providers, such as laboratories, pharmacies, or HIEs.

In establishing the criteria for the "upgrade" portion of "adopt, implement or upgrade" requirement, we propose "upgrade" to mean the expansion of the functionality of the certified EHR technology, such as the addition of clinical decision support, e-prescribing functionality, CPOE or other enhancements that facilitate the meaningful use of certified EHR technology. States must describe the process that would be in place in the SMHP for ensuring that providers have actually adopted, upgraded or implemented certified EHR technology. We encourage States to consider the submission of a vendor contract from providers to ensure the existence of EHR technology.

In listening sessions with State Medicaid Agencies' staff and Governors' offices staffs, States suggested verifying providers' adoption, implementation, or upgrading of certified EHR technology through system enhancements that track and audit providers' written or electronic attestations, through surveys, or through new claims codes that would serve as attestations. Additional suggestions from State staff included using EHR vendor audit logs for Medicaid EPs rendering service through the FQHCs and tracking EHR reporting of the Health Resources and Services Administration (HRSA)-mandated quality indicators. More information on feedback received as a result of these listening sessions can be found in section II.A. of this proposed rule. These suggestions may be relevant to the discussion below concerning the States process for developing a SMHP, verifying attestations and ensuring that providers are eligible to participate in the incentive payments program.

c. Other General Terminology

"EHR reporting period" and "payment period" relate to the requirements for Medicaid EPs participating in the Medicaid EHR incentive program. As discussed previously, the reporting period is significant for EPs and eligible hospitals because it will define the period during which the provider must establish efforts to adopt, implement, or upgrade certified EHR technology, or demonstrate meaningful use of, such technology. The reporting period also is significant for States, because States will refer to such reporting periods in assuring us that providers are eligible to participate in the Medicaid EHR incentive program. (Requirements relating to the components that must be included in the SMHP are specified in proposed § 495.354). States will need to refer to the providers' reports of the activities that establish their efforts to adopt, implement, or upgrade certified EHR technology. Similarly, once meaningful use of EHR technology is required to include the reporting of clinical quality measures, States will need to ensure such measures are reported in accordance with the appropriate period. States could not appropriately make incentive payments in the absence of such reporting.

As discussed in section II.A of this proposed rule and elsewhere in this section, we propose that the EHR reporting period would occur on a rolling basis during the first payment year (and also in 2010 for States approved for early implementation). For subsequent payment years, the EHR reporting period will be on an annual basis (that is, for the entire payment year).

States would be required to validate to us that the Medicaid EPs and hospitals meet all of the eligibility criteria to qualify for Medicaid incentive payments, including the applicable patient volume thresholds, hospital-based requirements, and all of the requirements described in this section. States would develop their own administration, payment and audit processes, and as described in § 495.332, we would require that States include in their SMHPs how they would obtain Medicaid EPs' and hospitals' attestations of eligibility to qualify for the Medicaid incentive payments. Permissible means for ensuring patient volume and all of the requirements described in this section include survey, attestation, or the creation of special codes on claims, subject to our prior approval.

Additionally, we may require a more robust method for ensuring compliance with the requirements listed in this section beyond attestation as this program matures. Therefore, we are soliciting comments, including the

impact that an alternative method may have on providers and States if an alternative method that is not attestation is required.

Section 1903(t)(6)(C)(ii) of the Act also indicates that in the case of an early adopter, that is, a Medicaid EP or eligible hospital that has already adopted certified EHR technology, such provider would receive payment in the first year and all subsequent years of the incentive program by demonstrating meaningful use. In other words, such a provider would not need to demonstrate that it has adopted, implemented, or upgraded certified EHR technology in year one of the program, if they can already demonstrate meaningful use of such technology. In the case of Medicaid EPs, we discuss our proposal approach to paying early adopters in section II.D.4.5.

It is expected that the bar for demonstrating meaningful use of certified EHR technology will rise in years to come, as discussed in section II.A. States have offered their suggestions to us as to how they would verify providers' meaningful use of certified EHR technology, including participation in the exchange of clinical and administrative data; National Committee for Quality Assurance (NCQA) certification as an advanced medical home (which includes an EHR requirement); e-prescribing, and conducting security and privacy audits. Many of these elements are discussed in the definition of "meaningful use" noted in section II.A.2. of this proposed rule. For purposes of participation in the Medicaid EHR incentive program, the specific definition of "meaningful use" in section II.A.2. of this proposed rule is what providers must demonstrate to the States, and what States must track and validate. States wishing to ask providers to demonstrate additional objectives to the definition of "meaningful use" as noted in this proposed rule would need to request our prior approval of such a revised definition in their SMHP, as described in section II.D.8 of this proposed rule.

We do not wish to see the bar for demonstration of meaningful use set so high, especially in the early years of this program that, it becomes a deterrent for broad provider participation. Examples of how States may consider adding to the Federal definition of meaningful use include requiring providers to participate in a health information exchange, and requiring that providers link to immunization, lead screening, or newborn screening registries. These mechanisms must be readily available to providers, and not represent a financial burden for participation. For example, States are discouraged from proposing additional meaningful use measures that would require providers to assume additional financial costs in order to qualify to participate in the Medicaid EHR incentive program.

States should carefully consider how to build upon their existing EHR activities and infrastructure without deterring eligible Medicaid providers from participating by compelling them to use a particular system. We encourage States that were awarded Federal HIT/EHR grants, such as the Medicaid Transformation Grants, to work to connect the tools and infrastructure developed under their Federal grant funds with providers' efforts to adopt, implement, and upgrade certified EHR technology and to become meaningful users of certified EHR technology. We would be evaluating States' HIT Planning Advanced Planning Documents (PAPDs) and SMHP with this objective in mind, as described section II.D.8 of this proposed rule.

The requirements to which States would hold eligible Medicaid providers accountable would vary based upon the number of years an eligible Medicaid provider participates in the program. In other words, regardless of the calendar year, a provider's first year as a participant in the Medicaid EHR incentive program is when that provider must demonstrate either adoption, implementation, upgrading or meaningful use of certified EHR technology. States' systems must be able to track providers' year of entry into the Medicaid EHR incentive program to determine the correct eligibility criteria and generate the appropriate Medicaid incentive payments.

In Table 32, we depict the requirements for eligible Medicaid professionals and hospitals that either adopt, implement, or upgrade certified EHR technology or that move directly to meaningful use of such technology. Additionally, we refer readers to Table 1 since the table references the stages of meaningful use. Readers may find this information helpful when considering the information in Table 32.

TABLE 32: Requirements for EPs Over Time to Demonstrate Eligibility for Incentive Payments

		States will monitor compliance of providers coming onto the program with different requirements depending on the year. Incentive determination will also be based on Y1 vs. subsequent years.						
	CY	Demonstration of Compliance						
←←← Becomes more difficult to establish meaningful use.	2011	Y1	Y1 users must demonstrate that they engaged in efforts to adopt, implement, or upgrade to certified EHR technology. However, if users already adopted, they may proceed to Y2 requirements in Y1.					
	2012	Y2	Y1	Y1, same as above. Y2 must become a meaningful EHR user. We expect to issue definition of meaningful use on a biannual basis beginning in 2011.				
	2013	Y3	Y2	Y1	Y1, same as above. Y2-3 will be the same.			
	2014	Y4	Y3	Y2	Y1	Y1, same as above. Y2-4, same as above.		
	2015	Y5	Y4	Y3	Y2	Y1	Y1, same as above. Y2-5, same as above.	
	2016	Y6	Y5	Y4	Y3	Y2	Y1	Y1, same as above. Y2-6, same as above.
	2017		Y6	Y5	Y4	Y3	Y2	
	2018			Y6	Y5	Y4	Y3	
	2019				Y6	Y5	Y4	
	2020					Y6	Y5	
	2021						Y6	

As previously noted, States would be required to verify providers' meaningful use of certified EHR technology. We also expect to test the reporting of additional clinical quality measures that may be used in future definitions of meaningful use. States may wish to participate in this testing and seek out eligible Medicaid providers to report on specific clinical quality measures, extractable from EHRs. States would be able to use this reporting to pilot-test requirements that could be included in future definitions of meaningful use.

Once States are giving providers the Medicaid HIT incentive payments for being meaningful users of EHRs, and starting in 2012 are collecting those providers' clinical quality measures data, States will be required to share any such reported data with CMS in an aggregated, de-identified manner, on an annual basis. The timetable and format for sharing the clinical quality measurement data would be provided to States in future policy guidance issued by CMS. States' failure to submit these required reports to us could result in discontinued funding or disallowances. See the discussion below regarding the SMHP and the State reporting requirements. We would use the States' reports, including data on meaningful use and clinical quality measures, in order for the Secretary to fulfill her responsibilities to Congress under section 1903(t)(10) of the Act. This provision requires that the Secretary report to Congress on the improvement of health outcomes, clinical quality, or efficiency as a result of implementing this program. For hospitals eligible for both Medicare and Medicaid EHR incentive programs, where hospitals are reporting meaningful use measures to CMS, we will make quality data on Medicaid eligible hospitals available to States.

d. Quality Measures

We refer readers to section II.A.3 of this proposed rule for a discussion of the clinical quality measure reporting required for demonstrating meaningful use of certified EHR technology. As discussed in that section we have proposed in II.A.3 of this proposed rule, additional clinical quality measures that could be used by Medicaid providers to meet the quality reporting aspect of meaningful use. These additional indicators address key Medicaid services, such as pediatrics, obstetrical/gynecologic, mental health and substance abuse services. Medicaid providers could report on these clinical quality indicators in lieu of the quality indicators that are listed in Table 3. We recognize that quality measures associated with the Stage 1 definition of meaningful use contain certain gaps for Medicaid providers, including in the areas of oral health, long-term care, newborn screening, and other areas of pediatric care. As discussed previously, we intend to update our definition of meaningful use biannually, and we expect that our updated, Stage 2 definition would include additional Medicaid clinical quality measures to be reported from EHRs. We intend to work with the quality measurement community to develop these Stage 2

quality measures (see section II.B.1.d. of this proposed rule).

8. Overview of Conditions for States To Receive Federal Financial Participation (FFP) for Incentive Payments and Implementation Funding

Section 1903(a)(3)(F) of the Act provides that States are eligible for 100 percent FFP for direct payment expenditures to certain Medicaid EPs and eligible hospitals to encourage the adoption and use of certified EHR technology. States are also eligible for 90 percent FFP for reasonable administrative expenses, contingent on State compliance with the following requirements: (1) Using the funds to administer Medicaid incentive payments for certified EHR technology, including tracking of meaningful use by Medicaid EPs and eligible hospitals; (2) conducting oversight of the Medicaid EHR incentive program, including routine tracking of meaningful use attestations and reporting mechanisms; and (3) pursuing initiatives to encourage the adoption of certified EHR technology for the promotion of health care quality and the exchange of health care information.

This section of the proposed rule discusses the requirements for States to request FFP from CMS for the Medicaid EHR incentive program. Additionally, this section is closely connected to the requirements outlined in Financial Oversight, Program Integrity and Providers Appeals for purposes of oversight and accountability.

In proposed § 495.302, we define terms used in the Medicaid subpart of the regulations governing State requests for FFP. Although some of these terms have been defined in other portions of our regulations, for ease of reference, and in order to define the terms in this specific context, we have separately included definitions in part 495. Other terms such as "HIT PAPD," "IAPD," "SMHP" are new terms which would be used in approving State plans for FFP.

- Acceptance Documents: The term "acceptance document" refers to written evidence of satisfactory completion of an approved phase or work or contract related to information technology projects for which approved Federal funding is utilized. The term is commonly used in information technology projects and is defined in this proposed rule to ensure that we are able to receive information from the State necessary to evaluate and monitor the progress of HIT projects requested or approved under this proposed rule.
- Acquisition: The term "acquisition" is defined in this proposed rule to indicate a State's intent to acquire health information technology equipment or services for the purpose of implementation and administration of the provisions under this proposed rule from commercial sources or from State or local government resources. We define and utilize this term in the context of HIT planning and implementation activities that will enable States to implement existing Federal requirements for competitive procurement of equipment or services.
- Service Oriented Architecture: The term "service oriented architecture" is defined in this proposed rule as a means of organizing and developing information technology capabilities as collaborating services that interact with each other based on open standards. We are defining this term in the context of HIT projects authorized under the HITECH Act to ensure that different systems and programming languages provide the basis for interoperability among and between applications that may reside on different platforms through a communication protocol to achieve health information exchange required under ARRA.
- State Self-Assessment: The term "State self assessment" uses a standard methodology and tools to document the way a State conducts business now and plans to conduct business in the future.
- Medicaid information technology architecture (MITA) is both an initiative and a framework. It is a national framework to support improved systems development and health care management for the Medicaid enterprise. It is an initiative to establish national guidelines for technologies and processes that enable improved program administration for the Medicaid enterprise. The MITA initiative includes an architecture framework, models, processes, and planning guidelines for enabling State Medicaid enterprises to meet common objectives with the framework while supporting unique local needs.
- Medicaid management information system (MMIS) means a mechanized claims processing and information retrieval system—referred to as Medicaid Management Information Systems (MMIS)—that meets specified requirements and that the Department has found (among other things) is compatible with the claims processing and information retrieval systems used in the administration of the Medicare program. The objectives of the MMIS are to include claims processing and retrieval of utilization and management information necessary for program administration and audit and must coordinate with other mechanized systems and subsystems that perform other functions, such as eligibility determination.

We are defining the "Medicaid Management Information System" as it relates to the mechanized claims processing systems at 42 CFR 433, Subpart C, since this term has not previously been codified in regulations and we are requiring that in implementing this program under the authority of section 1903(t)(6)(D) of the Act, certified EHR technology must be compatible with the MMIS. Additionally, we expect States would align their Medicaid EHR initiatives with those envisioned under MITA, in order to fully support the meaningful use of EHR envisioned under this new program. As part of their SMHP, States will be required to map different IT solutions to their existing Medicaid enterprise business requirements using the MITA business areas and processes list when preparing a baseline State self-assessment. Using the MITA State self-assessment provides a baseline that will facilitate collaboration between the States and CMS, between the State and industry and among the States themselves. The MITA "State self-assessment" process uses a standard methodology and tools to document the way a State conducts business now, and plans to conduct business in the future. The purpose of the SMHP is to identify the "As Is" state and "To Be" (target) state of a State's Medicaid business enterprise and to align business areas and processes in the user community. Once this alignment is complete, States may then add other Medicaid business processes by extending the MITA model during implementation to ultimately facilitate the EHR program. The State self-assessment would help to identify duplicative and overlapping business areas and processes and to identify gaps by adopting new business areas and processes needed to complete the EHR enterprise. Using an incremental approach and setting achievable goals for the near and mid term, would help the State assess its progress and identify targets of opportunity critical to achieving the long-term "To Be" vision for HIT by 2014.

Further, the Medicaid enterprise is comprised of internal and external communities of common business areas that share an interest in seeing that the mission and goals of the Medicaid program and improved health outcomes are achieved. These communities include the EPs and hospitals that would be receiving incentive payments. MITA's principles and tools fosters nationally integrated business and IT transformation. It does this by demonstrating that planned

enhancements support State and Medicaid strategic goals and how intra-state systems other than the MMIS have been considered in developing the solutions. By documenting the analysis of alternative solutions, particularly a review of solutions in other States or a description of data sharing components and the reasons to include them or exclude them at this time can then be considered in its solution.

As such, the MITA process establishes the guidelines necessary for EHRs implemented as a result of the Medicaid EHR incentive program to be interoperable with State Medicaid systems, and we believe that as States and providers implement EHRs, it is essential to plan technology upgrades that would facilitate health information exchange with Medicaid providers receiving incentive funding.

- State Medicaid Health Information Technology Plan (SMHP) means a document that describes the State's current and future HIT activities in support of the Medicaid EHR incentive program.
- Health Information Technology Planning Advance Planning Document (HIT PAPD) (and any necessary update documents) means a plan of action that requests FFP and approval to accomplish the planning necessary for a State agency to determine the need for and plan the acquisition of HIT equipment or services or both and to acquire information necessary to prepare a HIT implementation advanced planning document or request for proposal to implement the State Medicaid HIT Plan.
- Health Information Technology Implementation Advance Planning Document (HIT IAPD) (and any necessary update documents) means a plan of action that requests FFP and approval to acquire and implement the proposed State Medicaid HIT Plan services or equipment or both.

To qualify to receive FFP for administering the incentive program, States must develop a SMHP, an HIT PAPD, and an HIT IAPD. These documents would lay out the process States will use to implement and oversee the EHR incentive program, and would help States to construct an HIT roadmap to develop the systems necessary to support providers in their adoption and meaningful use of certified EHR technology. The development of a SMHP (see also § 495.332) provides States with the opportunity to analyze and plan for how EHR technology, over time, can be used to enhance quality and health care outcomes and reduce overall health care costs. The uses of EHR technology can be integrated with existing State resources to achieve these goals.

We provided guidance in a State Medicaid Director's letter on September 1, 2009, on this process and the State efforts necessary to receive the 90 percent FFP. As previously noted, as States begin the process of developing their SMHPs, they also can begin to receive the 90 percent FFP funding immediately to be used to support their initial EHR planning activities. For example, initial planning regarding the design and development of the anticipated SMHP may be eligible for the 90 percent FFP as an expense related to the administration of the Medicaid incentive payments under section 1903(a)(3)(F) of the Act and, more broadly, for promoting health information exchange. Our review process would ensure that States are complying with requirements in the Act, and that they demonstrate to the "satisfaction of the Secretary" that they are using the funds in the manner anticipated by the law; for example, because of our oversight responsibilities simply proposing activities does not ensure the 90 percent FFP. We would review and prior approve all elements of the State's SMHP, and APD documents.

States would be required to submit these advance planning documents in order for us to approve receipt of the 90 percent Federal match. Specifically, prior approval would be required for the HIT PAPD (see also § 495.336). The deliverable resulting from the HIT PAPD would be the SMHP. The SMHP would be reviewed and approved before it is included in an Implementation APD (IAPD) (see also § 495.338). The IAPD also must be prior approved. Until approval is granted States cannot draw down funds. The APD process allows States to update their APD when they anticipate changes in scope, cost, schedule, etc. This allows States to add additional tasks to the contract which they may have not thought of at the time the HIT PAPD was written, as they worked through the original tasks on the original submission. Something as complex as this will most likely result in an "as needed" and "annual" update to the original scope of work.

For purposes of the Medicaid EHR incentive program, we envision two high-level phases in the process of planning and implementing the incentive program, as well as the promoting the adoption of EHR. Phase I would include initial planning, including an assessment of the State EHR environmental landscape, and development of the SMHP. The vehicle for informing us of Phase I activities will be the HIT PAPD. Phase II will involve further development and full implementation of the SMHP. Consequently, we would be requiring the HIT IAPD as the vehicle for reporting of Phase II activities. We are also proposing to require a prior approval process, and anticipate that States would work closely with us in developing the HIT PAPD prior to initiating EHR planning activities and prior to submission of the initial HIT PAPD. State collaboration with us prior to initiating submission of these documents would assist States in understanding all of the requirements and would help us understand the State's strategy and plans which would lead to a more effective implementation. In addition, such coordination would facilitate improved understanding of existing State EHR planning and implementation efforts in progress that should be combined with this effort (that is, health information exchange, EHR demonstration, and Medicaid Transformation Grants).

Also, States would be required to obtain prior written approval of funding, planning documents, proposed budgets, project schedules, and certain implementation activities that a State may wish to pursue in support of the Medicaid EHR incentive program to encourage the adoption and use of certified EHR technology in line with the 90 percent FFP available to States. To minimize the burden on States, these prior approval conditions, and the prior approval process, would mirror that presently used in support of acquiring automated data processing equipment and services in conjunction with development and operation of State MMIS, or the State's automated mechanized claims processing and information retrieval system approved by CMS.

In considering the States' strategies for adoption of EHR and health information exchange, current efforts such as the State MMIS or automated mechanized claims processing and information retrieval system, contain a great deal of claims data and other Medicaid programmatic information. The State MMIS can be of significant value in analyzing the State's current position and moving the State forward to using certified EHR technology to promote health information exchange, enhance quality, and improve health care outcomes. Additionally, the MITA framework provides a conceptual model for building capacity in Medicaid EHR and health information exchange.

We are also proposing that State Medicaid programs must comply with current procurement standards. Specifically, we are including language

in this proposed rule in accordance with the procurement requirements in 45 CFR Part 95 Subpart F to incorporate much of the procurement standards previously contained in 42 CFR Part 74. Inclusion of these procurement requirements maintains the long-standing procurement standards and policies for State information technology contracts, as well as incorporate procurement standards under the authority of section 1902(a)(4) of the Act, specifically for the definition of sole source justification, requiring all procurement transactions to be conducted in a manner to provide, to the maximum extent practical, open and free competition and promote the administration of the Medicaid program in a cost effective manner. This proposed rule also addresses grantee responsibilities, codes of conduct, competition, procurement procedures, and access to records that are specific to the HIT requirements envisioned under the ARRA. Also, under the authority of section 1902(a)(4) of the Act, we are proposing contracting requirements, reporting requirements, systems of records access, software and ownership rights, and rules for charging equipment and cost allocation plans. All of these efforts would work to provide clarity for States when considering planning and implementation activities, and would also ensure that we are providing necessary direction for States in completing their HIT PAPD, HIT IAPD, and SMHP. We are proposing under the authority of 1902(a)(4) of the Act to establish requirements for termination of FFP in the case of States failing to provide access to information relating to any of the requirements of this subpart. Additionally, under section 1903(t)(10) of the Act, we are required to monitor and report on the progress of implementation of the EHR provisions. These proposed provisions would contribute to the overall effort in monitoring implementation efforts and provide relevant information to Congress and the public at large.

Consistent with our oversight responsibilities, we are also proposing to provide a framework for attestations. Specifically, in section II.D.7 of this proposed rule, we discuss that we would require that providers attest to their efforts to adopt, implement or upgrade certified EHR technology, and attest to their meaningful use of such technology. In this section, we discuss our proposal that State Medicaid agencies would attest, as outlined in section 1903(t)(6)(A)(i) of the Act, that States would make Medicaid incentive payments to a Medicaid EP or eligible hospital directly (or to an employer or facility to which such Medicaid EP or eligible hospital has assigned their Medicaid incentive payments) without any deduction or rebate, and that States would attest that payments to an entity promoting the adoption of certified EHR technology, as designated by the State, would only be made if participation in such a payment arrangement is voluntary for the Medicaid EP involved, and if such entity does not retain more than 5 percent of such assigned Medicaid incentive payments for costs not related to such technology. States would be required to attest that the entire incentive payment has been forwarded to the eligible Medicaid provider, and that no eligible Medicaid provider is required to return any portion of the incentive payment to the State Medicaid agency. We expect States to consider utilizing all existing fiscal relationships as intermediaries for disbursing the incentives. Since many States never pay the provider directly, but rather pay a managed care plan, which then pays the provider, the State may have no existing relationship and decide to contract with the managed care plan to pass this incentive to the EP. States must establish a process to ensure that any existing fiscal relationships with providers to disburse the Medicaid incentive payments through Medicaid managed care plans does not result in payments that exceed 105 percent of the capitation rate, in order to comply with the Medicaid managed care incentive payment rules at § 438.6(c)(5)(iii) and a methodology for verifying such information.

Additionally, we are proposing that termination of funding approved under this proposed Part 495 subpart D or disallowance of FFP may result if the State fails to meet the requirements and undertakings of the approved PAPD, SMHP, and IAPD, or fails to provide access to the required information.

Since section 4201 of the HITECH Act amends section 1903(a)(3) of the Act to provide for 90 percent FFP for costs associated with certain administrative activities performed by a State, we also are proposing to allow for claiming of such reasonable costs incurred on or after February 18, 2009, prior to publication of the final rule. Specifically, if a State can show that it has begun the initial planning stages of moving the State in the direction of meaningful use of certified EHR technology through such activities as training efforts, staff support, or contracting with a vendor, we may allow for retroactive FFP back to the date in which these efforts began, but not before February 18, 2009.

9. Financial Oversight, Program Integrity and Provider Appeals

Pursuant to section 1903(t)(9) of the Act, which requires States to conduct adequate oversight of the incentive program, and in order to ensure that ARRA funds are expended wisely and in a manner that impedes waste, fraud or abuse of Federal taxpayer money, at § 495.366, we propose requirements for States' financial oversight and monitoring of expenditures. Additionally, we are proposing at § 495.368 to provide State requirements for combating fraud and abuse.

Specifically, States would be responsible for estimating the expenditures for the Medicaid EHR incentive program on the State's quarterly budget estimate reports. These reports are used as the basis for Medicaid quarterly grant awards that would be advanced to the State for the Medicaid EHR incentive program. The State submits this Form electronically to CMS via the Medicaid and State CHIP Budget and Expenditure System (MBES/CBES). At the end of the quarter, the State would be responsible for submitting expenditures to us via the MBES Form CMS–64. The Form CMS–64 is the accounting statement that the State Agency, in accordance with 42 CFR 430.30(c), submits each quarter under Title XIX of the Act. The form is used to reconcile the Medicaid funding advanced to the State for the quarter made on the basis of the CMS–37, with actual expenditures for the quarter. It accounts for any overpayments, underpayments, refunds received by the State Medicaid agency, and income earned on grant funds. States must assure that requests for reimbursement of FFP comply with all sections of this new part and that the amounts reported on the Form CMS–64 and its attachments represent actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and which is available at the time the claim for reimbursement of provider payment incentives and administration funding is filed.

We would assure that State expenditures claimed for Federal matching under the Medicaid program are programmatically reasonable, allowable, and allocable in accordance with existing Federal laws, regulations, and policy guidance. CMS' Regional Office financial and auditing specialists will be responsible for monitoring State funding issues including the funding related to these Medicaid EHR payment incentives. Funding specialists would also review the flow of funds to determine that State funds are from

allowable sources and to insure that Medicaid payment incentives would be paid without reduction or rebate. Additionally, funding specialists would ensure that no other sources of funding are used to make Medicaid EHR payment incentives to providers other than State and local government funds. States would be responsible for establishing policies, computer systems, edits to process Medicaid EHR incentive payments; and for conducting analyses of providers' patterns of practice (data-mining) and taking other reasonable steps to ensure that no duplicate or otherwise improper EHR incentive payments have been made. States will be responsible for ensuring that provider information, including but not limited to, attestations, survey, and any information added to CMS' single provider election repository indicates that any falsification of documentation or concealment of material facts may be prosecuted under Federal and State laws. States would be responsible for recovering and returning to CMS FFP for any HIT incentive payments that are discovered to be improper. State Agencies must have information processing systems, including a MMIS—the automated mechanized claims processing and information retrieval system, to process Medicaid EHR incentive payments. MMIS systems can also help to manage information for program administration and audit purposes.

States must assure that any requests for reimbursement of the 90 percent Federal match for administration of the program are being requested only because the State has used the funds for purposes related to administering payments to qualified Medicaid providers for certified EHR technology, including for tracking of meaningful use of such technology, is conducting adequate oversight of the program including routine tracking of meaningful use attestations and reporting mechanisms; and is pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information because of such technology. Any initiatives for health information exchange must be consistent with Federal laws and regulations governing the exchange.

We would monitor State Agency compliance through systems performance reviews, on-site reviews, and audits of the APD process.

As a result of the authority extended to the Secretary under section 1902(a)(4) of the Act requiring the effective and efficient administration of the State plan, as well as section 1903(t)(9) of the Act, requiring that a State demonstrate to the satisfaction of the Secretary that it is conducting adequate oversight of the program, we are also proposing to establish § 495.370, Provider Appeals. This proposed section would specify that Medicaid providers who believe that they have been denied an incentive payment or have received an incorrect payment amount under this part because of incorrect determinations of eligibility, including, but not limited to, measuring patient volume; demonstrating meaningful use of, or the efforts to adopt, implement, or upgrade to, certified EHR technology; whether the professional is hospital-based; whether the professional is practicing predominantly in an FQHC or RHC; whether the hospital qualifies as an acute care or children's hospital; or whether the provider is already participating in the Medicare incentive program and therefore ineligible duplicate Medicaid incentive program payments can appeal the decision using current Federal processes established at 42 CFR 447.253(e).

III. Information Collection Requirements

Under the Paperwork Reduction Act of 1995, CMS is required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that CMS 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 PRA and collection of information requirements as a result of this proposed rule. The projected numbers of EPs and eligible hospitals, MA organizations, MA EPs and MA-affiliated hospitals are based on the numbers used in the Impact Analysis Assumptions as well as in Table 45 in the Regulatory Impact Analysis section.

A. ICRs Regarding Demonstration of Meaningful Use Criteria (§ 495.8)

In § 495.8(a)(1), we propose that to demonstrate meaningful use for CY 2011, an EP must attest, through a secure mechanism in a specified manner, to the following: (1) During the EHR reporting period, the EP used certified EHR technology and specify the technology used; and (2) during the EHR reporting period, the EP satisfied each of the applicable objectives and associated measures under § 495.6 (including quality measures). The EP must specify the EHR reporting period and provide the result of each applicable measure for all patients seen during the EHR reporting period for which a selected measure is applicable. We estimate that the certified EHR technology adopted by the EP will capture many of the Meaningful Use objectives and associated measures and generate automated numerator and denominator information, where required, or automated summary reports. Therefore, for these objectives and associated measures (Set A), we estimate that it would take no more than 0.5 hours for an EP to attest to them collectively as the EHR would be able to gather all of the information necessary for the provider. For objectives and associated measures requiring a numerator and denominator we limit to actions taken in the presence of certified EHR technology. We do not anticipate that an EP or eligible hospital will maintain two record keeping systems when certified EHR technology is present. Therefore, we assume that all patient records that would be in the denominator would be kept using certified EHR technology. Because generating this automated information requires the purchase of a certified EHR with the requisite technical functionality, reporting these measures will incur significant capital costs.

However, there are still some Meaningful Use objectives and associated measures (Set B) where reporting may require EPs to manually gather the information necessary to report numerators and denominators or to take any other additional steps before attesting that the objective has been met, we have estimated that it would take 1 hour for the EP to gather that information and report the result. For example, the measure "At least 80 percent of all patients who request an electronic copy of their health information are provided it within 48 hours" requires EPs to not only provide that information (a third-party disclosure) but also attest to the provision of that information for 80

percent of all patients who request that information. Another example is the CPOE measure. The numerator for the CPOE measure could be generated by the certified EHR technology adopted by the EP, as all orders entered through CPOE could be tracked. However, the denominator for this measure could require EPs to manually track the number of orders entered through paper-based processes. Alternatively, EPs may choose to purchase EHRs equipped with additional functionality to enable the tracking of all orders, whether entered using CPOE or otherwise, in which case reporting burden may be less than an hour but the capital costs will be higher. We invite comments on what the incremental costs of such additional functionality may be and what the reporting burden using EHRs equipped with this functionality might be.

Table 33 below lists those objectives and associated measures which we estimate will require 0.5 hours to fulfill ("Set A") and those objectives and associated measures which we estimate will take 1 hour each ("Set B"). We welcome comments on our burden estimates for each particular measure, as well as what the incremental capital costs attributable to each measure might be. Estimates of total capital costs at the bottom of Table 33 are derived from the estimates used in the "Industry Costs" section in Section V.G.4.

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TABLE 33: Burden and Capital Costs associated with Meaningful Use Objectives and Associated Measures

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
Set A	Implement drug-drug, drug-allergy, drug-formulary checks	Implement drug-drug, drug-allergy, drug-formulary checks	The EP/eligible hospital has enabled this functionality Reporting requirement: Attestation of implementation	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with medication error e-prescribing functions
	Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT ®	Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT ®	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry or an indication of none recorded as structured data Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate diagnoses in coded format

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Maintain active medication list	Maintain active medication list	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate medication information in coded format
	Maintain active medication allergy list	Maintain active medication allergy list	At least 80% of all unique patients seen, by the EP or admitted to the eligible hospital have at least one entry or (an indication of "none" if the patient has no medication allergies) recorded as structured data Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate medication allergy information in coded format

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Record demographics o preferred language o insurance type o gender o race o ethnicity o date of birth	Record demographics o preferred language o insurance type o gender o race o ethnicity o date of birth o date and cause of death in the event of mortality	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate this information in coded format
	Record and chart changes in vital signs: o height o weight o blood pressure o Calculate and display: BMI o Plot and display growth charts for children 2-20 years, including BMI.	Record and chart changes in vital signs: o height o weight o blood pressure o Calculate and display: BMI o Plot and display growth charts for children 2-20 years, including BMI.	For at least 80% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital, record blood pressure and BMI; additionally plot growth chart for children age 2-20 Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate this information in coded format
	Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	At least 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital have "smoking status" recorded Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate this information in coded format

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Report ambulatory quality measures to CMS or the States	Report hospital quality measures to CMS or the States	For 2011, provide aggregate numerator and denominator through attestation as discussed in section II(A)(3) of this proposed rule For 2012, electronically submit the measures as discussed in section II(A)(3) of this proposed rule	For 2011, the burden associated with these measures is estimated to be (an additional) 0.5 hour to select the measures and to attest to the numerator and denominator for each. For 2012, the burden is estimated to be (an additional) 0.5 hour to e report and send the electronic submission.	TBD – Cost of the functionality to capture and report on quality measures
	Send reminders to patients per patient preference for preventive/ follow up care		Reminder sent to at least 50% of all unique patients seen by the EP that are age 50 or over Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of having functionality to send reminders to patients
	Implement clinical 5 decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement 5 clinical decision support rules related to a high priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement 5 clinical decision support rules relevant to the clinical quality metrics the EP/Eligible Hospital is responsible for as described further in section II(A)(3). Reporting requirement: attest to the implementation	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with clinical decision support functionality

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Check insurance eligibility electronically from public and private payers	Check insurance eligibility electronically from public and private payers	Insurance eligibility checked electronically for at least 80% of all unique patients seen by the EP or admitted to the eligible hospital Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost administrative simplification functionality
	Submit claims electronically to public and private payers.	Submit claims electronically to public and private payers.	At least 80% of all claims filed electronically by the EP or the eligible hospital Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with administrative simplification functionality
	Provide clinical summaries for patients for each office visit		Clinical summaries provided for at least 80% of all office visits Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost an EHR system capable of storing this information and transmitting it to patients

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Capability to exchange key clinical information (for example, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information Reporting requirement: attestation that at least one test was performed	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost an EHR system capable of storing this information and transmitting it to providers and patient authorized entities
	Capability to submit electronic data to immunization registries and actual submission where required and accepted	Capability to submit electronic data to immunization registries and actual submission where required and accepted	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries Reporting requirement: attestation that at least one test was performed	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with functionality that can capture immunization information and submit that information to immunization registries

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
		Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received	Performed at least one test of the EHR system's capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically) Reporting requirement: attestation that at least one test was performed or that no public agencies have the capacity to receive	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with functionality that can capture lab results information and submit that information to public health agencies

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or eligible hospital submits such information have the capacity to receive the information electronically) Reporting requirement: attestation that at least one test was performed or that no public agencies have the capacity to receive	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with functionality that can capture syndromic surveillance data and submit that information to public health agencies
	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 per 45 CFR 164.308 (a)(1) and implement security updates as necessary Reporting requirement: attestation that a risk analysis was conducted or reviewed	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	N/A as conducting or reviewing a security risk analysis does not necessarily hinge on the purchase of an EHR or particular EHR functionalities

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
Total Burden and Incremental Capital Cost for Set A Measures				0.5 hours + 0.5 hour for quality measure attestation/reporting	TBD -- some increment of the total capital costs
SET B	Use CPOE	Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP)	For EPs, CPOE is used for at least 80% of all orders For eligible hospitals, CPOE is used for 10% of all orders Reporting requirement: numerator and denominator data	1 hour to manually derive the denominator (unless EHR is equipped with extra functionality to generate numerator and denominator data automatically) and attest to the measure. Total: 1 hour	TBD – cost of a CPOE module; additionally, the cost of extra functionality to generate numerator and denominator information automatically
	Generate and transmit permissible prescriptions electronically (eRx)		At least 75% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology Reporting requirement: numerator and denominator data	1 hour to manually derive the denominator (unless EHR is equipped with extra functionality to generate numerator and denominator data automatically) and attest to the measure. Total: 1.0 hour	TBD – cost of an e-prescribing system; additionally, the cost of extra functionality to generate numerator and denominator information automatically
	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate at least one report listing patients of the EP or eligible hospital with a specific condition. Reporting requirement: attest that at least one report was generated	1 hour to generate the report and attest to the measure Total: 1.0 hour	TBD – cost of having an EHR registry function

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Incorporate clinical lab-test results into EHR as structured data	Incorporate clinical lab-test results into EHR as structured data	At least 50% of all clinical lab tests ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data Reporting requirement: numerator and denominator data	1 hour to manually derive the denominator (unless EHR is equipped with extra functionality to generate numerator and denominator data automatically) and attest to the measure. Total: 1.0 hour	TBD – cost of extra functionality to generate numerator and denominator information automatically
	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies), upon request	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request	At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours Reporting requirement: numerator and denominator data	1 hour to account for the burden associated with determining the denominator and attest to the measure Total: 1.0 hour	TBD – cost an EHR system capable of storing this information and transmitting it to patients
		Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request	At least 80% of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it Reporting requirement: numerator and denominator data	1 hour to account for the burden associated with determining the denominator and attest to the measure Total: 1.0 hour	TBD – cost an EHR system capable of storing this information and transmitting it to patients

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP		At least 10% of all unique patients seen by the EP are provided timely electronic access to their health information Reporting requirement: numerator and denominator data	1 hour to account for the burden associated determining whether information is timely and attest to the measure Total: 1.0 hour	TBD – cost an EHR system capable of storing this information and making it continuously available to patients
	Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation for at least 80% of relevant encounters and transitions of care Reporting requirement: numerator and denominator data	1 hour to account for the burden associated with determining the denominator of all relevant encounters and transitions of care, and attest to the measure Total: 1.0 hour	TBD – cost an e-prescribing system capable of medication reconciliation
	Provide summary care record for each transition of care and referral	Provide summary care record for each transition of care and referral	Provide summary of record for at least 80% of transitions of care and referrals Reporting requirement: numerator and denominator data	1 hour to account for the burden associated with determining the denominator of all relevant encounters and transitions of care and attest to the measure Total: 1.0 hour	TBD – cost an EHR system capable of storing this information and transmitting it to patients
Estimated Total Burden and Incremental Capital Cost per Respondent for Set B measures				**7.0 hours for eligible hospitals** **8.0 hours for EPs**	**TBD – some increment of the total capital costs**

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
Estimated Total Burden and Total Capital Cost per Respondent for attestation to EHR technology, Set A Set B measures, and attestation and reporting of quality measures				8 hours for hospitals 9 hours for EPs	Hospitals: $5 million to install; $1 million annual maintenance/training costs EPs: $54,000 to install; $10,000 annual maintenance/training costs

*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 additional burden associated with the conduct or review of such analyses.

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First, we will discuss the burden associated with EP attestation to EHR technology and Meaningful Use Set A objectives/measures, and ambulatory quality measures. We estimate that it will take no more than 0.5 hour for an EP to attest that during the EHR reporting period, he or she used certified EHR technology and specify the technology, and satisfied each of the applicable Meaningful Use Set A objectives/measures. We also estimate that it will take an EP an additional 0.5 hour to select and attest to the ambulatory quality measures for CY 2011.The total burden hours for an EP to attest to the above is one hour. We estimate that there are about 442,600 non-hospital-based Medicare and Medicaid EPs (323,500 Medicare EPs, 80,900 dual Medicare/Medicaid EPs and 38,200 Medicaid-eligible-only EPs) who may attest to the above (after registration) in CY 2011 to receive an EHR incentive payment. We estimate the burden for the 28,000 MA EPs in the MAO burden estimate section. The total estimated annual attestation burden hours for EHR technology, Meaningful Use Set A objectives/measures, and ambulatory quality measures are 442,600 for all EPs (442,600 EPs × 1 hour). The cost burden for an EP to attest to the above information is $79.33 (1 hour × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all EPs to attest to EHR technology, Meaningful Use Set A objectives/measures, and ambulatory quality measures is $35,111,458 (442,600 EPs × $79.33). We invite public comments on the estimated percentages and the numbers of (registered) EPs that will attest to the above in CY 2011 because such information would help us determine more accurately the burden on the EPs.

Next, we discuss the burden for EPs to gather information and attest to Meaningful Use Set B objectives/measures. We estimate that it takes about 8 hours for each EP to comply with this requirement. As stated, we estimate that there are about 442,600 non-hospital-based EPs in CY 2011. The total estimated annual attestation burden hours for all EPs for the Meaningful Use Set B objectives and measures included in Table 33 is 3,540,800 (442,600 EPs × 8 hours). The cost burden for an EP to attest to the above information is $634.64 (8 hours × $79.33/hour (the mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics is $79.33) and $280,891,664 for EPs as a whole (3,540,800 hours × $79.33/hour). We invite public comments on the estimated percentages and the numbers of (registered) EPs that will attest to Set B objectives and measures in CY 2011 because such information would help us determine more accurately the burden on the EPs.

To estimate capital costs, we assume a certified EHR will cost roughly $54,000 as explained in section V.G.4 of this proposed rule. If 442,600 EPs adopt these EHRs, total capital costs prior to incentives would be roughly $23.9 billion. We also estimate that in 2011, $200 million of Medicare incentive payments (the midpoint of the low and high estimates in Tables 36 and 37) and $900 million of Medicaid incentive payments (the midpoint of the low and high estimates in Tables 45 and 46) would be provided to EPs to help offset those costs. Therefore, we estimate that total net capital costs for EPs in 2011 would be $22.8 billion ($23.9 billion − $200 million − $900 million). These capital costs would decrease over the course of the EHR incentive programs as additional incentives are provided. Therefore, in 2012, the total net capital costs for EPs would be $20.6 billion (22.8 billion − $1.6 billion of Medicare incentives − $650 million of Medicaid incentives). Over the course of 2011 and 2012, the average net capital costs would be $21.7 billion.

We expect that there will be a steady growth in EPs. We estimate that in 2012, there are about 447,400 non-hospital-based Medicare, and Medicaid EPs (326,900 Medicare EPs, 81,700 dual Medicare/Medicaid EPs and 38,800 Medicaid-eligible-only EPs) who are qualified to receive EHR incentive payment. In § 495.8(a)(2), we propose that to demonstrate meaningful use for CY 2012 and subsequent years, a (registered) EP is required to attest, through a secure mechanism in a specified manner, to the following: (1) During the EHR reporting period, the EP used certified EHR technology and specify the technology used; and (2) during the EHR reporting period, the EP satisfied each of the applicable objectives and associated measures under § 495.6 except § 495.8(d)(3) "Report ambulatory quality measures to CMS or the States (in the case of Medicaid EPs)."

For burden estimate purposes, we believe the burden associated with gathering the information necessary to provide the attestations for the measures in Table 33, as well as the burden associated with providing the actual attestation, will remain unchanged from CY2011. As detailed in Table 33, some measures (Set A) will require a total of

0.5 hours to report while others (Set B) will require 1 hour.

First, we will discuss the burden for an EP to attest that during the reporting period, he or she used certified EHR technology, specify the EHR technology, and he or she satisfied each of the applicable Set A objectives measures in CY 2012. We estimate it will take no more than 0.5 hour for an EP to attest to the above requirements. For burden estimate purposes, we estimate that all 447,400 non-hospital-based Medicare, and Medicaid EPs (326,900 Medicare EPs, 81,700 dual Medicare/Medicaid EPs and 38,800 Medicaid-eligible-only EPs) may attest (after registration) in 2012 to receive an EHR incentive payment. We estimate the burden for the 28,000 MA EPs in the MAO burden estimate section. We estimate it will take an EP 0.5 hour to attest. The total estimated annual attestation burden hours for all EPs are 223,700 (447,400 EPs × 0.5 hour). The cost burden for an EP to attest to the above information is $39.67 (0.5 hour × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all EPs to attest is $17,746,121 (223,700 hours × $79.33). We invite public comments on the estimated percentages and the numbers of registered EPs that will attest to EHR technology used and Meaningful Use Set A objectives/measures in CY 2012 because such information would help us determine more accurately the burden on the EPs.

Next, we will discuss the estimated burden for EP attestation for Meaningful Use Set B objectives/measures. We estimate it will take an EP 8 hours to gather information and attest to the Meaningful Use Set B objectives/measures. We estimated annual attestation burden hours in CY 2012 for all EPs for the Set B objectives and measures included in Table 33 is 3,579,200 (447,400 EPs × 8 hours). Therefore, the cost burden for an EP to attest to the above information is $634.64 per EP (8 hours × $79.33/hour (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics) and $283,937,936 for EPs as a whole (3,579,200 hours × $79.33/hour (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics).

For "Report ambulatory quality measures to CMS or the States" as stated in § 495.8(a)(2), we propose that in CY 2012, EPs must report, clinical quality information in the form and manner specified by CMS, electronically to CMS. We estimate that the reporting/submission of these data to CMS should not take more than 0.5 hour. The total annual burden hours for all EPs to report and submit the ambulatory quality measures are 223,700 (447,400 EPs × 0.5 hour). We believe that an EP may assign a medical secretary to submit the specific ambulatory clinical quality measures to CMS or the States. Therefore, the cost burden for an EP to submit these clinical quality measures is $7.41 (0.5 hour × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total annual cost burden for all EPs to report the clinical quality measures is $3,312,997 (223,700 hours × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)).

Similar to the requirements for EPs, we propose in § 495.10(b)(1) that to demonstrate meaningful use for FY 2011, an eligible hospital or CAH must attest, through a secure mechanism in a specified manner, to the following: (1) During the EHR reporting period, the eligible hospital or CAH used certified EHR technology and specify the technology used; and (2) during the EHR reporting period specified by the eligible hospital or CAH, the eligible hospital or CAH satisfied each of the applicable objectives and associated measures under § 495.6 (including quality measures). The eligible hospital or CAH must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the eligible hospital during the EHR reporting period for which a selected measure is applicable.

We estimate that the certified EHR technology adopted by the eligible hospital or CAH will capture many of the objectives and associated measures. We estimate that it would take no more than 0.5 hour for an eligible hospital or CAH to attest that during the EHR reporting period, they used EHR technology, specify the technology used, and satisfied each of the applicable Meaningful Use objectives and associated measures listed in Table 33–Set A. Because generating this automated information requires the purchase of a certified EHR with the requisite technical functionality, reporting these measures will incur significant capital costs.

Where reporting may require eligible hospitals or CAHs to manually gather the information necessary to report numerators and denominators or to take any other additional steps before attesting that the objective has been met, we have estimated that it would take 1 hour for an eligible hospital or CAH to gather that information and report the result. These measures are listed in Table 33–Set B. Alternatively, eligible hospitals or CAHs may choose to purchase EHRs equipped with additional functionality to enable more efficient reporting, in which case reporting burden may be less than an hour but the capital costs will be higher. We invite comments on what the incremental costs of such additional functionality may be and what the reporting burden using EHRs equipped with this functionality might be.

First, we will discuss the burden for eligible hospitals and CAHs to attest to the technology used and the Meaningful Use Set A objectives/measures and hospital quality measures in FY 2011. We estimate that in FY 2011, there are about 5,011 Medicare and Medicaid eligible hospitals and CAHs that may be qualified to receive EHR incentive payment. We estimate that it will take no more than 1 hour for an eligible hospital or CAH to attest (0.5 hour to attest to the EHR technology used and Meaningful Use Set A objectives/measures, and 0.5 hour to attest to the hospital quality measures—a total of 1 hour.) We estimate that there are about 5,011 Medicare and Medicaid hospitals (including 3,620 acute care hospitals, 1,302 critical access hospitals, 78 Medicaid children's hospitals, and 11 Medicaid cancer hospitals). For burden estimate purposes, we estimate that 5,011 Medicare and Medicaid hospitals may attest (after registration) in FY 2011 to receive an EHR incentive payment. The total estimated annual attestation burden hours for all hospitals are 5,011 (5,011 hospitals and CAHs × 1 hour). We believe that an eligible hospital or CAH may assign an attorney to attest on their behalf. The cost burden for an eligible hospital or CAH to attest to the above information is $59.98 (1 hour × $59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all eligible hospitals and CAHs to attest is $300,560 (5,011 × $59.98). We invite public comments on the estimated percentages and the numbers of (registered) eligible hospitals and CAHs that will attest in FY 2011 because such information would help us determine more accurately the burden on the hospitals and CAHs. We also invite comments on the type of personnel or staff that would most likely attest on behalf of eligible hospitals and CAHs.

Next, we will discuss the burden for eligible hospitals and CAHs to gather information and attest to Meaningful Use Set B objectives/measures for FY 2011. We estimate that it may take an eligible hospital and CAH 7 hours to comply with this requirement. As stated, we estimate there are about 5,011

eligible hospitals and CAHs that may attest to Meaningful Use Set B objectives/measures. Therefore, the total estimated annual attestation burden hours for all eligible hospitals and CAHs for the Set B objectives and measures included in Table 33 is 35,077 (5,011 hospitals and CAHs × 7 hours). We estimate that the hospital or CAH may use an attorney to attest on their behalf. Therefore, the cost burden for an eligible hospital or CAH to attest to Meaningful Use Set B objectives/measures is $419.86 (7 hours × $59.98/hour (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics) and $2,103,918 for eligible hospitals and CAHs as a whole (35,077 hours × $59.98/hour (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)), not including capital costs.

To estimate capital costs, consistent with the sources cited in V.G.4, we assume that achieving meaningful use will require roughly a $5 million capital investment for the average hospital. If 5,011 hospitals adopt these EHRs, total capital costs prior to incentives would be roughly $25.1 billion. We also estimate that in 2011, $2.1 billion of Medicare incentive payments (the mid-point of the low and high estimates in Tables 39 and 40) and $900 million of Medicaid incentive payments (the mid-point of the low and high estimates in Tables 45 and 46) would be provided to eligible hospitals and CAHs to help offset those costs. Therefore, we estimate that total net capital costs for hospitals in 2011 would be $22.1 billion ($25.1 billion − $2.1 billion − $900 million). These capital costs would decrease over the course of the EHR incentive programs as additional incentives are provided. Therefore, in 2012, the total net capital costs for hospitals would be $19 billion (22.1 billion − $2.2 billion of Medicare incentives − $900 million of Medicaid incentives). Over the course of 2011 and 2012, the average net capital costs would be $20.6 billion.

Similar to the requirements for EPs, we propose in § 495.8(b)(2) that to demonstrate meaningful use in FY 2012 and subsequent years, an eligible hospital or CAH must attest, through a secure mechanism in a specified manner, to the following: (1) During the EHR reporting period, the eligible hospital or qualifying CAH used certified EHR technology and specify the technology used; and (2) during the EHR reporting period specified by the eligible hospital or CAH, the eligible hospital or CAH satisfied each of the applicable objectives and associated measures under § 495.6. except § 495.6(e)(2). The eligible hospital or CAH must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the eligible hospital during the EHR reporting period for which a selected measure is applicable. We estimate that the certified EHR technology adopted by the eligible hospital or CAH will capture many of the objectives and associated measures. Therefore, we estimate that it would take no more than 0.5 hour for an eligible hospital or CAH to attest to the EHR technology used and objectives and associated measures listed in Table 33–Set A. Because generating this automated information requires the purchase of a certified EHR with the requisite technical functionality, reporting these measures will incur significant capital costs. We do not anticipate there is a significant growth in the number of hospitals or CAHs. We estimate that in FY 2012, the total burden attestation burden hours for hospitals and CAHs are 2,506 (5,011 hospitals and CAHs × 0.5 hour). We estimate that an eligible hospital or CAH may assign an attorney to attest on their behalf. The attestation burden for an eligible hospital or CAH is $29.99 (0.5 hour × $59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics). The total cost burden for all hospitals and CAHs to attest to EHR technology used, and Meaningful Use Set A objectives/measures is $150,310 (2,506 hours × $59.98). We also invite comments on the type of personnel or staff that would mostly likely attest on the behalf of eligible hospitals and CAHs.

Where reporting may require eligible hospitals or CAHs to manually gather the information necessary to report numerators and denominators or to take any other additional steps before attesting that the objective has been met, we have estimated that it would take 1 hour for the eligible hospitals or CAHs to gather that information and report the result for each of these measures or a total of 7 hours to comply with this requirement in FY 2012. These measures are listed in Table 33–Set B. Alternatively, eligible hospitals or CAHs may choose to purchase EHRs equipped with additional functionality to enable more efficient reporting, in which case reporting burden may be less than an hour but the capital costs will be higher. We invite comments on what the incremental costs of such additional functionality may be and what the reporting burden using EHRs equipped with this functionality might be.

For burden estimate purposes, we estimate that there are 5,011 Medicare and Medicaid hospitals and CAHs that may attest to the above requirements in FY 2012. Therefore, the total estimated annual attestation burden hours for all eligible hospitals and CAHs for the Set B objectives and measures included in Table 33 are 35,077 (5,011 hospitals and CAHs × 7 hours). We estimate that the hospital or CAH may use an attorney to attest on behalf of its organization. Therefore, the cost burden for an eligible hospital or CAH to attest to the above information is $419.86 (7 hours × $59.98/hour (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)) and $2,103,918 for eligible hospitals and CAHs as a whole (35,077 hours × $59.98/hour (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)), not including capital costs.

We estimate the capital cost for 2012 is $20.6 billion which is the same as 2011, which was discussed earlier.

Under § 495.8, for "Report hospital quality measures to CMS or the States", we propose that in FY 2012, eligible hospitals must report clinical quality measures through electronic submission from certified EHR technology. The reporting of these data to CMS or States should not take more than 0.5 hour. The total annual reporting burden hours for eligible hospitals and CAHs is 2,506 (5,011 hospitals and CAHs × 0.5 hour). We believe that an eligible hospital or CAH may assign a medical secretary to report/submit the hospital quality measures to CMS or the States. The reporting cost burden for an eligible hospital or CAH is $7.41 (0.5 hour × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total annual reporting cost burden for all eligible hospitals and CAHs is $37,113 (2,506 hours × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)).

B. ICRs Regarding Participation Requirements for EPs, Eligible Hospitals, and CAHs (§ 495.10)

Since the EHR incentive payment program is new, we do not have enough information to estimate the information collection requirements burden beyond the first payment year for an EP, eligible hospital, or CAH for this provision. Furthermore, the EPs, eligible hospitals, and CAHs can enroll any time during the first 5 years; therefore, it is difficult to predict with certainty the burden beyond the first payment year as the burden depends on the number of participants. Therefore, we provide a best estimate of what we believe the burden associated with this provision might be.

Under § 495.10 (a)(b)(c), we propose that in order for an EP, eligible hospital, or CAH to participate in the Medicare or Medicaid EHR incentive program, they must submit, in a manner specified by CMS, the following initial registration information in the first payment year: (1) Name of the EP, eligible hospital or CAH; (2) the National Provider Identifier (NPI); (3) business address and business phone; (4) Taxpayer Identification Number (TIN) to which the EP wants the incentive payment made; and (5) for an eligible hospital and CAH, their CMS Certification Number (CCN) and its TIN. We estimate that the initial burden associated with the above requirements would be the time required to submit the required registration information.

We estimate that in FY 2011, there are 5,011 Medicare and Medicaid eligible hospitals, and CAHs that may be qualified to receive EHR incentive payment. Since we cannot predict how many eligible hospitals, and CAHs will participate in the EHR incentive payment program, we estimate that all 5,011 hospitals may register for the incentive program for burden estimate purposes. We estimate that it would take no more than 0.5 hour for an eligible hospital or CAH to register. We estimate the total annual burden hours for registration will be 2,506 (5,011 hospitals × 0.5 hour). Once the decision to participate in the incentive program is made, we believe eligible hospitals or CAHs may assign a medical secretary to submit the registration information. The cost burden for an eligible hospital or CAH to register is $7.41 (0.5 hour × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We estimate that the total annual cost burden for eligible hospitals and CAHs to register is $37,106 (5,011 hospitals × 0.5 hour × $14.81) (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invite public comments on the estimated percentages or the number of eligible hospitals and CAHs that will register for the EHR incentive payment program in 2011 and subsequent years. Such information would help us determine more accurately the burden on the eligible hospitals and CAHs.

We estimate that all 442,600 non-hospital-based Medicare, and Medicaid EPs may register in 2011 to receive an EHR incentive payment. We estimate that it would take no more than 0.5 hour to complete the registration. The total estimated annual registration burden hours for all EPs are 221,300 (442,600 EPs × 0.5 hour) in the first payment year. We cannot predict if an EP will register himself or herself or assign a medical secretary to do it on his or her behalf. Therefore, we are doing one high end burden estimate for an EP and one low end burden estimate for a medical secretary. The cost burden for an EP who chooses to register in the EHR incentive payment program himself or herself is $39.67 (0.5 hour × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all EPs who register for the EHR incentive payment program themselves is $17,555,729 (221,300 hours × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). Similarly, the cost burden for an EP who chooses to use medical secretary to register on their behalf is $7.41 (0.5 hour × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all EPs who choose to use medical secretaries to register on their behalf is $3,277,453 (221,300 hours × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invite comments on whether we should use the higher cost burden estimate ($17,555,729) or the lower cost burden estimate ($3,277,453). We only use the average of the two estimates in the tally in Table 34. We invite public comments on the estimated percentages or the numbers of EPs that will register in 2011 and subsequent years and this information would help us determine more accurately the burden on EPs affected by this proposed rule.

In § 495.10(d), we propose that if there are subsequent changes in the initial registration information, the EP is responsible for providing us with updated changes in the manner specified by us. Based on our experience with provider enrollment, we estimate that about 11 percent of the Medicare and Medicaid EPs may need to update their registration information during a one-year period. We estimate that EPs in this 11 percent (447,400 EPs (estimated number of EPs in CY 2012) × 11 percent = 49,214 EPs) may only have one occasion that requires updating of information in a given year. For each occasion, we estimate that it would take no more than 0.5 hour to notify us of the changes. With that, we estimate that the annual total burden hours for 49,214 EPs to update changes are 24,607 (49,214 EPs × 0.5 hour). However, we cannot predict if the EP will update the registration information himself or herself or assign a medical secretary to do it. Therefore, we are doing two burden estimates for an EP and his/her medical secretary. The cost burden for an EP who chooses to update the registration information himself or herself is $39.67 (0.5 hour × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all 49,214 EPs to update registration information themselves is $1,952,073 (49,214 EPs × 0.5 hour × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). Similarly, the cost burden for the EP who chooses to use a medical secretary to update registration information on their behalf is $7.41 (0.5 hour × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for 48,686 EPs who choose to use medical secretaries to update registration information on their behalf is $364,429 (49,214 EPs × 0.5 hour × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We only use the average of the two estimates in the tally in Table 34. We invite comments on whether we should use the higher cost burden estimate ($1,952,073) or the lower cost burden estimate ($364,429). We also invite public comments on the estimated percentages and the numbers of EPs that will need to submit subsequent registration changes to us over the course of the EHR incentive payment program and such information would help us determine more accurately the burden on the EPs.

Similarly, for hospitals and CAHs, we propose that if there are subsequent changes in the initial registration information, the eligible hospital or CAH is responsible for providing us with updated information in the manner specified by us. Based on our experience with provider enrollment, we estimate that about 8 percent of the Medicare and Medicaid eligible hospitals and CAH (5,011 hospitals and CAHs × 8 percent = 401 hospitals) may need to update their registration information during a one-year period. We estimate that eligible hospitals in this 8 percent pool may only have 1 occasion that requires updating of registration information in a given year. For each occasion, we estimate that it would take no more than 0.5 hour to notify us of the changes. With that, we estimate that the total annual burden hours for eligible hospitals and CAHs to update CMS of registration changes are 201 (401 hospitals and CAHs × 0.5 hour). We believe that eligible hospitals or CAHs may assign a medical secretary

to update the registration information. We estimate the total annual cost burden for eligible hospitals and CAHs to update CMS of registration changes is $2,969 (401 hospitals and CAHs × 0.5 hour × $14.81) (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invite public comments on the estimated percentages and the numbers of eligible hospitals and CAHs that will submit subsequent registration changes to us over the course of the EHR incentive payment program and this information would help us determine more accurately the burden on the eligible hospitals and CAHs.

In § 495.10(e)(1), we propose that for participation in the EHR incentive payment programs, prior to the first payment year, an EP must notify us in a specified manner as to whether he or she elects to participate in the Medicare or Medicaid EHR incentive program. We estimate that in 2011, there are about 80,900 dual Medicare/Medicaid EPs who may make the initial Medicare and Medicaid program selection. The standard full amount of Medicaid incentive payments that an EP could receive is larger than the standard full amount for the Medicare EP incentive payments. Therefore, for burden estimate purposes, we believe that all of the 80,900 dual Medicare/Medicaid EPs may make the Medicaid program selection for burden estimate purposes. We estimate that it would take no more than 0.5 hour to submit the initial Medicare or Medicaid selection notification to us. We cannot predict if the EP will submit the notification to CMS himself or herself or assign a secretary to do it. Therefore, we are doing one high end estimate and one low end burden estimate for an EP and a medical secretary respectively. The total estimated burden hours for all the dual Medicare/Medicaid EPs to notify CMS of program selection are 40,450 (80,900 EPs × 0.5 hour) in the first payment year. The cost burden for these EPs who notify CMS of Medicare or Medicaid program selection himself or herself is $39.67 (0.5 hour × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all dual Medicare/Medicaid EPs to notify CMS of program selection themselves is $3,208,899 (40,450 hours × $79.33). Similarly, the cost burden for an EP who chooses to use medical secretaries to notify CMS of program selection is $7.41 (0.5 hour × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all dual Medicare/Medicaid EPs who use medical secretaries to notify CMS of program selection is $599,065 (40,450 hours × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We only use the average of the two estimates in the tally in Table 34. We invite comments on whether we should use the higher cost burden estimate ($3,208,899) or the lower cost burden estimate ($599,065). We also invite public comments on the estimated percentages and the number of dual Medicare/Medicaid EPs that will submit initial Medicare or Medicaid program selection in 2011, 2012, 2013, or 2014 and this information would help us determine more accurately the burden on the EPs affected by the proposed rule.

Under § 495.10(e)(2), we propose that EPs may switch from Medicare to Medicaid EHR incentive program or vice versa one time, and only for payment year 2014 or before. Since we have no knowledge of how many EPs will make the subsequent changes in program selection, we assume that all 81,700 (estimated number of dual Medicare/Medicaid EPs for CY 2012) dual Medicare/Medicaid EPs may make subsequent program selection changes for burden estimate purposes. We estimate that it would take no more than 0.5 hour to submit the Medicare/Medicaid selection change to us. We cannot predict if the EP will submit the change to CMS himself or herself or assign a secretary to do it. Therefore, we are doing one high end burden estimate for an EP and one low end estimate for a medical secretary. The total estimated burden hours for all dual Medicare/Medicaid EPs to notify CMS of program changes are 40,850 (81,700 EPs × 0.5 hour) in a given year. The cost burden for the EP who choose to notify CMS of Medicare/Medicaid program change himself or herself is $39.67 (0.5 hour × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all dual Medicare/Medicaid EPs to notify CMS of program changes themselves is $3,240,630 (40,850 hours × $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). Similarly, the cost burden for an EP who chooses to use a medical secretary to notify CMS of program changes is $7.41 (0.5 hour × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all dual Medicare/Medicaid EPs who use medical secretaries to notify CMS of program changes is $604,989 (40,850 hours × $14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invite comments on whether we should use the higher cost burden estimate ($3,240,630) or the lower cost burden estimate ($604,989). We only use the average of the two estimates in the tally in Table 34. We also invite public comments on the estimated percentages and the numbers of dual Medicare/Medicaid EPs that will submit initial Medicare or Medicaid program changes in 2012, 2013, or 2014 and this information would help us determine more accurately the burden on the EPs affected by the proposed rule.

C. ICRs Regarding Identification of Qualifying MA Organizations, MA–EPs and MA-Affiliated Eligible Hospitals (§ 495.202)

Proposed § 495.202(a)(1) states that beginning with bids due in June 2010 (for plan year 2011), MA organizations seeking reimbursement for qualifying MA EPs and qualifying MA-affiliated eligible hospitals under the MA EHR incentive program are required to identify themselves to CMS in a form an manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act. The burden associated with this requirement is providing a list of MA EPs and qualifying MA-affiliated eligible hospitals who may potentially seek for EHR incentive payments. However, for EPs, we believe there is no extra burden incur from this requirements as MA organizations can identify the same lists of names of EPs as they used to satisfy the collection requirements for § 495.204(b)(2) and (5). In other words, when identifying amounts of compensation per § 495.204(b)(2) and (5), qualifying MA organizations will be simultaneously identifying EPs under this requirement. For hospitals, we estimate that it may take no more than 0.25 hour for a MA organization to identify their MA-affiliated hospitals to CMS. There are 29 MA-affiliated eligible hospitals and 12 MA organizations or an average of 2.42 eligible hospitals for each MA organization. The total burden hours for all MA organizations to identify their affiliated hospitals to CMS are 3 hours. We believe a MA organization may use a billing clerk to identify the eligible hospital to us. The cost burden for a MA organization is $3.86 (0.25 hour × $15.44 (mean hourly rate for billing clerks based on the May 2008 Bureau of Labor Statistics)). The total cost burden for all MA organizations to identify their eligible

hospitals to us is $46.32 ($3.86 × 12 MA organizations).

We proposed in § 495.202(a)(3) that qualifying MA organizations offering MA plan types other than HMOs are required to attest to the fact that they meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3)-section 2791(b)(3) of the PHS Act. There is minimal burden associated with this requirement as qualifying MA organizations sponsoring MA coordinated care plans, like PPOs, PSOs, and RPPOs, are not expected to employ physicians that meet the definition of MA EP in section 1853(1)(2) of the Act and therefore, we do not expect any to need to attest. Similarly, we do not expect any MA organizations that offer other plan types other than coordinated care plans to request need to attest to their status for similar reasons.

In § 495.202(a)(4), we propose requiring that, beginning with bids due in June 2014 (for plan year 2015), all MA organizations with potentially qualifying MA EPs or potentially qualifying MA-affiliated eligible hospitals under the MA EHR incentive program to identify themselves to CMS in a form and manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act. We cannot estimate the collection burden for this requirement as the timeframe goes beyond the scope of the effective date of the proposed information collection period (three years from the effective date of the final rule).

In § 495.202(b)(1), we propose that a qualifying MA organization, as part of its initial bid starting with plan year 2011, must make preliminary identification of potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals for which the organization is seeking incentive payments. The burden for this requirement is already addressed in § 495.202 (a)(1) and § 495.204(b)(2)(5). In § 495.202(b)(2), we propose that MA-affiliated organizations must provide and attest to the following information on their MA-affiliated EPs and eligible hospitals: (A) Name of the EP or eligible hospital; (B) address of the EP or eligible hospital; and (C) NPI. We believe that it is customary and business practices of an MA organization to keep the information in (A), (B), and (C) on file. The burden for this requirement is the time it takes to attest to CMS that the MA EPs or MA-affiliated eligible hospitals meet the eligibility criteria. We estimate it should not take more than 0.5 hour for a MA organization to comply with this attestation requirement. The total burden hours for all MA organizations to attest are 6 hours. We believe that MA organizations may use an attorney to attest on their behalf. The cost burden for a MA organization to attest is $29.99 (0.5 hour × $59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)). The total cost burden for all MA organizations to attest is $359.88 ($29.99 × 12 MA organizations). We invite comments on the type of personnel who will mostly likely attest on behalf of MA organizations.

Proposed § 495.202(b)(4) states that all qualifying MA organizations, as part of their initial bids in June 2014 for plan year 2015, must identify potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals. An attestation that each professional or hospital either meets or does not meet the eligibility criteria must be included as part of the identification submission. We cannot estimate the collection burden for this requirement as the timeframe goes beyond the scope of the effective date of the proposed information collection period (3 years from the effective date of the final rule).

D. ICRs Regarding Incentive Payments to Qualifying MA Organizations for MA–EPs and Hospitals (§ 495.204)

Under § 495.204(b)(2), we propose that a qualifying MAO would need to report to CMS within 30 days 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. Since the tracking of salaries or compensation for MA EPs constitutes usual and customary business practices, the only burden associated with this requirement is the time required to submit the aggregated annual amount of revenue received by each qualifying MA EP for enrollees in MA plans of the MA organization. We estimate that there are 12 MA organizations and 28,000 MA EPs, or an average of 2,333 (28,000 EPs/12 MA organizations) MA EPs affiliated with each qualifying MA organization. We believe that it will take a MA organization 40 hours annually to report the required aggregate revenue data for all its salaried MA EPs, given that all the data are readily available. The total estimated annual burden hours for all MA organizations to comply with this requirement is 480 (12 MA organizations × 40 hours). We believe MA organizations may involve a billing clerk to report the required data to CMS. We estimate the cost burden for a MA organization to report is $617.6 (40 hours × $15.44 (mean hourly rate for billing clerk based on the May 2008 Bureau of Labor Statistics)). We estimate the total annual cost burden for all MA organizations to comply with this requirement is $7,411 (12 MA organizations × $617.6).

Under § 495.204(b)(4), we propose that for qualifying MA EPs who are compensated on a salaried basis, CMS requires the qualifying MA organization to develop a methodology for estimating the portion of each qualifying MA EP's salary attributable to providing services that would otherwise be covered under Part B to MA plan enrollees of the MA organization. The methodology: (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 salaried qualifying MA EP. We estimate that it may take a MA organization one and a half hour to develop the methodology. We estimate that there are about two MA organizations that may have the need to develop the methodology. The total burden hours for the MA organizations to develop the methodology are 3 hours (1.5 hours × 2 MA organizations). A MA organization may use an accountant to develop the methodology. The cost burden for a MA organization is $47.48 (1.5 hours × $31.65 (mean hourly rate for accountants based on the May 2008 Bureau of Labor Statistics)). The total cost burden for the MA organizations to develop the methodology is $94.95 ($47.48 × 2 MA organizations).

In § 495.204(b)(5), we propose that for qualifying MA EPs who are not salaried, qualifying MA organizations would need to obtain, and submit to CMS, attestations from such qualifying MA EPs as to the amount of compensation received by such EPs for MA plan enrollees of the MA organization. We estimate that about 10 percent of the MA EPs (28,000 EPs × 10 percent = 2,800 EPs) are not salaried and that is an average of 233 (2,800 EPs/12 MA organizations = 233 EPs) non-salaried EPs in each MA organization. We estimate that it may take up to 0.25 hour to electronically obtain and compile each attestation into a document for transmission to CMS. The total burden hours for a MA organization are 58.3 (0.25 hour × 233 EPs). The total estimated burden hours for all MA organizations are 699 (58.3 × 12 MA organizations). We believe an MA organization may involve a billing clerk to compile and submit the

compensation information from such attestations. We estimate the cost burden for a MA organizations to comply with this requirement is approximately $899.38 (0.25 hour × 233 EPs × $15.44 (mean hourly rate for billing clerk based on the May 2008 Bureau of Labor Statistics)). We estimate the total annual cost burden for all MA organizations to comply with this requirement is $10,792.56 (58.3 hours × 12 organizations × $15.44).

E. ICRs Regarding Meaningful User Attestation (§ 495.210)

Under § 495.210(b), we propose requiring qualifying MA organizations to attest within 30 days after the close of a calendar year whether each qualifying MA EP is a meaningful EHR user. We anticipate that the adopted EHR technology will capture the data for determination whether each qualifying MA EP is a meaningful EHR user. The burden associated with this requirement is the time necessary to attest to the required information. We estimate that there are 12 MA organizations and 28,000 MA EPs, or an average of 2,333 MA EPs affiliated with each qualifying MA organization. We believe that it will take a MA organization about 40 hours annually to attest whether each qualifying MA EP is a meaningful user, given that all the data are captured in the certified EHR technology. The total estimated annual burden hours for all MA organizations to comply with this requirement is 480 (12 MA organizations × 40 hours). We believe MA organizations may involve an attorney to attest on their behalf. We estimate the cost burden for a MA organization to attest is $2,399 (40 hours × $59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)). We estimate the total annual cost burden for all MA organizations to comply with attestation for MA EPs is $28,790 (12 MA organizations × $2,399). We invite comments on the type of personnel, who will mostly attest on behalf of MA organizations.

Section 495.204(c)(2) states that to the extent data are available, qualifying MA organizations must receive hospital incentive payments through their affiliated hospitals under the Medicare FFS EHR hospital incentive program, rather than through the MA EHR hospital incentive program. Under § 495.210(c), we proposed that qualifying MA organizations be required to attest within 30 days after the close of a calendar year whether each qualifying MA-affiliated eligible hospital is a meaningful EHR user. As stated in the preamble, the EHR incentive payments for Medicare FFS and MA-affiliated hospitals are treated the same as all Medicare-certified MA affiliated hospitals and they will attest like other Medicare FFS hospitals. This means that § 495.210(c) only applies to a MA-affiliated hospital that is not Medicare certified and such type of hospitals do not exist currently. We do not expect there to be any MA-affiliated hospitals that will not be covered under the Medicare FFS EHR hospital incentive program because section 1852(a)(1)(A) of the Act requires MA organizations to provide Part A inpatient services solely through providers that meet applicable requirements of the Medicare program. We have already addressed the attestation burden on hospitals, including MA-affiliated hospitals under § 495.10(b)(2)(i)(ii).

F. ICRs Regarding Establishing Patient Volume (§ 495.306)

Proposed § 495.306(a) states that to establish patient volume, a Medicaid provider must annually meet one of the requirements contained in § 495.306(a)(1). Proposed § 495.306(a)(1)(i) states that except as specified in paragraph (a)(1)(ii) of this section, a Medicaid professional must attest that a minimum of 30 percent of their patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid. Proposed § 495.306(a)(1)(ii)(A) states that a pediatrician must attest that a minimum of 20 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid. Proposed § 495.306(a)(1)(ii)(B) states that a Medicaid professional practicing predominantly in a FQHC or RHC must attest that a minimum of 30 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was with needy individuals as defined in § 495.302. Proposed § 495.306(a)(2) states that an acute care hospital must attest that a minimum of 10 percent of all patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid.

The burden associated with the requirements in this section is the time and effort necessary to submit the information to CMS. In each instance, we estimate that it will take no longer than 0.5 hour to submit the necessary information to CMS. For proposed § 495.306(a)(1)(i) through (ii), we estimate that 119,000 entities will submit the required information. Similarly, we estimate the total annual burden to be 59,500 hours in both § 495.306(a)(1)(i) and § 495.306(a)(1)(ii). The total labor cost associated with the requirement in § 495.306(a)(1)(i) is $4,720,135. The total labor cost associated with the requirement in § 495.306(a)(1)(ii) is $4,720,135. We reached these costs estimates since it will be important for physicians (rather than staff assistants) to establish patient volume at $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)).

The burden associated with the requirements in proposed § 495.306(a)(1)(ii)(B) and § 495.306(a)(2) is the time and effort necessary to submit the information to CMS. In each instance, we estimate that it will take no longer than 0.5 hour to submit the necessary information to CMS. For proposed § 495.306(a)(1)(ii)(B) and § 495.306(a)(2), we estimate that 3,361 entities will submit the required information. Similarly, we estimate the total annual burden to be 1,815.50 hours in both § 495.306(a)(1)(ii)(B) and § 495.306(a)(2). The total labor cost associated with the requirement in § 495.306(a)(1)(ii)(B) is $144,024. This cost burden is based on the physician establishing patient volume at $79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total labor cost associated with the requirement in § 495.306(a)(2) is $25,617. This cost burden is based on a secretary reporting patient volume on behalf of the acute care hospital at $14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

G. ICRs Regarding Process for Payments (§ 495.312)

Proposed § 495.312(b) states that in order to receive a payment under this part, a provider must report the required data under this subpart within the EHR reporting period described in § 495.6. The data required is the information necessary to document that the provider is a meaningful user or an adopter, implementer, or upgrader of certified EHR technology and the data reported to the single provider election repository. The burden associated with this requirement is the time and effort necessary to report the required data to States during the EHR reporting period. This burden is accounted for in our burden discussions for sections A and B of the information collection section, § 495.10 and § 495.12, respectively.

H. ICRs Regarding Activities Required To Receive an Incentive Payment (§ 495.314)

Proposed § 495.314(a)(1) states that in the first payment year, to receive an

incentive payment, the Medicaid EP or eligible hospital must meet one of the following criteria. The Medicaid EP or eligible hospital must demonstrate that during the EHR reporting period for a payment year, it has adopted, implemented, or upgraded certified EHR technology, as defined in § 495.302; or, the Medicaid EP or eligible hospital must demonstrate that during the EHR reporting period for a payment year it is a meaningful user of certified EHR technology as defined in § 495.6.

The burden associated with the requirements in proposed § 495.314(a)(1) is the time and effort necessary for a Medicaid EP or eligible hospital to demonstrate that it meets one of the criteria in § 495.314(a)(1)(i) through (ii). We already accounted for this burden in the earlier discussion of the burden associated with § 495.10.

Proposed § 495.314(a)(2) states that a provider may notify the State of its nonbinding intention to participate in the incentives program prior to having fulfilled all of the eligibility criteria. This requirement constitutes a third-party disclosure. The burden associated with this requirement is the time and effort necessary for a provider to send notification to the State. We estimate that this burden will be the same burden associated with § 495.12 as stated above, since the information necessary to notify the State of the providers non-binding intention to participate in the program could be the same information as submitted by those providers that have committed to participating in the program, that is, the National Provider Identifier, the tax identification number, etc.

Proposed § 495.314(b)(1) states that in the second, third, fourth, fifth, and sixth payment years, to receive an incentive payment, the Medicaid EP or eligible hospital must demonstrate that during the EHR reporting period for the applicable payment year, it is a meaningful user of certified EHR technology, as defined in § 495.6. The burden associated with this requirement is the time and effort necessary for a Medicaid EP or eligible hospital to demonstrate that it is a meaningful user of certified EHR technology. We discussed the burden associated with this requirement in our discussion of the burden associated with § 495.10.

I. ICRs Regarding State Monitoring and Reporting Regarding Activities Required To Receive an Incentive Payment (§ 495.316)

Proposed § 495.316(a) would require States to be responsible for tracking and verifying the activities necessary for a Medicaid EP or eligible hospital to receive an incentive payment for each payment year, as described in § 495.314. Burden is calculated for each State's process for the administration of the Medicaid incentive payments, including tracking of attestations and oversight, and the process for approving, processing, and making timely payments.

We estimate that there will be approximately 50 States, the District of Columbia, and 5 Territories per year requesting reimbursement for the administration of and paying of Medicaid incentive payments to providers for the meaningful use of electronic health record systems. For States to collect and submit the information required, we estimate it will take 5 hours per State. The estimated annual burden for States associated with the aforementioned submission requirements is 280 hours (56 States-Territories × 5.0 hours/State-Territory). The cost burden was estimated based on an employee contracting with the State Agency. The burden associated with § 495.316 is already in the OMB approval process. We announced the information collection in a **Federal Register** notice that published on September 11, 2009 (74 FR 467330).

J. ICRs Regarding State Responsibilities for Receiving FFP (§ 495.318)

Proposed § 495.318 states that in order to be provided FFP under section 1903(a)(3)(F) of the Act, a State must demonstrate to the satisfaction of the Department, that the State is conducting the activities listed at § 495.318(a) through (c). This burden is the same as that listed above in the burden discussion for § 495.316.

K. ICRs Regarding Prior Approval Conditions (§ 495.324)

Proposed § 495.324(a) would require a State to obtain prior written approval from the Department as specified in paragraph (b) of this section, when the State plans to initiate planning and implementation activities in support of Medicaid provider incentive payments encouraging the adoption and use of certified EHR technology with proposed Federal financial participation (FFP). Specifically, proposed § 495.324(b) states that to receive 90 percent match, each State must receive prior approval for all of the requirements listed in § 495.324(b)(1) through (3).

Proposed § 495.324(c) would require a State to obtain prior written approval from the Department of its justification for a sole source acquisition, when it plans to acquire non-competitively from a nongovernmental source HIT equipment or services, with proposed FFP under this subpart if the total State and Federal acquisition cost is more than $100,000. Burden must be calculated for State Medicaid Agencies to submit the planning and implementation documents and the SMHP to CMS including, among other things, an alternative approach to the established timeframe for measuring patient volume, the process for verifying eligibility, annual reports specifying provider adoption, implementation, and/or upgrading of certified EHR technology activities and payments, proposed additional quality measures, and the data supporting the adoption, implementation, or upgrading and meaningful use of certified EHR technology. This burden is the same as that listed above in the burden discussion for § 495.316.

L. ICRs Regarding Termination of Federal Financial Participation (FFP) for Failure To Provide Access to Information (§ 495.330)

Proposed § 495.330(a) states that the Department terminates FFP at any time if the Medicaid agency fails to provide State and Federal representatives with full access to records relating to HIT planning and implementation efforts, and the systems used to interoperate with electronic HIT, including on-site inspection. Proposed § 495.330(b) states that the Department may request such access at any time to determine whether the conditions in this subpart are being met. The burden associated with the requirements in this section is the time and effort necessary to make the information available to the Department upon request so it can monitor compliance. The Department estimates that it will make 1 request per State/Territory per year for information and that it will take each State 5 hours to compile and furnish the information. We estimate that there will be approximately 50 States, the District of Columbia, and 5 Territories per year submitting this information. For States to collect and submit the information required, we estimate it will take 5 hours per State. The estimated annual burden for States associated with the aforementioned submission requirements is 280 hours (56 States-Territories × 5.0 hours/State-Territory).

The annual cost burden for a State employee to provide the above information is $9,904 (280 hours × $35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)). We believe that it is possible that a secretary may compile State information and provide the information to the Department. In that case the annual cost

burden for the secretary to provide this information is $3,951 (280 hours × $14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

M. 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 adopting, implementing, or upgrading and meaningful use of certified EHR technology. This burden is the same as that listed above in the burden discussion for § 495.316.

N. ICRs Regarding Access to Systems and Records (§ 495.346)

Proposed § 495.346 states that the State agency must allow the Department access to all records and systems operated by the State in support of this program, including cost records associated with approved administrative funding and incentive payments to Medicaid providers. State records related to contractors employed for the purpose of assisting with implementation or oversight activities or providing assistance, at such intervals as are deemed necessary by the Department to determine whether the conditions for approval are being met and to determine the efficiency, economy, and effectiveness of the program.

This section imposes both recordkeeping and reporting requirements. The burden associated with this requirement is the time and effort necessary for a State to both maintain records and to make them available to the Department upon request. The Department believes that the burden associated with maintaining the records is exempt under 5 CFR 1320.3(b)(2) as this burden is part of a usual and customary business practice; the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities (for example, in compiling and maintaining business records) will be excluded from the "burden" if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary.

However, there is burden associated with making the information available to the Department upon request. This burden is described in the burden discussion for § 495.330.

O. ICRs Regarding Procurement Standards (§ 495.348)

Proposed § 495.348(c) states that a grantee must maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts. The burden associated with this requirement is the time and effort necessary for a grantee to develop and maintain written standards of conduct. We estimate that it will take each of the 56 grantees 0.5 hour to develop and maintain standards of conduct. The total estimated annual burden is 28 hours (56 grantees × 0.5 hours). The annual cost burden for a grantee to develop and maintain standards of conduct is $990 (28 hours × $35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)).

Proposed § 495.348(e) would require that all grantees establish written procurement procedures. At a minimum, the standards must provide for the information listed in § 495.348(e)(1) through (13). The burden associated with this requirement is the time and effort necessary for a grantee to develop and maintain written procurement procedures. We estimate that it will take each of the 56 grantees 0.5 hour to develop and maintain written procurement procedures. The total estimated annual burden is 28 hours (56 grantees × 0.5 hours). The annual cost burden for a grantee to develop and maintain written procurement procedures is $990 (28 hours × $35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)).

Proposed § 495.348(f) imposes a recordkeeping requirements. This section states that a system for contract administration must be maintained to ensure contractor performance with the terms, conditions and specifications of the contract and to ensure adequate and timely follow up on all purchases. The burden associated with this requirement is the time and effort necessary to develop and maintain a system for contract administration. We estimate that it will take each of the 56 grantees 5 hours to develop and maintain a system for contract administration. The total estimated annual burden is 280 hours (56 grantees × 5 hours). The annual cost burden for a grantee to develop and maintain a system for contract administration is $9,904 (280 hours × $35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)).

P. ICRs Regarding State Medicaid Agency Attestations (§ 495.350)

Proposed § 495.350 would require States to provide assurances to the Department that amounts received with respect to sums expended that are attributable to payments to a Medicaid provider for the adoption of EHR are paid directly to such provider, or to an employer or facility to which such provider has assigned payments, without any deduction or rebate. The burden associated with this requirement is the time and effort necessary for a State to verify that the sums expended are attributable to payments to a Medicaid provider for the adoption of EHR are paid directly to such provider, or to an employer or facility to which such provider has assigned payments, without any deduction or rebate. Additionally, there is burden associated with submitting an attestation to the Department to that effect. The estimated burden associated with these requirements is 0.5 hour to verify the information and 0.5 hour to submit the attestation to the Department, for a total of 1 hour. We estimate that there will be approximately 50 States, the District of Columbia and 5 Territories per year verifying this information and submitting attestations to the Department. The estimated annual burden for States associated with the aforementioned submission requirements is 56 hours (56 States-Territories × 1 hours State-Territory). The annual cost burden for a State employee to provide the above information is $1,981 (56 hours × $35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)). We believe that it is possible that a secretary may compile State information and provide the information to the Department. In that case the annual cost burden for the secretary to provide this information is $790 (56 hours × $14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

Q. ICRs Regarding Reporting Requirements (§ 495.352)

Proposed § 495.352 would require each State to submit to the Department on a quarterly basis a progress report documenting specific implementation and oversight activities performed during the quarter, including progress in implementing the State's approved Medicaid HIT plan. The burden associated with this requirement is the

time and effort necessary for a State to draft and submit quarterly progress reports to the Department. We estimate that there will be approximately 50 States, the District of Columbia, and 5 Territories per year drafting and submitting the quarterly progress reports. For States to collect and submit the information required, we estimate it will take 5 hours per State. The estimated annual burden for States associated with the aforementioned submission requirements is 280 hours (56 States-Territories × 5 hours/State-Territory).

The annual cost burden for a State employee to provide the above information is $9,904 (280 hours × $35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)). We believe that it is possible that a secretary may compile State information and provide the information to the Department. In that case the annual cost burden for the secretary to provide this information is $3,951 (280 hours × $14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

R. ICRs Regarding Retroactive Approval of FFP With an Effective Date of February 18, 2009 (§ 495.362)

Proposed § 495.362 states that for administrative activities performed by a State, without obtaining prior approval, which are in support of planning for incentive payments to providers, a State may request consideration of FFP by recorded request in a HIT implementation planning advance planning document or implementation advance planning document update. While this requirement is subject to the PRA, we believe the burden is already covered in the discussion of proposed § 495.332 through § 495.344.

S. ICRs Regarding Financial Oversight and Monitoring Expenditures (§ 495.366)

Proposed § 495.366(a)(2) would require a State to have a process in place to report actual expenditures for the Medicaid EHR payment incentive program using the Medicaid Budget Expenditure System. Since States already have to report Medicaid expenditures to the Medicaid Budget and Expenditure System, there is no need for States to develop and implement a reporting process. However, States will need to estimate and report the expenditures related to the provider incentive payments and the cost of the administration of the incentive payments. We estimate that it will take each of the 50 States, the District of Columbia and 5 Territories, 5 hours to compile and report this information. The estimated annual burden for States associated with the aforementioned requirements is 280 hours (56 States-Territories × 5 hours State-Territory).

The annual cost burden for a State employee to provide the above information is $9,904 (280 hours × $35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)). We believe that it is possible that a secretary may compile State information and provide the information to the Department. In that case the annual cost burden for the secretary to provide this information is $3,951 (280 hours × $14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

Proposed § 495.366(a)(2) would require a State to have an automated payment and information retrieval mechanized system (Medicaid Management Information System), to make EHR payment incentives, to ensure Medicaid provider eligibility, to ensure the accuracy of payment incentives, and to identify potential improper payments. Since States already have an automated payment and information retrieval system, there is no need to estimate this burden.

Proposed § 495.366(b) lists the information collection requirements associated with provider eligibility as a basis for making payment. States must, subject to § 495.332, collect and verify information on Medicaid providers. This burden is the same as that listed above in the discussion of § 495.316.

Proposed § 495.366(c) discusses information collection requirements pertaining to meaningful use and efforts to adopt, implement, or upgrade to certified electronic health record technology to make payment. Specifically, proposed § 495.366(c)(1) states that subject to § 495.332, the State must annually collect and verify information regarding the efforts to adopt, implement, or upgrade certified EHR technology and the meaningful use of said technology before making any payments to providers. This burden has already been discussed in our burden explanation for § 495.10.

Proposed § 495.366(d)(1) states that subject to paragraph § 495.332, the State must assure that State expenditures are claimed in accordance with, including but not limited to, applicable Federal laws, regulations and policy guidance. Proposed § 495.366(d)(2) specifies that subject to § 495.332, the State must have a process in place to assure that expenditures for administering the Medicaid EHR incentive payment program will not be claimed at amounts higher than 90 percent of the cost of such administration. Proposed § 495.366(d)(3) states that subject to § 495.332, the State must have a process in place to assure that expenditures for payment of Medicaid EHR incentive payments will not be claimed at amounts higher than 100 percent of the cost of such payments to Medicaid providers. This burden is the same as that listed above in the discussion of § 495.316.

Proposed § 495.366(e) discusses the information collection requirements associated with improper Medicaid electronic health record payment incentives. The burden associated with the requirements listed in proposed § 495.366(e)(1) through (7) is the time and effort necessary to develop processes to provide the necessary assurances discussed in this section. This burden is the same as that listed above in the discussion of § 495.316.

T. ICRs Regarding Appeals Process for a Medicaid Provider Receiving Electronic Health Record Incentive Payments (§ 495.370)

Proposed § 495.370(a) would require states to have a process in place consistent with the requirements established in § 447.253(e) of this chapter for a provider or entity to appeal incentive payments, incentive payment amounts, provider eligibility determinations, and the demonstration of adopting, implementing, or upgrading and meaningful use of certified EHR technology. This burden is the same as that listed above in the discussion of § 495.316.

These numbers are subject to a substantial amount of uncertainty and actual experience may be significantly different. The range of possible experience is greater than under most other rules for the following reason; specifically, this rule provides the option for States to participate in the Medicaid certified electronic health record technology incentive payment program. To the extent that States participate more or less than assumed here (that is, the number of States, EPs and hospitals) the burden associated may be greater than or less than estimated.

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TABLE 34: Burden and Cost Estimates Associated with Information Collection Requirements

Reg Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting ($)	Total Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Costs ($)
§495.8 (a)(1)– EHR Technology Used, Set A Objectives/Measures & Quality Measures (EPs) (2011)	0938-New	442,600	442,600	1	442,600	79.33	35,111,458	0	35,111,458
§495.8 (a)(1)– Set B Objectives/Measures (EPs) (2011)	0938-New	442,600	442,600	8	3,540,800	79.33	280,891,664	21,700,000,000	21,980,891,664
§495.8(a)(2) - EHR Technology Used & Set A Objectives/Measures (EPs) (2012)	0938-New	447,400	447,400	0.5	223,700	79.33	17,746,121	0	17,746,121
§495.8 (a)(2)– Set B Objectives/ Measures (EPs) (2012)	0938-New	447,400	447,400	8	3,579,200	79.33	283,937,936	4,500,000,000	4,783,937,936
§495.8 (a)(2)– Ambulatory Quality Measures (EPs) (2012)	0938-New	447,400	447,400	0.5	223,700	14.81	3,312,997	0	3,312,997
§495.8 (b)(1)-- EHR Technology Used, Set A Objectives/Measures & Quality Measures (hospitals/CAHs) (2011)	0938-New	5,011	5,011	1	5,011	59.98	300,560	0	300,560
§495.8(b)(1) – Set B Objectives/ Measures (hospitals/CAHs) (2011)	0938-New	5,011	5,011	7	35,077	59.98	2,103,918	20,600,000,000	20,602,103,918
§495.8 (b)(2)-- l EHR Technology Used & Set A Objectives/Measures (hospitals/CAHs) (2012)	0938-New	5,011	5,011	0.5	2,506	59.98	150,310	0	150,310
§495.8 (b)(2)– Set B Objectives/ Measures (hospitals/CAHs) (2012)	0938-New	5,011	5,011	7	35,077	59.98	2,103,918	5,000,000,000	5,002,103,918
§495.8 (b)(2)– Hospital Quality Measures (hospitals/CAHs) (2012)	0938-New	5,011	5,011	0.5	2,506	14.81	37,113	0	37,113
§495.10(a) – (c) – high (EPs) (2011)	0938-New	442,600	442,600	0.5	221,300	79.33	17,555,729	0	17,555,729
§495.10(a) – (c) -- low (EPs) (2011)	0938-New	442,600	442,600	0.5	221,300	14.81	3,277,453	0	3,277,453
§495.10(a) – (c) – average (EPs) (2011)		442,600	442,600	0.5	221,300	47.07	10,416,591	0	10,416,591
§495.10(d) -- high (EPs) (2012)	0938-New	49,214	49,214	0.5	24,607	79.33	1,952,0732	0	1,952,0732
§495.10(d) – low (EPs) (2012)	0938-New	49,214	49,214	0.5	24,607	14.81	364,429	0	364,429
§495.10(d) – average (EPs) (2012)		49,214	49,214	0.5	24,607	47.07	1,158,251	0	1,158,251
§495.10(e)(1) – high (EPs) (2011)	0938-New	80,900	80,900	0.5	40,450	79.33	3,208,899	0	3,208,899
§495.10(e)(1) – low (EPs) (2011)	0938-New	80,900	80,900	0.5	40,450	14.81	599,065	0	599,065
§495.10(e)(1) – average (EPs) (2011)		80,900	80,900	0.5	40,450	47.07	1,903,982	0	1,903,982
§495.10(e)(2) – high (EPs) (2012)	0938-New	81,700	81,700	0.5	40,850	79.33	3,240,630	0	3,240,630
§495.10(e)(20 – low (EPs) (2012)	0938-New	81,700	81,700	0.5	40,850	14.81	604,989	0	604,989
§495.10(e)(2) – average (EPs) (2012)		81,700	81,700	0.5	40,850	47.07	1,922,810	0	1,922,810

Reg Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting ($)	Total Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Costs ($)
§495.10(a) – (b) (hospital) (2011)	0938-New	5,011	5,011	0.5	2,506	14.81	31,706	0	31,706
§495.10(d) – (hospital) (2012)	0938-New	401	401	0.5	201	14.81	2,969	0	2,969
§495.202(a) (2011)	0938-New	12	12	0.25	3	15.44	46	0	46
§495.202(b)(2) (2011)	0938-New	12	12	0.5	6	59.98	360	0	360
§495.204(b)(2) (2011-2012)	0938-New	12	12	40	480	15.44	7,411	0	7,411
§495.204(b)(4) (2011-2012)	0938-New	2	2	1.5	3	31.65	95	0	95
§495.204(b)(5) (2011-2012)	0938-New	12	12	58.3	699	15.44	10,793	0	10,793
§495.210(b) (2011-2012)	0938-New	12	12	40	480	59.98	28,790	0	28,790
§495.306(a)(1)(i)	0938-New	119,000	119,000	0.5	59,500	79.33	4,720,135	0	4,720,135
§495.306(a)(1)(ii)(A)	0938-New	119,000	119,000	0.5	59,500	79.33	4,720,135	0	4,720,135
§495.306(a)(1)(ii)(B)	0938-New	3,631	3,631	0.5	1,816	79.33	144,024	0	144,024
§495.306(a)(2)	0938-New	3,631	3,631	0.5	1,816	14.11	25,617	0	25,617
§495.316	0938-New	56	56	5	280	100	28,000	0	28,000
§495.330(a) - high	0938-New	56	56	5	280	35.37	9,904	0	9,904
§495.330(a) - low	0938-New	56	56	5	280	14.11	3,951	0	3,951
§495.330(a) - average		56	56	5	280	24.74	6,927	0	6,927
§495.348(c)	0938-New	28	56	0.5	28	35.37	990	0	990
§495.348(e)	0938-New	28	56	0.5	28	35.37	990	0	990
§495.348(f)	0938-New	28	56	5	280	35.37	9,904	0	9,904
§495.350--high	0938-New	56	56	1	56	35.37	1,981	0	1,981
§495.350--low	0938-New	56	56	1	56	14.11	790	0	790
§495.350--average		56	56	1	56	24.74	1,385	0	1,385
§495.352--high	0938-New	56	56	5	280	35.37	9,904	0	9,904
§495.352--low	0938-New	56	56	5	280	14.11	3,591	0	3,591
§495.352--average		56	56	5	280	24.74	6,927	0	6,927
§495.366--high	0938-New	56	56	5	280	35.37	9,904	0	9,904
§495.366--low	0938-New	56	56	5	280	14.11	3,591	0	3,591
§495.366--average		56	56	5	280	24.74	6,927	0	6,927
Total 2011*					**4,413,559**		**340,479,335**	**42,300,000,000**	**42,640,480,720**
Total 2012*					**4,258,153**		**320,091,475**	**9,500,000,000**	**9,820,091,475**

Note: Where there are low, high, and average estimates listed for the provisions, only the average figures are used for the purpose of burden calculation

* Burden not otherwise designated by year, that is, 2011, 2012, or 2011-2012, is considered to be annual burden and is included in the sum total burden for both 2011 and 2012.

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If you comment on these information collection and recordkeeping requirements, please do either of the following:

Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–0033–P—Meaningful Use] Fax: (202) 395–5806; or E-mail: *OIRA_submission@omb.eop.gov.*

IV. Response to Comments

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

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the proposed impacts of this rule as required by Executive Order 12866, the Regulatory Flexibility Act (RFA), section 1102(b) of the Social Security Act regarding rural hospital impacts, the Unfunded Mandates Reform Act, Executive Order 13132 on Federalism, and the Congressional Review Act.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year). This proposed 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 RIA that to the best of our ability presents the costs and benefits of the proposed rule. We request comments on the analysis provided in this proposed rule.

This proposed rule is one of three coordinated rulemakings undertaken to implement the goals and objectives of the HITECH Act related to the adoption and meaningful use of certified EHR technology. The other two are HHS's interim final rule establishing certification criteria, standards, and implementation specifications for certification of EHR systems, and the proposed rule on EHR certification programs. Each rule will assess the direct economic effects of the provisions it creates. This proposed rule on Medicare and Medicaid EHR Incentive Programs addresses the impacts related to the actions taken by EPs or eligible hospitals to become meaningful users of certified EHR technology, including purchasing or developing in-house certified EHR technology or EHR technology modules.

A number of factors will affect the adoption of EHR systems and demonstration of meaningful use. Many of these are addressed in this analysis. Readers should understand that these forecasts are subject to substantial uncertainty. Demonstration of meaningful use will depend in part on the final provisions of these three rulemakings, which will depend in turn on comments we now solicit but have not yet received. These three rules deal primarily with standards and requirements for FYs 2011 and 2012, but overall rates of meaningful use of certified EHR technology will depend in part on future rulemakings issued by the HHS.

The HITECH Act provides incentives for the meaningful use of certified EHR technology. Additionally, the Medicaid program also provides incentives for the adoption, implementation, and upgrade of certified EHR technology. 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 penalties, 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 massive payment reductions under the sustainable growth rate (SGR) formula for determining Medicare payments. Under the current law, physician payments will be reduced by at least 21 percent beginning in CY 2010. Such reductions would almost certainly 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 would exert only a minor influence on physician behavior relative to these very large payment reductions. However, the Congress has legislatively avoided physician payment reductions in each of the past 7 years. Behavioral changes resulting from these scheduled physician payment reductions are not included in our estimate and likewise we do not assume any additional behavioral changes from EHR incentive payments for physicians.

All of these factors taken together make it impossible to predict with precision the timing or rates of adoption and ultimately meaningful use. Therefore, we present a range of estimates, which capture how different scenarios will impact overall costs. Our "high" scenario of meaningful use demonstration assumes that roughly a decade from now, nearly 100 percent of hospitals and 70 percent of EPs will be "meaningful users" in the Medicare EHR incentive program. This estimate is based on the substantial economic incentives created by the combined direct and indirect factors affecting providers. We appreciate that in the real world nothing is ever 100 percent, and can even identify factors that would certainly lead providers to forego implementing an EHR. For example, a physician nearing retirement with a low Medicare caseload might well decide to accept the relatively low adverse consequences of declining to demonstrate meaningful use of certified EHR technology. Alternatively, EPs and eligible hospitals and CAHs may choose not to adopt EHRs if the total costs of purchasing certified EHRs and the total costs of complying with this rule are higher than the value of the total EHR incentive payments (and adjustments, if applicable). However, we have no reliable basis for estimating the rate of such "holdouts." To emphasize the uncertainties involved, we have also created a "low" estimate for the demonstration of meaningful use each year. This might best be viewed as a more pessimistic view of the rate at which adoption approaches 100 percent.

Both the high and low estimates are based on current law. That is, we assume that the incentive payments and potential reimbursement reductions set forth in the HITECH Act will remain unchanged. We also assume that the scheduled physician payment

reductions will occur. We appreciate that this assumption reflects the standard practice used in forecasts of government spending (including effects on the private sector) by the Boards of Trustees for the Hospital Insurance and Supplementary Medical Insurance Trust Funds, the Social Security trustees, the Office of the Actuary in HHS, and the Congressional Budget Office. However, we note that if this assumption is rendered invalid by future Congressional action, the combination of positive and negative incentives in the HITECH Act are such that we believe adoption rates would differ from those estimated in this RIA.

There are many estimates of current EHR adoption and usage rates. There are at least two EHR functions—e-prescribing and billing—for which adoption and usage rates for both physicians and hospitals may exceed 50 percent. However, high estimates are misleading because they focus on particular elements, not on comprehensive systems that provide a full range of functions, similar in scope to those established in the companion interim final rule that adopts standards, implementation specifications, and certification criteria for the technical requirements and capabilities that EHR systems will need to meet in order to be certified. Based on several peer-reviewed studies, only a small proportion of physicians and hospitals have invested in EHR technology that encompasses such a broad range of functions. For example, a study entitled "Electronic Health Records in Ambulatory Care—A National Survey of Physicians" (Catherine DesRoches *et al.,* New England Journal of Medicine, July 3, 2008), found that in 2007 only "four percent of physicians reported having an extensive, fully functional electronic-records system, and 13 percent reported having a basic system." (Additional results from the same survey can be found at the Department's Health IT Adoption Initiative Web site at *http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&cached=true&objID=1152*) Another study entitled "Use of Electronic Health Records in U.S. Hospitals" (Ashish Jha *et al.,* New England Journal of Medicine, April 16, 2009) found that in 2007 "only 1.5 percent of U.S. hospitals have a comprehensive electronic-records system * * * and an additional 7.6 percent have a basic system." Computerized order entry for drugs was fully implemented in only 17 percent of hospitals.

Most physicians and hospitals have not yet invested in the hardware, software, testing and training to implement EHRs for a number of reasons—lack of standards, lack of interoperability, limited physician acceptance, fear of maintenance costs, and lack of capital. Perhaps most importantly, adoption of EHR technology necessitates major changes in business processes and practices throughout a provider's office or facility. Business process reengineering on such a scale is not undertaken lightly. However, the availability of the HITECH Act incentives, grants for technical support, more consistent use of standards and specified certification criteria, and other factors addressed in this RIA are sure to increase the adoption of EHR technology very substantially over the next 10 years—perhaps approaching complete adoption for physicians, hospitals, and many other types of providers.

Section II. of this proposed rule describes the categories of EPs, eligible hospitals, and CAHs under Medicare and Medicaid, and outlines the eligibility criteria, so those details are not repeated here.

Overall, we expect spending under the EHR incentive program for transfer payments to Medicare and Medicaid providers to be between $14 and $27 billion over 10 years (these estimates include net payment adjustments for providers who do not achieve meaningful use in 2015 and beyond in the amount of −$2.3 billion to −$5.1 billion). We have also estimated "per entity" costs for EPs and eligible hospitals, which aggregate to total spending. We estimate also that adopting entities will achieve dollar savings at least equal to their total costs, and that there will be additional benefits to society whose magnitude is uncertain, but will certainly be many billions of dollars over time.

While implementation costs will be significant for each participating entity, we anticipate that the short-term costs to demonstrate meaningful use of certified EHR technology will be outweighed by the long-term benefits, including practice efficiencies and improvements in medical outcomes. Although both cost and benefit estimates are highly uncertain, we have prepared a RIA that to the best of our ability presents the costs and benefits of the proposed rulemaking.

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires agencies to prepare an Initial Regulatory Flexibility Analysis to describe and analyze the impact of proposed 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 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 healthcare EPs, eligible hospitals, and CAHs are either non-profit 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 Initial Regulatory Flexibility Analysis. We welcome comments on the analysis.

We believe that the adoption of EHRs will have an impact on virtually every EP and eligible hospital, as well as CAHs and some physicians and hospitals affiliated with MA plans. 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 will be subject to significant Medicare payment reductions after the fifth year. The anticipation of these Medicare payment adjustments will also motivate EPs, eligible hospitals, and CAHs to adopt and meaningfully use certified EHR technology.

For some EPs and eligible hospitals, the EHR technology that they have in place before the HITECH requirements, will be able to 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 will also require an upgrade to meet the HITECH certification requirements.

We believe that most EPs using EHR systems will require significant changes to achieve certification and/or the EPs will have to make process changes to achieve meaningful use. Further, given what we know about the current low levels of EHR adoption, we believe that the majority of EPs will need to purchase certified EHR technology and implement this new technology and have their staff trained 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. Additionally EPs and eligible hospitals will have to demonstrate meaningful use of their certified EHR technology as defined in the preamble. Since the definition for stage 1 meaningful use has not yet been finalized and may be altered due to public comment, it is difficult to determine how hard it will be for providers to achieve meaningful use.

1. Number of Small Entities

In total, we estimate that there are approximately 624,000 healthcare organizations (EPs or eligible hospitals) 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, eligible non-physicians (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 MAO physicians or hospitals. We further estimate that EPs will spend approximately $54,000 to purchase a certified EHR and $10,000 annually for ongoing maintenance, while we estimate the hospitals will spend approximately $5 million to purchase a certified EHR and $1 million annually for ongoing maintenance. See the Assumptions section (section V.G.3 of this proposed rule) for details on our estimates for the number of entities that are eligible for the incentive, within each eligibility type category (EPs and eligible hospitals).

2. Alternatives Considered

This proposed rule implements new provisions of the Act for providing incentives for EPs, eligible hospitals, and CAHs that adopt and meaningfully use certified EHR technology. HHS has no discretion to change the incentive payments or payment reductions specified in the statute for providers that adopt or fail to adopt EHR and achieve meaningful use of EHR technology. The only substantial alternatives within the discretion of the Department revolve around how best to meet the requirements of the HITECH Act regarding requirements for meaningful use for FY 2011 and beyond. Requirements that are too stringent could have the adverse effect of preventing many EPs, eligible hospitals, and CAHs from achieving meaningful use and thus preventing them from receiving an incentive payment. Our meaningful EHR use requirements for 2011 are designed to encourage more widespread adoption of certified EHR technology and allow more EPs, eligible hospitals, and CAHs to qualify for incentives while they are also adjusting their practice patterns and training staff to operate the EHR technology in preparation for more stringent meaningful use requirements over time. We recognize that there may be incremental costs that result from requiring additional functionality over the base level defined in the ARRA. For example, ARRA does not require certified EHRs to include functionalities associated with administrative simplification, but we have proposed them in this rule. We have not been able to find research that allows us to quantify these incremental costs and request comments on possible estimates or further sources of information that will help us develop estimates.

We note that with regard to reporting of quality measures for purposes of demonstrating meaningful use, we considered requiring EPs, eligible hospitals, and CAHs to report quality measures electronically in the initial year of the program; however, ultimately we determined that many providers would not be able to comply with a requirement to report all quality measures at the beginning of the program. The alternative approach, consistent with the requirements of this proposed rule, is to require reporting of quality measures in phases. In 2011, there will be a requirement to report quality measures through attestation with a numerator and denominator. Electronic quality measure reporting will begin in CY 2012. Additional quality measure reporting will be added in later years.

Under Medicaid, we considered numerous alternatives regarding how to demonstrate eligibility for the incentive payments as well as adoption and meaningful use of the certified EHR technology. These alternatives, including the period for demonstrating adequate patient volume, and the requirements and methods for demonstrating meaningful use are discussed in section II.D. of this proposed rule.

3. 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. (The statute provides for hardship exemption in such cases.) Accordingly, we believe that the object of the RFA to minimize burden on small entities are met by this rule as proposed. We invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the EPs and eligible hospitals affected by the proposed rule.

C. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a RIA if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would affect the operations of a substantial number of small rural hospitals because they are required to adopt certified EHR technology by 2015, or face adjusted payments. As stated above, we have determined that this proposed rule would create a significant impact on a substantial number of small entities, and have prepared a Regulatory Flexibility Analysis as required by the RFA and, for small rural hospitals, section 1102(b) of the Act. Furthermore, any impacts that would arise from the implementation of certified EHR technology in a rural eligible hospital would be positive, with respect to the streamlining of care and the ease of sharing information with other EPs to avoid delays, duplication, or errors.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2009, that threshold is approximately $130 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 rule imposes no substantial mandates on States. 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 cost, 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 after FY 2015 are effectively mandates. We note that we have no discretion as to 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 $130 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. We welcome comments on any aspects of this proposed rule that mandate costs that could be reduced or ameliorated.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule would 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 to administer the program. As previously stated, we believe that those administrative costs are minimal. We note that this proposed rule does add a new business requirement for States, because of the systems that will need to be implemented to track and report on provider attestations, applications, and payments. States will also expend funds on the systems that must be built to conduct the tracking and reporting activities. However, the Federal share of the 90 percent match will protect the States from burdensome financial outlays.

F. Anticipated Effects

The objective of the remainder of this RIA is to summarize the costs and benefits of the HITECH incentive program for the Medicare FFS, Medicaid, and Medicare Advantage (MA) programs. We also provide assumptions and a narrative addressing the potential costs to the industry for implementation of this technology.

G. HITECH Impact Analysis

1. Need for Regulation

This proposed rule would implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology. The proposed rule would specify the—initial criteria an EP and eligible hospital must meet in order to qualify for the incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs and eligible hospitals failing to meaningfully use certified EHR technology; and other program participation requirements.

2. Alternatives Considered

As previously discussed in the alternatives section of the regulatory flexibility analysis, HHS has no discretion to change the incentive payments or payment reductions specified in the statute for providers that adopt or fail to adopt EHR and achieve meaningful use of EHR technology. However, the Department has discretion around how best to meet the HITECH Act requirements for meaningful use for FY 2011 and beyond.

We recognize that there may be additional costs that result from various discretionary policy choices such as requiring additional functionality over the base level defined in the ARRA. For example, ARRA does not require certified EHRs to include functionalities associated with administrative simplification, but we have proposed them in this rule. While ARRA also requires that certified EHRs have the capability to support CPOE, we have used our discretion in developing the "CPOE use" measure discussed in section III.

We have not been able to find research that allows us to quantify these incremental costs and request comments on possible estimates or further sources of information that will help us develop estimates (please refer to the analysis below as well as to the rightmost column in Table 33). In addition, we welcome information on benefits of specific provisions of this rule so that we can conduct, for the final rule, a more robust assessment of alternatives comparing incremental costs and benefits of each requirement.

3. Background and Assumptions

The principal costs of this proposed rule are the 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. 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 who are unable to demonstrate meaningful use starting in 2015; (2) the criteria for the demonstration of meaningful use of certified EHR technology have not been finalized and will change over time; (3) HHS has not yet defined certified EHR technology; (4) 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; and (5) the ultimate impact of certified EHR technology on expenditures for medical treatments (for example, reducing errors, expedited treatment) cannot be known with certainty at this time. The net costs and savings shown for this program represent a range of possible scenarios, and actual impacts could differ. We welcome public input on all aspects of the costs and benefits of this proposed rule.

As written in the preamble, this proposed rule describes the incentive payments for EPs, eligible hospitals, and CAHs for adopting and demonstrating meaningful use of certified EHR technology. This impact analysis addresses the costs and benefits to the Medicare and Medicaid programs, as

well as general implementation costs for eligible hospitals and EPs.

Detailed information about the incentive program, the specific payment amounts and how those payments will be paid, is provided in section II. of this proposed rule. Based on input from a number of internal and external sources, including the Government Accountability Office (GAO) and CBO, we calculated the numbers of EPs and eligible hospitals under Medicare, Medicaid, and MA and used them throughout the analysis.

- About 553,200 original Medicare FFS EPs in 2011 (some of which will also be Medicaid EPs).
- About 27 percent of the total EPs are hospital-based Medicare EPs, and are not eligible for the program. This leaves approximately 404,400 nonhospital-based Medicare EPs in 2011.
- Twenty percent of the nonhospital-based Medicare EPs (approximately 80,900 Medicare EPs in 2011) are also eligible for Medicaid (meet the 30 percent Medicaid patient volume criteria) but can only be paid under one program. Any EP in this situation will choose to receive the Medicaid incentive payment, because it is larger.
- About 38,200 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible non-physicians such as certified nurse-midwives, nurse practitioners and physicians assistants) will be eligible to receive the Medicaid incentive payments.
- 5,011 eligible hospitals, comprised of the following:
  - ++ 3,620 acute care hospitals.
  - ++ 1,302 CAHs (Medicare only).
  - ++ 78 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) would be eligible for incentive payments.
- Payments can begin as early as FY 2011.

4. Industry Costs and Adoption Rates

To estimate the impact on healthcare providers we used information from four studies cited previously. Based on these studies, we estimate for EPs, 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. Though reports vary widely, we anticipate that the average would be $5 million for installation. We estimate $1 million for maintenance, upgrades, and training each year. Though we cite these existing studies, we realize that these estimates vary widely, in part, because different providers have adopted different types of EHRs, each with their own set of functionalities. Because providers who would like to qualify as "meaningful users" of EHRs will need to purchase "certified EHRs," we further acknowledge that "certified EHRs" may differ in many important respects from the types of EHRs used in these studies and the functionalities they contained. For that reason, we welcome industry input on the costs of implementing and maintaining certified EHR technology. We would be particularly interested in estimates of what a "qualified EHR" as defined in ARRA would cost (that is, an EHR with the capability to collect and store patient demographic data and support CPOE, clinical decision support, and registry functions) for both EPs and hospitals. To the extent that there may be additional costs that result from various discretionary policy choices in this rulemaking, such as requiring additional functionality over the base level defined in the ARRA, we would be interested to know what those incremental additional costs may be.

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. We welcome comments on our estimates, including costs estimates and adoption rate estimates.

For an eligible Medicaid EP, the first year incentive is based in part on the adoption, implementation, and upgrade costs. Previously, we noted that section 1903(t)(4)(C) of the Act gives the Secretary the authority to determine average allowable costs for certified EHR technology. The Secretary is to study average costs associated with the purchase, initial implementation, and upgrade of certified EHR technology, including support services and initial training.

Sections 1903(t)(1)(A) and 1903(t)(4) of the Act specify that EPs may not receive incentive payments in excess of 85 percent of the net average allowable costs of certified EHR technology, with such net average allowable costs capped at $25,000 in the first year (for the purchase, implementation or upgrade of certified EHR technology) and $10,000 in each of the subsequent years.

a. Costs of EHR Adoption for EPs

Previously, we described four studies used to estimate costs of implementation including the purchase and installation of hardware and software, training, as well as productivity losses associated with implementation and training. Each of these studies was conducted several years ago, and did not control for type of EHR, functionality, physician practice type or size. Furthermore, EHRs were not being built against any particular consensus standard, nor was the concept of "meaningful use" a factor. Thus, the cost of implementing and maintaining certified EHR technology which meets the requirements established in this regulation might exceed the estimates from these studies.

One average estimate of the cost per physician for implementation is around $35,000. Therefore, in a practice with five physicians, the cost could be $175,000. A similar study of community health centers estimated costs to average $54,000 per physician FTE. In this study, the authors explained that implementation costs varied between entities for hardware, software, installation, and training. After implementation, there were ongoing operating costs estimated at $21,000 per year for a practice of four physicians. The CBO 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. In the CBO study, operating costs added $3,000 to $9,000 per physician per year. Finally, a 2005 paper from AHRQ stated that the average purchase and implementation cost of an EHR could be $32,606 per FTE physician. Maintenance costs were an additional $1,500 per physician, per month, or $18,000 per year. Smaller practices had the highest implementation costs per physician at $37,204. Based on the studies cited, eligible providers will be eligible to receive the maximum incentive permitted under the statute, because the implementation and maintenance costs

we have estimated exceed the caps for net average allowable costs set in the statute.

In calculating the impact of the EHR incentive program for Medicaid EPs, we assumed that approximately 20 percent of the EPs eligible for the Medicare incentive payment program are also eligible for Medicaid EHR incentive payments (about 80,000 in 2011). Since the Medicaid incentive payments are higher than those for Medicare are and EPs can only receive payments from on program, we assume the dually eligible EPs will receive their payments through the Medicaid program. Medicaid also offers incentive payments for pediatricians, dentists, certified nurse-midwives, nurse practitioners and certain physicians' assistants. While minimal, we have incorporated the sum of these groups in Table 51. We have estimated a range of Medicaid EPs that will be meaningful users each calendar year. The last line represents the range of predicted meaningful EHR users each calendar year. The Medicaid penetration rate for EPs is consistent with the analysis that was used for the Medicare EPs, but without the behavioral limitations imposed by the Medicare current statute SGR payment reductions. We assumed a modest behavioral response by Medicaid EPs to the Medicaid incentive payments resulting in an increase over baseline participation.

b. Costs of EHR Adoption for Eligible Hospitals

In 2006, the AHA conducted a survey to evaluate annual hospital costs: the range was enormous—ranging from $30,500 to $93.8 million, with a median amount of $3.8 million. In another article from HealthDayNews, EHR system costs 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 AHA study, nearly 3,050 U.S. hospitals were surveyed about the use of EHR systems. Only 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. Almost eight percent of hospitals had an EHR system that includes physician and nursing notes, but these systems did not have decision support. 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. Researchers found that 17 percent of the hospitals had the capacity for e-prescribing, a key feature in any modern day system. 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 the smallest of margins. Because uptake is low, it is difficult to get a solid average estimate for implementation and maintenance costs that can be applied across the industry.

Although we have provided some estimates on implementation/upgrade costs in this analysis, 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, administrative costs related to reporting, and the like are unknown at this time and difficult to quantify, we invite public comment and additional information to assist in our analysis. We also note that there may be EPs that voluntarily choose not to participate in the program, and that those EPs may anticipate potential costs resulting from that decision. Therefore, we have set a placeholder in our accounting statement at this time and request public comment on industry costs on those that may or may not choose to implement the program that could inform our analysis for the final rule.

We did not include cost estimates on Federal hospitals in this analysis, since the Veterans Affairs hospitals have already implemented comprehensive electronic health record systems. There may be costs if those systems have to be significantly upgraded to meet the certification criteria, but no estimates were gathered for this analysis.

5. Medicare Incentive Program Costs

a. Medicare Eligible Professionals (EPs)

To determine the estimated costs of the Medicare incentives for EPs we first needed to determine the EPs with Medicare claims. Then, we calculated that about 27 percent of those EPs are hospital-based based on the definition proposed in § 495.6, and therefore, do not qualify for incentive payments. They are subtracted from the total number of EPs who have claims with Medicare. These numbers were tabulated from Medicare claims data. We have also estimated that about 20 percent of EPs that are not hospital-based will qualify for Medicaid incentive payments and will choose that program because the payments are higher. Of the remaining EPs, we have 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 certified EHR technology are uncertain, so we established high and low scenario to account for high and low rates of demonstration of meaningful use.

The percentage of Medicare EPs who will satisfy the criteria for demonstrating meaningful use of certified EHR technology and will qualify for incentive payments is a key, but highly uncertain factor. Our Medicare EHR adoption assumptions for EPs are also affected by the current situation with Medicare physician fee schedule payment rates. As noted previously, under current law (that is, the SGR system formulas), physician payments will be reduced by at least 21 percent beginning in CY 2010. Such reductions would almost certainly 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 would exert only a minor influence on physician behavior relative to these very large payment reductions. Behavioral changes resulting from these scheduled payment reductions are not included in our estimate and likewise do not assume any additional behavioral changes from EHR incentive payments.

Accordingly, the estimated number of nonhospital based Medicare EPs who will demonstrate meaningful use of certified EHR technology over the period CYs 2011 through 2019 is as shown in Table 35.

TABLE 35—MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH AND LOW SCENARIO

	Calendar year								
	2011	2012	2013	2014	2015	2016	2017	2018	2019
EPs who have claims with Medicare (thousands)	553.2	558.9	564.6	570.3	576.0	581.7	587.5	593.3	599.0
Non-Hospital Based EPs (thousands)	404.4	408.6	412.7	416.9	421.1	425.3	429.5	433.7	437.9
EPs that are both Medicare and Medicaid EPs (thousands)	80.9	81.7	82.5	83.4	84.2	85.1	85.9	86.7	87.6
Low Scenario:									
Percent of EPs who are Meaningful Users	10	13	15	18	21	24	28	32	36
Meaningful Users (thousands)	33.8	41.3	49.8	59.5	70.3	82.4	95.6	110.0	125.4
High Scenario:									
Percent of EPs who are Meaningful Users	36	40	44	49	53	58	62	66	70
Meaningful Users (thousands)	115.8	131.0	146.8	163.1	179.7	196.4	212.9	229.0	244.6

Under the HITECH Act, EPs can receive up to 5 years of Medicare incentive payments for the meaningful use of certified EHR technology. These payments are the lesser of 75 percent of the physician's allowed charges for the year or a specified maximum amount, which declines from a possible $18,000 incentive payment for the first payment year to a $2,000 incentive payment for the fifth payment year. EPs in HPSAs receive incentives that are 10 percent higher than the maximum amounts. Hospital-based EPs are not eligible for the Medicare EP incentive payments. EPs may choose to receive incentive payments from either Medicare or Medicaid, but not from both.

The standard full amount of Medicaid incentive payments that an EP could receive is larger than the standard full amount for the Medicare EP incentive payments: about $65,000 versus $44,000 for Medicare. Details about the Medicaid payments are described in the section V.G.3 of this proposed rule. Medicare incentive payments can first be paid to EPs in CY 2011; and 2012 is the last year that an EP can start to receive incentives and obtain the full 5 years of payments. EPs who first qualify in CY 2013 would be limited to an incentive of $15,000 for the first year, and may be eligible to receive 4 years of incentive payments. EPs who first qualify in CY 2014 would be limited to an incentive of $12,000 for the first year and may be may be eligible to receive 3 years of incentive payments. For the Medicare program, incentives are not payable after CY 2016, and EPs who first demonstrate meaningful use in CY 2015 or later are not eligible for EHR incentive payments.

Medicare payment adjustments will apply in CY 2015 and later to EPs who cannot demonstrate meaningful use of certified EHR technology, regardless of whether they received an EHR incentive payment or not. Specifically, the Medicare Physician Fee Schedule payments for an EP who cannot demonstrate meaningful use of certified EHR technology would be reduced by 1 percentage point in CY 2015, two percentage points in CY 2016, and 3 percentage points in CY 2017, and between 3 and 5 percentage points in starting in CY 2018. The HITECH Act gives the Secretary the authority, beginning in CY 2018, to increase these reductions by 1 percentage point each year, but not more than 5 percentage points overall, if the Secretary finds the proportion of EPs who are meaningful EHR users is less than 75 percent.

Each year a transfer will be made between the general fund of the Treasury and the Part B account of the Supplemental Medical Insurance (SMI) trust fund to offset the incentives paid or payment adjustments made during the year. In this way, the Part B beneficiary premium will not be affected by the EP payment incentives.

We estimate that there are 12 MA plans that might be eligible to participate in the EHR incentive program. Those plans have about 28,000 EPs.

Our estimates of the incentive payment costs and payment adjustment savings reflect our assumptions about the proportion of EPs who will demonstrate meaningful user of certified EHR technology. These assumptions were developed based on a review of recent studies and discussions with subject matter experts. We project that a growing proportion of EPs will adopt certified EHR technology that meets the standards even in the absence of the legislated incentives. This number could be higher or lower depending on the final meaningful use definition adopted, physicians' access to capital and implementation expertise, the success of the other HITECH programs in reaching physicians, and other factors.

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). We took the estimated rate of

EHR adoption from the study with the most rigorous definition, assuming that meaningful use would be a standard at least as strict as that one (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). We then inflated that number (4 percent) to a 2011 baseline using the numbers of physicians reporting in that survey that they had EHR implementation underway. We assumed that the same proportion of them would be implementing fully-functional EHRs as in the baseline (30 percent of those with basic systems.) We then trended this number forward using the trajectory mapped out by Ford et al. using the data from the period prior to FY 2004 since the slower rate of adoption during the FY 2005 through 2007 period was thought to be caused by policy uncertainty which this regulation should resolve.

However, actual adoption trends could be significantly different from these assumptions, given the elements of uncertainty we describe throughout this analysis.

The estimated net costs for the low scenario of the Medicare EP portion of the HITECH Act are shown in Table 36. This provision is estimated to decrease Part B expenditures by a net total of $0.6 billion during FYs 2011 through 2019.

TABLE 36—ESTIMATED COSTS (+) AND SAVINGS (−) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, LOW SCENARIO

[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2009				
2010				
2011	$0.1			$0.1
2012	0.9			0.9
2013	0.8			0.8
2014	0.7			0.7
2015	0.5	−$0.4		0.1
2016	0.3	−0.6		−0.3
2017	0.1	−0.9		−0.8
2018		−1.0		−1.0
2019		−1.1		−1.1
Total, 2009–2014	2.4			2.4
Total, 2009–2019	3.2	−3.9		−0.6

The estimated net costs for the high scenario of the Medicare EP portion of the HITECH Act are shown in Table 37. This provision is estimated to increase Part B expenditures by a net total of $5.4 billion during FYs 2011 through 2019.

TABLE 37—ESTIMATED COSTS (+) AND SAVINGS (−) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO

[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2009				
2010				
2011	$0.3			$0.3
2012	2.2			2.2
2013	1.8			1.8
2014	1.5			1.5
2015	1.0	−$0.2		0.8
2016	0.6	−0.3		0.2
2017	0.1	−0.5		−0.4
2018		−0.5		−0.5
2019		−0.5		−0.5
Total, 2009–2014	5.8			5.8
Total, 2009–2019	7.5	−2.1		5.4

b. Medicare Eligible Hospitals

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 assumption about how rapidly hospitals would 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 admission 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 $9,000 to a high of $10.4 million, with the median being $3.6 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 2007 AHA annual 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 powerful 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 either neither CPOE or lab reporting. The CPOE for medication standard was chosen because expert input indicated that the CPOE standard in the proposed meaningful use definition will be the hardest one for hospitals to meet. Table 38 provides these proportions.

TABLE 38—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	146	18	372	47	274	35	792	23
Small/Medium	683	30	1,268	55	359	16	2,310	67
Large (400+ beds)	169	49	162	47	17	5	348	10
Total	998	29	1802	52	650	19	3,450	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 would 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. We request public input on the costs of adoption and attaining the meaningful use standard and the determinants of those costs.

Under the HITECH Act, an eligible hospital can receive up to 4 years of Medicare incentive payments for the demonstration of meaningful use of certified EHR technology. These payments reflect the ratio of Medicare inpatient days to total inpatient days and are adjusted by transition factors of 100, 75, 50, and 25 percent for the first through fourth implementation years respectively. Medicare incentive payments can first be paid to hospitals in FY 2011, and FY 2013 is the last year that a hospital can start to receive incentives and obtain the full 4-year transition rates. Eligible hospitals that first qualify in FY 2014 or FY 2015 will only receive the transition portions that apply to eligible hospitals who implement their EHR in FY 2013 (for example, 75 percent in FY 2014 and 50 percent in FY 2015). Eligible hospitals that first demonstrate meaningful use in FY 2016 or later are not eligible for incentive payments. Payment adjustments will be applied beginning in FY 2015 to eligible hospitals that cannot demonstrate meaningful use of certified EHR technology. Special rules apply to CAHs.

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.

Again due to uncertainties, we are providing ranges for our estimates. Our high scenario estimated net costs for section 4102 of the HITECH Act are shown in Table 39: Estimated costs (+) and savings (–) for eligible hospitals adopting certified EHRs. This provision is estimated to increase Medicare hospital expenditures by a net total of $11.2 billion during FYs 2011 through 2019.

TABLE 39—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO

[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2009				
2010				
2011	$2.4		(1)	$2.4
2012	2.7		(1)	2.7
2013	2.4		(1)	2.4
2014	2.3		(1)	2.3
2015	1.3	−$0.1	(1)	1.2
2016	0.5	−0.1	(1)	0.4
2017			(1)	(1)

TABLE 39—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO—Continued

[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2018	.....	.....	(1)	(1)
2019	.....	.....	(1)	(1)
Total, 2009–2014	9.8	.....	–0.1	9.7
Total, 2009–2019	11.6	–$0.2	–0.2	11.2

[1] Savings of less than $50 million.

We are also providing the estimates for a low scenario in Table 40.

TABLE 40—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, LOW SCENARIO

[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2009	.....	.....	.....	.....
2010	.....	.....	.....	.....
2011	$1.7	.....	(1)	$1.7
2012	1.6	.....	(1)	1.6
2013	1.5	.....	(1)	1.5
2014	1.8	.....	(1)	1.8
2015	1.4	–$0.4	(1)	1.0
2016	0.6	–0.3	(1)	0.3
2017	.....	–0.3	(1)	–0.3
2018	.....	–0.2	(1)	–0.2
2019	.....	.....	(1)	(1)
Total, 2009–2014	6.6	.....	–$0.1	6.5
Total, 2009–2019	8.6	–1.1	–0.2	7.4

[1] Savings of less than $50 million.

Based on the comparison of Medicare incentive payments and implementation/operating costs for each eligible hospital (described above), we made the assumptions shown in Table 41, related to the prevalence of certified EHR technology for FY 2011 through 2018. 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 41 shows the high scenario estimates:

TABLE 41—ASSUMED PROPORTION OF ELIGIBLE HOSPITALS WITH CERTIFIED EHR TECHNOLOGY, BY PERCENTAGE OF SYSTEM COST COVERED BY MEDICARE INCENTIVE PAYMENTS, HIGH SCENARIO

Fiscal year	Incentive payments as percentage of EHR technology cost				
	100+%	75–100%	50–75%	25–50%	0–25%
2011	0.8	0.5	0.3	0.2	0.1
2012	0.95	0.65	0.5	0.35	0.2
2013	1.0	0.8	0.7	0.6	0.4
2014	1.0	0.95	0.85	0.75	0.6
2015	1.0	1.0	0.95	0.9	0.8
2016	1.0	1.0	1.0	0.95	0.9
2017	1.0	1.0	1.0	1.0	0.95
2018	1.0	1.0	1.0	1.0	1.0

For instance, under the high scenario 50 percent of eligible hospitals whose incentive payments would cover between 75 percent and 100 percent of the cost of a certified EHR system were assumed to have a certified system in

FY 2011. In FY 2012, 65 percent of those hospitals were assumed to have a certified EHR system. All such hospitals were assumed to have a certified EHR system in FY 2015 and thereafter.

High rates of EHR adoption are anticipated prior to FY 2015 due to the large payment adjustments that will be imposed on eligible hospitals that are unable to demonstrate meaningful use beginning in FY 2015. Specifically, the Medicare "market basket" payment updates would be reduced (on a noncumulative basis) by one-fourth, one-half, and three-fourths for FYs 2015, 2016, and 2017 and later, respectively, for eligible hospitals that were not meaningful users of certified EHR technology. However, we heard 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, and so we provide a range which reflects what we believe are reasonably anticipated low to high rates of adoption.

Table 42 shows the low scenario estimates.

TABLE 42—ASSUMED PROPORTION OF ELIGIBLE HOSPITALS WITH CERTIFIED EHR TECHNOLOGY, BY PERCENTAGE OF SYSTEM COST COVERED BY MEDICARE INCENTIVE PAYMENTS, LOW SCENARIO

Fiscal year	Incentive payments as percentage of EHR technology cost				
	100+%	75–100%	50–75%	25–50%	0–25%
2011	0.6	0.35	0.2	0.2	0.05
2012	0.65	0.4	0.25	0.15	0.1
2013	0.75	0.55	0.4	0.25	0.15
2014	0.9	0.75	0.55	0.4	0.3
2015	1.0	0.9	0.75	0.6	0.5
2016	1.0	1.0	0.9	0.85	0.75
2017	1.0	1.0	0.95	0.9	0.85
2018	1.0	1.0	1.0	0.95	0.9
2019	1.0	1.0	1.0	1.0	1.0

For large, organized facilities such as hospitals, we believe that the revenue losses caused by these payment adjustments would be a substantial incentive to adopt certified EHR technology, even in instances where the Medicare incentive payments would 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 42, we estimated that the great majority of eligible hospitals would qualify for at least a portion of the Medicare incentive payments that they could potentially receive, and only a modest number would incur penalties. Nearly all eligible hospitals are projected to have implemented certified EHR technology by FY 2019. Table 43 shows our high scenario estimated range of 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 would actually be paid each year.

TABLE 43—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, HIGH SCENARIO

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2011	43.4	43.4
2012	58.5	58.5
2013	73.9	73.9
2014	84.8	84.8
2015	93.6	50.2
2016	97.3	35.1
2017	99.1	.....
2018	100.0	.....

For instance in FY 2012 under the high scenario, 58.5 percent of the total amount of incentive payments which could be payable in that year would be for eligible hospitals who have demonstrated meaningful use of certified EHR technology and therefore will be paid. In FY 2015 under the high scenario, 93.6 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 would have already received 4 years of incentive payments, and therefore 50.2 percent of all possible incentive payments actually paid in that year.

Table 44 shows the low scenario estimates.

TABLE 44—ESTIMATED PERCENTAGE OF MEDICARE INCENTIVES WHICH COULD BE PAID FOR THE MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE IN YEAR, LOW SCENARIO

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2011	30.5	30.5
2012	35.5	35.5
2013	46.2	46.2
2014	61.7	61.7
2015	77.8	47.3
2016	90.9	42.3
2017	94.5	.....
2018	97.3	.....

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 penalties 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 1,302 CAHs eligible to receive EHR incentives payments, and that will participate in the incentive program beginning in FY 2011. The statistics for their incentives are incorporated into the overall Medicare and Medicaid program costs.

6. Medicaid Incentive Program Costs

Under section 4201 of the HITECH Act, States can voluntarily participate in the Medicaid incentive payment program and we have based our Medicaid incentive program costs on all States participating. Eligible hospitals and EPs can also qualify for a Medicaid incentive payment for adopting, implementing, or upgrading and up to 5 years of incentive payments for demonstrating meaningful use certified EHR technology. Under Medicaid, EPs include physicians and pediatricians, dentists, certified nurse-midwives, nurse practitioners, and certain physician assistants. Initial incentive payments are available through 2016. The Medicaid hospital incentives are similar to those specified in section 4102 of the HITECH Act for Medicare, except that they are payable for up to 6 years based on the ratio of Medicaid inpatient days to total days, and are not phased down by the Medicare eligible hospital transition factors. Medicaid hospitals can begin incentive payments through 2016. There are also additional hospitals, such as children's and cancer hospitals that are only eligible for Medicaid incentives.

EPs may qualify for Medicaid incentive payments if at least 30 percent of their patient volume is from Medicaid. (Separate rules apply for pediatricians.) As mentioned above, the Medicaid maximum incentive payments are larger than the corresponding Medicare payments. Various maximums are specified for eligible hospital and EP incentive payments. There are no Medicaid penalties for nonadoption of EHR systems or for failing to demonstrate meaningful use. 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 45 shows our high estimates for the net Medicaid costs for eligible hospitals and EP.

TABLE 45—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (–) UNDER MEDICAID, HIGH SCENARIO

[In $billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2009	.....	.....	.....	.....
2010	.....	.....	.....	.....
2011	1.1	1.2	(1)	2.3
2012	1.2	0.9	(1)	2.1
2013	0.7	0.9	(1)	1.6
2014	0.4	0.9	(1)	1.3
2015	0.3	0.9	(1)	1.2
2016	0.2	1.0	(1)	1.2
2017	0.1	0.4	(1)	0.5
2018	0.0	0.3	(1)	0.3
2019	0.0	0.2	(1)	0.2
Total, 2009–2014	3.4	3.8	0.0	7.2
Total, 2009–2019	4.1	6.6	−0.1	10.6

[1] Savings of less than $50 million.

Table 46 shows the low estimates for Medicaid costs and savings.

TABLE 46—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (–) UNDER MEDICAID, LOW SCENARIO

[In $billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2009	.....	.....	.....	.....
2010	.....	.....	.....	.....
2011	0.7	0.6	(1)	1.3
2012	0.6	0.4	(1)	1.0
2013	0.4	0.4	(1)	0.9
2014	0.5	0.5	(1)	1.0
2015	0.6	0.5	(1)	1.1
2016	0.6	0.5	(1)	1.1
2017	0.3	0.2	(1)	0.5
2018	0.1	0.2	(1)	0.2
2019	0.0	0.1	(1)	0.1
Total, 2009–2014	2.3	1.9	0.0	4.2
Total, 2009–2019	3.8	3.5	–0.1	7.3

[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 above, we assumed that 20 percent of the non-hospital-based Medicare EPs would 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 that will be achieved. Therefore, as we estimated for the Medicare EPs, we are providing high and low scenario estimates for Medicaid EPs.

Our high scenario estimates are listed in the Table 47.

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TABLE 47: Assumed Number of Nonhospital Based Medicaid EPs Who Will Be Meaningful Users of Certified EHR Technology, High Scenario
(All population figures are in thousands)

		Calendar Year								
		2011	2012	2013	2014	2015	2016	2017	2018	2019
	EPs who have claims with Medicare	553.2	558.9	564.6	570.3	576.0	581.7	587.5	593.3	599.0
	Non Hospital –Based EPs (-27%)	404.4	408.6	412.7	416.9	421.1	425.3	429.5	433.7	437.9
A	EPs who meet the Medicaid patient volume threshold	80.9	81.7	82.5	83.4	84.2	85.1	85.9	86.7	87.6
B	Medicaid[1] only EPs	38.2	38.8	39.4	40.1	40.7	41.3	42.0	42.6	43.3
	Total Medicaid EPs (A + B)	119.1	120.5	122.0	123.4	124.9	126.4	127.9	129.3	130.8
	Percent of EPs receiving incentive payment during year	46.5%	61.6%	71.1%	76.8%	80.6%	84.3%	40.1%	25.0%	15.2%
	Number of EPs receiving incentive payment during year	55.4	74.2	86.7	94.8	100.7	106.6	51.2	32.4	19.9
	Percent of EPs who have ever received incentive payment	46.5%	61.6%	71.1%	76.8%	80.6%	84.3%	88.1%	91.9%	93.7%
	Number of EPs who have ever received incentive payment	55.4	74.2	86.7	94.8	100.7	106.6	112.7	118.9	122.6

[1] \Includes non hospital-based eligible pediatricians, dentists, certified nurse-midwives, nurse practitioners and physicians assistants. This number is not based on the tabulated Medicare data. It was arrived at by computing a ratio of certified nurse-midwives to total nurse-midwives in the States of New York and New Jersey and then applying that ratio to the country to arrive at the total number of Medicaid certified nurse-midwives. This same logic was also used for nurse practitioners and physicians assistants. The number of pediatricians and dentists is based on Medicaid provider historical experience and available studies. It should also be noted that in computing the hospital-based percentages, the 27 percent used for physicians was not applied across all providers types since the information available indicated that individual hospital-based percentage for certified nurse-midwives is 26 percent, nurse practitioners is 28 percent, and physicians assistants is 48 percent. We chose New York and New Jersey because we were able to obtain data from those States. We welcome comments with additional data sources to further refine the estimates.

Under the high scenario, we assumed an increase over baseline participation of Medicaid EPs because of the incentive payments, with the proportion of EPs ever receiving incentive payments increasing from 46.5 percent in CY 2011 to 93.7 percent by CY 2019. About 55,000 EPs are projected to qualify for incentive payments in CY 2011, resulting in a CY 2011 cost of about $1.2 billion. 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 is a meaningful user or because he or she is engaged in efforts to adopt, implement, or upgrade certified EHR technology, these participation rates include not only meaningful users but eligible providers implementing certified EHR technology as well. Table 48 shows our low scenario estimates.

TABLE 48: Assumed Number of Nonhospital Based Medicaid EPs Who Will Be Meaningful Users of Certified EHR Technology, Low Scenario
(All population figures are in thousands)

		Calendar Year								
		2011	2012	2013	2014	2015	2016	2017	2018	2019
	EPs who have claims with Medicare	553.2	558.9	564.6	570.3	576.0	581.7	587.5	593.3	599.0
	Non Hospital – Based EPs (-27%)	404.4	408.6	412.7	416.9	421.1	425.3	429.5	433.7	437.9
A	EPs who meet the Medicaid patient volume threshold	80.9	81.7	82.5	83.4	84.2	85.1	85.9	86.7	87.6
B	Medicaid[1] only EPs	38.2	38.8	39.4	40.1	40.7	41.3	42.0	42.6	43.3
	Total Medicaid EPs (A + B)	119.1	120.5	122.0	123.4	124.9	126.4	127.9	129.3	130.8
	Percent of EPs receiving incentive payment during year	25.4%	30.8%	35.1%	38.6%	41.7%	45.1%	20.9%	15.3%	10.8%
	Number of EPs receiving incentive payment during year	30.2	37.1	42.9	47.6	52.1	57.0	26.7	19.8	14.1
	Percent of EPs who have ever received incentive payment	25.4%	30.8%	35.1%	38.6%	41.7%	45.1%	48.8%	52.8%	56.2%
	Number of EPs who have received ever incentive payment	30.2	37.1	42.9	47.6	52.1	57.0	62.4	68.3	73.5

[1]Includes non hospital-based eligible pediatricians, dentists, certified nurse-midwives, nurse practitioners, and physicians assistants. This number is not based on the tabulated Medicare data. It was arrived at by computing a ratio of certified nurse-midwives to total nurse-midwives in the States of New York and New Jersey and then applying that ratio to the country to arrive at the total number of Medicaid certified nurse-midwives. This same logic was also used for nurse practitioners and physicians assistants. The number of pediatricians and dentists is based on Medicaid provider historical experience and available studies. It should also be noted that in computing the hospital-based percentages, the 27 percent used for physicians was not applied across all providers types since the information available indicated that individual hospital-based percentage for certified nurse-midwives is 26 percent, nurse practitioners is 28 percent, and physicians assistants is 48 percent. We chose New York and New Jersey because we were able to obtain data from those States. We welcome comments with additional data sources to further refine the estimates.

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b. Medicaid Hospitals

Medicaid incentive payments to most acute-care hospitals were estimated using the same adoption assumptions and methodology as described previously for Medicare eligible hospitals and shown in Table 49. 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 and children's hospitals can receive Medicaid incentive payments for no less than 3 years but no more than 6 years and 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 certified EHR technology are discussed under "general

considerations." We estimated the Medicaid incentives payable to children's hospitals as an add-on to the base estimate, using data on the number of children's hospitals compared to non-children's hospitals.

TABLE 49—ESTIMATED PERCENTAGE OF POTENTIAL MEDICAID INCENTIVES ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE EACH YEAR, HIGH SCENARIO

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2011	60.7	60.7
2012	75.5	75.5
2013	86.0	86.0
2014	91.5	30.8
2015	96.3	20.8
2016	98.3	12.3
2017	99.5	6.8
2018	100.0	2.0
2019	100.0	0.0

Table 50 shows our low scenario estimates.

TABLE 50—ESTIMATED PERCENTAGE OF POTENTIAL MEDICAID INCENTIVES ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE EACH YEAR, LOW SCENARIO

Fiscal year	Percent associated with eligible hospitals	Percent payable in year
2011	35.6	35.6
2012	40.6	40.6
2013	50.9	50.9
2014	66.8	31.2
2015	81.6	41.0
2016	92.6	41.7
2017	95.5	25.8
2018	97.4	11.0
2019	100.0	0.0

7. Benefits for All EPs and All Eligible Hospitals

In this proposed rule we have not quantified the overall benefits to the industry, nor to eligible hospitals or EPs in the Medicare, Medicaid, or MA programs. We believe that the first 5 years of the incentive program will be dedicated to implementation activities, from installation of the technology to training to operational and behavioral changes. Information on the costs and benefits of adopting systems specifically meeting the requirements in this rule does not yet exist—and information on costs and benefits overall is limited (Goldzweig *et al.* 2009 "Costs and Benefits of Health Information Technology: New Trends from the Literature" *Health Affairs.*) We would welcome industry input on the impact of this proposed rule on adoption, the costs of adopting and meeting the meaningful use criteria, and on resulting benefits to providers.

Nonetheless, 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. Furthermore, there is limited but growing evidence to support the cost saving benefits anticipated from wider adoption of EHRs. For example, at one hospital emergency room in Delaware, the ability to download and create a file with a patient's medical history saved the ER $545 per use, mostly on 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 Centers.) Some vendors have estimated that EHRs could result in cost savings of between $100 and $200 per patient per year. As 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.

Some vendors have estimated that EHRs could result in cost savings of between $100 and $200 per patient per year. As 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.

8. 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, they 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. Further, the report points out that there is a potential to gain both internal and external savings from widespread adoption of

health IT, noting that internal savings would 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. The benefits resulting specifically from this proposed regulation 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. We would welcome additional data on the costs and benefits of specific provisions of this rule and the incentive program as a whole so that we can conduct, for the final rule, a more robust assessment of societal benefits to determine whether the benefits of the regulation justify its costs (as directed by Executive Order 12866).

9. General Considerations

The estimates for the HITECH Act provisions were based on the economic assumptions underlying the President's 2010 Budget. Under the statute, Medicare incentive payments for certified EHR technology are excluded from the determination of MA capitation benchmarks. As noted previously, there is considerable uncertainty about the rate at which eligible hospitals and EPs will adopt EHRs and other HIT. Nonetheless, we believe that the Medicare incentive payments and the prospect of significant payment penalties for nonparticipation will result in the great majority of hospitals implementing certified EHR technology in the early years of the Medicare EHR incentive program. We expect that a steadily growing proportion of practices will implement certified EHR technology 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 will administer the requirements in such a way as to encourage adoption of certified EHR technology and facilitate qualification for incentive payments, and will adopt progressively demanding standards each 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 would achieve these efficiencies sooner than would otherwise occur, without the EHR incentives.

The CBO has estimated a modest level of such savings attributable to EHRs, with much of the amount associated with reductions in adverse drug-to-drug interactions. We believe that most of such savings will result from the existing statutory requirements for e-prescribing and that the acceleration of other efficiency savings will be relatively modest in comparison to the incentive and payment adjustments. 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.
- 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, 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 at this time. 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. We invite comments on all of our assumptions.

All financial analysis is calculated over a 10-year planning horizon, because though the incentive payments for Medicare EPs, CAHs and eligible hospitals will only be paid for 5 years, the Medicaid incentives will cease in CY 2021. Starting in CY 2015, payment adjustments will be made to the Medicare physician fee schedule.

10. Summary

The total cost to the Medicare and Medicaid programs is estimated to be range from $14.1 (low scenario) to 27.3 (high scenario) billion over a 10-year timeframe. 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 operations.

TABLE 51: Estimated EHR Incentive Payments and Benefits Impacts on the Medicare and Medicaid Programs of the HITECH EHR Incentive Program. (Fiscal Year) – (in billions) Low Scenario

Fiscal Year	Medicare Eligible		Medicaid Eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2011	$1.7	$0.1	$0.7	$0.6	$3.1
2012	$1.6	$0.9	$0.6	$0.4	$3.5
2013	$1.5	$0.8	$0.4	$0.4	$3.1
2014	$1.8	$0.7	$0.5	$0.5	$3.5
2015	$1.0	$0.1	$0.6	$0.5	$2.2
2016	$0.3	-$0.3	$0.6	$0.5	$1.1
2017	-$0.3	-$0.8	$0.3	$0.2	-$0.6
2018	-$0.2	-$1.0	$0.1	$0.2	-$0.9
2019	—	-$1.1	—	$0.1	-$1.0
TOTAL	**$7.4**	**-$0.6**	**$3.8**	**$3.5**	**$14.1**

Table 53 shows the total costs from 2009 through 2019 for the high scenario after which the payment adjustments will be invoked.

Table 52: Estimated EHR Incentive Payments and Benefits Impacts on the Medicare and Medicaid Programs of the HITECH EHR Incentive Program. (Fiscal Year) – (in billions)
High Scenario

Fiscal Year	Medicare Eligible		Medicaid Eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2011	$2.4	$0.3	$1.1	$1.2	$5.0
2012	$2.7	$2.2	$1.2	$0.9	$7.0
2013	$2.4	$1.8	$0.7	$0.9	$5.8
2014	$2.3	$1.5	$0.4	$0.9	$5.1
2015	$1.2	$0.8	$0.3	$0.9	$3.2
2016	$0.4	$0.2	$0.2	$1.0	$1.8
2017	—	-$0.4	$0.1	$0.4	$0.1
2018	—	-$0.5	—	$0.3	-$0.2
2019	—	-$0.5	—	$0.2	-$0.3
TOTAL	**$11.2**	**$5.4**	**$4.1**	**$6.6**	**$27.3**

11. Explanation of Benefits and Savings Calculations

In our analysis, we assume that benefits to the program would accrue in the form of savings to Medicare, through the Medicare EP payment adjustments. Expected qualitative benefits, such as improved quality of care, better health outcomes, reduced errors and the like, unable to be quantified at this time. We invite public comment on the subject of benefits to the Medicare and Medicaid programs.

H. 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 proposed rule. Monetary annualized benefits and non-budgetary 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. We invite public comments that may inform additional analysis on the subject of industry costs to implement EHR technology at the final rule stage.

TABLE 53: Accounting Statement: Classification of Estimated Expenditures CYs 2010 through 2019

	Category: Transfers	
Annualized Monetized	Low Estimate	High Estimate
7%	1,710.7 million	3,228.5 million
3%	1,536.9 million	2,960.4 million
From Whom to Whom	Federal government to eligible professionals and hospitals.	
	Category: Industry Costs Associated with Reporting Requirements	
	Low Estimate	High Estimate
	626.62 million	652.35 million
From Whom to Whom	Private industry.	
	Category: Other Industry Costs	
Annualized Monetized	Low Estimate	High Estimate
7%	TBD	TBD
3%	TBD	TBD
From Whom to Whom	Private industry.	

In accordance with the provisions of Executive Order 12866, this proposed rule 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 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, 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 & Medicare Services proposed to amend 42 CFR Chapter IV as follows:

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 Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

2. Section 412.64 is amended by—

A. Revising paragraph (d)(2)(i)(B).

B. Adding a new paragraphs (d)(2)(i)(C) and (d)(3).

The revision and additions read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(B) For fiscal year 2007 through 2014, by 2 percentage points.

(C) For fiscal year 2015 and subsequent fiscal years, by one-fourth.

* * * * *

(3) 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 of this chapter, three-fourth of the applicable percentage change specified in paragraph (d)(1) of this section is reduced—

(i) For fiscal year 2015, by 33⅓ percent;

(ii) For fiscal year 2016, by 66⅔ percent; and

(iii) For fiscal year 2017 and subsequent fiscal years, by 100 percent.

* * * * *

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).

Subpart E—Payments to Providers

4. Section 413.70 is amended by—

A. Revising paragraph (a)(1).

B. Adding new paragraphs (a)(5) and (a)(6).

The revision and additions read as follows:

§ 413.70 Payment for services of a CAH.

(a) *Payment for inpatient services furnished by a CAH (other than services of distinct part units).* (1) Effective for cost reporting periods beginning on or after January 1, 2004, payment for inpatient services of a CAH, other than services of a distinct part unit of the CAH and other than the items included in the incentive payment described in paragraph (a)(5) of this section and subject to the adjustments described in paragraph (a)(6) of this section, is 101 percent of the reasonable costs of the CAH in providing CAH services to its inpatients, as determined in accordance with section 1861(v)(1)(A)of the Act and the applicable principles of cost reimbursement in this part and in Part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH inpatient services:

(i) Lesser of cost or charges;

(ii) Ceilings on hospital operating costs;

(iii) Reasonable compensation equivalent (RCE) limits for physician services to providers; and

(iv) The payment window provisions for preadmission services, specified in § 412.2(c)(5) of this subchapter and § 413.40(c)(2) of this part.

* * * * *

(5) A qualifying CAH receives an incentive payment for the reasonable costs of purchasing certified EHR technology in a cost reporting period during a payment year as determined under § 495.106 of this chapter in lieu of payment for such reasonable costs under paragraph (a)(1) of this section.

(6)(i) For cost reporting periods beginning in or after FY 2015, if a CAH is not a qualifying CAH, as defined in § 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:

(A) For cost reporting periods beginning in FY 2015, 100.66 percent;

(B) For cost reporting periods beginning in FY 2016, 100.33 percent; and

(C) For cost reporting periods beginning in FY 2017 and each subsequent fiscal year, 100 percent.

(ii) A CAH may, on a case-by-case basis, be exempt from the application of the adjustments made under this paragraph, if CMS or its Medicare contractors determine, on an annual basis, that requiring the CAH to become a qualifying CAH under § 495.106 of this chapter would result in a significant hardship, such as in the case of a CAH in a rural area without sufficient Internet access.

(iii) In no case may a CAH be granted an exemption under this paragraph (a)(6) for more than 5 years.

(iv) There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

(A) The methodology and standards for determining the amount of payment under paragraph (a)(5) of this section.

(B) The methodology and standards for determining the amount of payment adjustments made under this paragraph (a)(6).

(C) The methodology and standards for determining a CAH to be a qualifying CAH under § 495.106 of this chapter.

(D) The methodology and standards for determining if the hardship exemption applies to a CAH under paragraph (a)(6)(ii) of this section.

(E) The specification of the cost reporting periods, payment years, or fiscal years as applied under this paragraph.

(F) The calculation of reasonable costs under § 495.106(c) of this chapter.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

5. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart G—Payments to Medicare Advantage Organizations

6. Section 422.304 is amended by adding a new paragraph (f) to read as follows:

§ 422.304 Monthly payments.

* * * * *

(f) *Separate payment for meaningful use of certified EHRs.* In the case of qualifying MA organizations, as defined in § 495.200 of this chapter, entitled to MA EHR incentive payments per § 495.220 of this chapter, such payments are made in accordance with sections 1853(l) and (m) of the Act and subpart C of Part 495 of this chapter.

7. Section 422.306 is amended by:

A. Removing "and" from the end of paragraph (b)(2)(ii);

B. Removing the period at the end of paragraph (b)(2)(iii) and adding "; and" in its place; and

C. Adding a new paragraph (b)(2)(iv) to read as follows:

§ 422.306 Annual MA capitation rates.

* * * * *

(b) * * *

(2) * * *

(iv) Adjusted to exclude costs attributable to payments under sections 1848(o) and 1886(n) of the Act of Medicare FFS incentive payments for meaningful use of electronic health records.

* * * * *

8. Section 422.308 is amended by—

A. Redesignating paragraph (a) as paragraph (a)(1).

B. Adding a new paragraph (a)(2).

The addition reads as follows:

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

* * * * *

(a) * * *

(2) The amount calculated in paragraph (a)(1) of this section must exclude expenditures attributable to sections 1848(a)(7) and (o) and sections 1886(b)(3)(B)(ix) and (n) of the Act.

* * * * *

9. Section 422.322 is amended by—

A. Adding paragraph (a)(3).

B. Revising paragraph (b).

§ 422.322 Source of payment and effect of MA plan election on payment.

(a) * * *

(3) Payments under subpart C of part 495 of this chapter for meaningful use of certified EHR technology are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. In applying section 1848(o) of the Act under sections 1853(l) and 1886(n)(2) of the Act under section 1853(m) of the Act, CMS determines the amount to the extent feasible and practical to be similar to the estimated amount in the aggregate that would be payable for services furnished by professionals and hospitals under Parts B and A, respectively, under title XVIII of the Act.

(b) *Payments to the MA organization.* Subject to § 412.105(g), § 413.86(d), and § 495.204 of this chapter and §§ 422.109, 422.316, and 422.320, CMS' payments under a contract with an MA organization (described in § 422.304) with respect to an individual electing an MA plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

* * * * *

SUBCHAPTER G—STANDARDS AND CERTIFICATIONS

10. A new part 495 is added to read as follows:

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

Subpart A—General Provisions

Sec.
495.2 Basis and purpose.
495.4 Definitions.
495.6 Meaningful use objectives measures for EPs, eligible hospitals, and CAHs.
495.8 Demonstration of meaningful use criteria
495.10 Participation requirements for EPs and eligible hospitals, and qualifying CAHs.

Subpart B—Requirements Specific to the Medicare Program

495.100 Definitions.
495.102 Incentive payments to EPs.
495.104 Incentive payments to eligible hospitals.
495.106 Incentive payments to CAHs.
495.108 Posting of required information.

Subpart C—Requirements Specific to Medicare Advantage (MA) Organizations

495.200 Definitions.
495.202 Identification of qualifying MA organizations, MA–EPs, and MA-affiliated eligible hospitals.
495.204 Incentive payments to qualifying MA organizations for MA–EPs and hospitals.
495.206 Timeframe for payment to qualifying MA organizations.
495.208 Avoiding duplicate payment.
495.210 Meaningful user attestation.
495.212 Limitation on review.

Subpart D—Requirements Specific to the Medicaid Program

495.300 Basis and purpose.
495.302 Definitions.
495.304 Medicaid provider scope and eligibility.
495.306 Establishing patient volume.
495.308 Net average allowable costs as the basis for determining the incentive payment.
495.310 Medicaid provider incentive payments.
495.312 Process for payments.
495.314 Activities required to receive an incentive payment.
495.316 State monitoring and reporting regarding activities required to receive an incentive payment.
495.318 State responsibilities for receiving FFP.
495.320 FFP for payments to Medicaid providers.
495.322 FFP for reasonable administrative expenses.
495.324 Prior approval conditions.
495.326 Disallowance of Federal financial participation (FFP).
495.328 Request for reconsideration of adverse determination.
495.330 Termination of Federal financial participation (FFP) for failure to provide access to information.
495.332 State Medicaid (HIT) plan requirements.
495.334 State self-assessment requirements.
495.336 Health information technology planning advance planning document requirements (HIT PAPD).
495.338 Health information technology implementation advance planning document requirements (HIT IAPD).
495.340 As-needed HIT PAPD update and as-needed HIT IAPD update requirements.
495.342 Annual HIT IAPD requirements.
495.344 Approval of the State Medicaid HIT plan, the HIT PAPD and update, the HIT IAPD and update, and the annual HIT IAPD.
495.346 Access to systems and records.
495.348 Procurement standards.
495.350 State Medicaid agency attestations.
495.352 Reporting requirements.
495.354 Rules for charging equipment.
495.356 Nondiscrimination requirements.
495.358 Cost allocation plans.
495.360 Software and ownership rights.
495.362 Retroactive approval of FFP with an effective date of February 18, 2009.
495.364 Review and assessment of administrative activities and expenses of Medicaid provider health information technology adoption and operation.
495.366 Financial oversight and monitoring of expenditures.
495.368 Combating fraud and abuse.
495.370 Appeals process for a Medicaid provider receiving electronic health record incentive payments.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 495.2 Basis and purpose.

This part implements the following:

(a) Section 1848(o) of the Act by establishing payment incentives under Medicare Part B for physicians and other professionals who adopt and meaningfully use certified electronic health record technology.

(b) Section 1853(1) of the Act to provide incentive payments to Medicare Advantage organizations for their affiliated professionals who meaningfully use certified EHR technology and meet certain other requirements.

(c) Section 1886(n) of the Act by establishing incentives payments for the meaningful use of certified EHR technology by subsection (d) hospitals, as defined under section 1886(d)(1)(B) of the Act, participating in Medicare FFS program.

(d) Section 1814(l) of the Act to provide an incentive payment to critical access hospitals who meaningfully use certified EHR technology based on the hospitals' reasonable costs.

(e) Section 1853(m) of the Act to provide incentive payments to MA organizations for certain affiliated hospitals that meaningfully use certified EHR technology.

(f) Sections 1903(a)(3)(F) and 1903(t) of the Act to provide 100 percent Federal financial participation (FFP) to States for incentive payments to certain eligible providers participating in the Medicaid program to purchase, implement, and operate (including support services and training for staff) certified EHR technology and 90 percent FFP for State administrative expenses related to such incentive payments.

(g) Sections 1848(a)(7), 1853(l)(4), 1886(b)(3)(ix)(1), and 1853(m)(4) of the Act, providing for payment reductions for inpatient services furnished on or after October 1, 2014 to Medicare beneficiaries by hospitals that are not meaningful users of certified electronic health record technology, and for covered professional services furnished on or after January 1, 2015 to Medicare beneficiaries by physicians and other professionals who are not meaningful users of certified electronic health record technology.

§ 495.4 Definitions.

In this part, unless otherwise indicated—

Certified electronic health record technology means a qualified EHR that meets the certification requirements specified in 45 CFR 170.102.

Critical access hospital (CAH) means a facility that has been certified as a critical access hospital under section 1820(e) of the Act and for which Medicare payment is made under section 1814(l) of the Act for inpatient services and under section 1834(g) of the Act for outpatient services.

EHR reporting period means either of the following:

(1) For an EP—

(i) For the first payment year, any continuous 90-day period within a calendar year;

(ii) For the second, third, fourth, fifth or sixth payment year, the calendar year.

(2) For an eligible hospital or a CAH—

(i) For the first payment year, any continuous 90-day period within a fiscal year; and

(ii) For the second, third, fourth, fifth or sixth payment year, the fiscal year.

Eligible hospital means an eligible hospital as defined under § 495.100 or Medicaid eligible hospital under subpart D of this part.

Eligible professional (EP) means an eligible professional as defined under § 495.100 or a Medicaid eligible professional under subpart D of this part.

Fifth payment year means the fifth payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

First payment year means the first payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

Fourth payment year means the fourth payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

Hospital-based EP is an EP (as defined under this section) who furnishes 90 percent or more of his or her covered professional services in the CY preceding the payment year in a hospital setting. A setting is considered a hospital setting if it is identified by the codes used in the HIPAA standard transactions that identifies the site of service as an inpatient hospital, outpatient hospital, or emergency room.

Meaningful EHR user means—

(1) An EP, eligible hospital or CAH that, for an EHR reporting period for a payment 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

(2) A Medicaid EP or Medicaid eligible hospital, that meets paragraph (1) of this definition and any additional criteria for meaningful use imposed by the State and approved by CMS under § 495.316 and § 495.332.

Payment year means—

(1) For an EP other than a Medicaid EP, a calendar year beginning with CY 2011; and

(2) For a CAH or an eligible hospital other than a Medicaid eligible hospital, a Federal fiscal year beginning with FY 2011.

(3) For a Medicaid EP,

(i) The timeframe specified in paragraph (1) of this definition; or

(ii) In accordance with subpart D of this part and with CMS approval, CY 2010.

(4) For a Medicaid eligible hospital,

(i) The timeframe specified in paragraph (2) of this definition; or

(ii) In accordance with subpart D of the part and with CMS approval, FY2010.

Qualified EHR means an electronic record of health related information on an individual that includes patient demographic and clinical health information, such as medical history and problem lists; and has the capacity to meet all of the following:

(1) Provide clinical decision support.

(2) Support physician order entry.

(3) Capture and query information relevant to health care quality.

(4) To exchange electronic health information with, and integrate such information from other sources.

Second payment year means the second payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

Sixth payment year means the sixth payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

Third payment year means the third payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

§ 495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs.

(a) *Stage 1 criteria for EPs*—(1) *General rule regarding Stage 1 criteria for meaningful use for EPs.* Except as specified in paragraph (a)(2) of this section, EPs must meet all objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (d) of this section to receive an incentive payment.

(2) *Exceptions for Medicaid EPs*—(i) *Exception for Medicaid EPs receiving payment in CY 2010.* If CMS has approved a State's request to begin providing incentive payments to EPs in CY 2010 for adopting, implementing or upgrading certified EHR technology, the objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (d) are applicable to an EP whose second payment year is CY 2011.

(ii) *Exception for Medicaid EPs who adopt, implement or upgrade in their first payment year.* For Medicaid EPs who adopt, implement, or upgrade certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (d) apply beginning with the second payment year, and do not apply to the first payment year.

(b) *Stage 1 criteria for eligible hospitals and CAHs*—(1) *General rule regarding Stage 1 criteria for meaningful use for eligible hospitals or CAHs.* Except as specified in paragraph (b)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (e) of this section to receive an incentive payment.

(2) Exception for Medicaid eligible hospitals. For Medicaid eligible hospitals who adopt, implement, or upgrade certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (e) apply beginning with the second payment year.

(c) *Stage 1 criteria for EPs and eligible hospitals or CAHs.* An EP, eligible hospital or CAH must satisfy the following objectives and associated measures:

(1)(i) *Objective.* Implement drug-drug, drug-allergy, drug-formulary checks.

(ii) *Measure.* The EP, eligible hospital or CAH has enabled this functionality.

(2)(i) *Objective.* Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT ®.

(ii) *Measure.* At least 80 percent of all unique patients seen by the EP or admitted to an eligible hospital or CAH have at least one entry or an indication of none recorded as structured data.

(3)(i) *Objective.* Maintain active medication list.

(ii) *Measure.* At least 80 percent of all unique patients seen by the EP or admitted by the eligible hospital or CAH have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data.

(4)(i) *Objective.* Maintain active medication allergy list.

(ii) *Measure.* At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH have at least one entry (or an indication of "none" if the patient has no medication allergies) recorded as structured data.

(5)(i) *Objective.* Record the following demographics:

(A) Preferred language.

(B) Insurance type.

(C) Gender.

(D) Race.

(E) Ethnicity.

(F) Date of birth.

(G) For eligible hospitals or CAHs, the date and cause of death in the event of mortality.

(ii) *Measure.* At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH have the demographics specified in paragraphs (c)(5)(i)(A) through (G) of this section recorded as structured data.

(6)(i) *Objective.* (A) Record and chart changes in the following vital signs:

(*1*) Height.

(*2*) Weight.

(*3*) Blood pressure.

(B) Calculate and display the body mass index (BMI) for patients 2 years and older.

(C) Plot and display growth charts for children 2 to 20 years including body mass index.

(ii) *Measure.* For at least 80 percent of all unique patients age 2 years or older seen by the EP or admitted to the eligible hospital, record blood pressure and BMI and plot the growth chart for children age 2 to 20 years old.

(7)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* At least 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital or CAH have "smoking status" recorded.

(8)(i) *Objective.* Incorporate clinical lab-test results into EHR as structured data.

(ii) *Measure.* At least 50 percent of all clinical lab tests results ordered by the EP or authorized provider of the hospital during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

(9)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research and outreach.

(ii) *Measure.* Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.

(10)(i) *Objective.* Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.

(ii) *Measure.* Implement five clinical decision support rules relevant to the clinical quality metrics reported under this subpart.

(11)(i) *Objective.* Check insurance eligibility electronically from public and private payers.

(ii) Measure. Insurance eligibility is checked electronically for at least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH.

(12)(i) *Objective.* Submit claims electronically to public and private payers.

(ii) *Measure.* At least 80 percent of all claims filed electronically by the EP or the eligible hospital or CAH.

(13)(i) *Objective.* Perform medication reconciliation at relevant encounters and each transition of care.

(ii) *Measure.* Perform medication reconciliation for at least 80 percent of relevant encounters and transitions of care.

(14)(i) *Objective.* Provide summary care record for each transition of care and referral.

(ii) *Measure.* Provide summary of care record for at least 80 percent of transitions of care and referrals.

(15)(i) *Objective:* Capability to submit electronic data to immunization registries and actual submission where required and accepted.

(ii) *Measure:* Performed at least one test of certified EHR technology's capability to submit electronic data to immunization registries.

(16)(i) *Objective.* Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically).

(17)(i) *Objective.* Protect electronic health information created or maintained by 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) and implement security updates as necessary.

(d) *Additional Stage 1 criteria for EPs.* An EP must meet the following objectives and associated measures:

(1)(i) *Objective.* Use computerized provider order entry (CPOE).

(ii) *Measure.* CPOE is used for at least 80 percent of all orders.

(2)(i) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(ii) *Measure.* At least 75 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.

(3)(i) *Objective.* Report ambulatory quality measures to CMS or, in the case of Medicaid EPs, the States.

(ii) *Measure.* Successfully report to CMS (or, in the case of Medicaid EPs, the States) clinical quality measures in the form and manner specified by CMS.

(4)(i) *Objective.* Send reminders to patients per patient preference for preventive/follow-up care.

(ii) *Measure.* Reminder sent to at least 50 percent of all unique patients seen by the EP that are 50 years of age and over.

(5)(i) *Objective.* Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, and allergies) upon request.

(ii) *Measure.* At least 80 percent of all patient requests for an electronic copy of their health information are provided it within 48 hours.

(6)(i) *Objective.* Provide patients with timely electronic access to their health information (including diagnostic test results, problem list, medication lists, and allergies) within 96 hours of the information being available to the EP.

(ii) *Measure.* At least 10 percent of all unique patients seen by the EP are provided timely electronic access to their health information.

(7)(i) *Objective.* Provide clinical summaries to patients for each office visit.

(ii) *Measure.* Clinical summaries provided to patients for at least 80 percent of all office visits.

(8)(i) *Objective.* Capability to exchange key clinical information among providers of care and patient authorized entities electronically.

(ii) *Measure.* Perform at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(e) *Additional Stage 1 criteria for eligible hospitals or CAHs.* Eligible hospitals or CAHs must meet the following objectives and associated measures:

(1)(i) *Objective.* Use computerized provider order entry (CPOE) for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP).

(ii) *Measure.* CPOE is used for at least 10 percent of all orders.

(2)(i) *Objective.* Report hospital quality measures to CMS or, in the case of Medicaid eligible hospitals, the States.

(ii) *Measure.* Successfully report to CMS (or, in the case of Medicaid eligible hospitals, the States) clinical quality measures in the form and manner specified by CMS.

(3)(i) *Objective.* Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, and procedures), upon request.

(ii) *Measure.* At least 80 percent of all patient requests for an electronic copy of their health information are provided it within 48 hours

(4)(i) *Objective.* Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

(ii) *Measure.* At least 80 percent of all patients who are discharged from an eligible hospital or CAH and who request an electronic copy of their discharge instructions and procedures are provided it.

(5)(i) *Objective.* Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, and diagnostic test results) among providers of care and patient-authorized entities electronically.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(6)(i) *Objective.* Capability to provide electronic submission of reportable lab results (as required by State or local

law) to public health agencies and actual submission where it can be received.

(ii) *Measure.* Performed at least one test of certified EHR technology capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which the eligible hospital submits such information have the capacity to receive the information electronically).

§ 495.8 Demonstration of meaningful use criteria.

(a) *Demonstration by EPs.* An EP must demonstrate that he or she satisfies each of the applicable objectives and associated measures under § 495.6 of this subpart as follows:

(1) For CY 2011,

(i) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State), that during the EHR reporting period, the EP used certified EHR technology, and specify the technology used.

(ii) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State), that during the EHR reporting period, the EP satisfied each of the applicable objectives and associated measures under § 495.6 of this part. The EP must specify the EHR reporting period and provide the result of each applicable measure for all patients seen during the EHR reporting period for which a selected measure is applicable.

(iii) For Medicaid EPs, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, demonstrate meeting such criteria using the method approved by CMS.

(iv) *Exception for Medicaid EPs.* If a Medicaid EP has adopted, implemented or upgraded certified EHR technology described in § 495.4 of this subpart, the provider must demonstrate meaningful use in the second payment year as described in § 495.6 and § 495.8 of this subpart.

(2) For CY 2012 and subsequent years—

(i) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State) that during the EHR reporting period, the EP used certified EHR technology and specify the technology used.

(ii) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State), that during the EHR reporting period, the EP satisfied each of the applicable objectives and associated measures under § 495.6, except § 495.6(d)(3) "Report ambulatory quality measures to CMS or, in the case of Medicaid EPs, the states."

(iii) For § 495.6(d)(3), "Report ambulatory quality measures to CMS or, in the case of Medicaid EPs, the States", report electronically to CMS (or in the case of Medicaid EPs, the States) clinical quality information in the form and manner specified by CMS.

(iv) For Medicaid EPs, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, demonstrate meeting such criteria using the method approved by CMS.

(b) *Demonstration by eligible hospitals and CAHs.* To successfully demonstrate meaningful use an eligible hospital or CAH must the following requirements:

(1) For FY 2011—

(i) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the eligible hospital or CAH used certified EHR and specify the technology used.

(ii) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the eligible hospital or CAH satisfied each of the applicable objectives and associated measures under § 495.6. The eligible hospital or CAH must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the eligible hospital during the EHR reporting period for which a selected measure is applicable.

(iii) *Exception for Medicaid eligible hospitals.* If a Medicaid eligible hospital has adopted, implemented or upgraded certified EHR technology for the first payment year, the eligible hospital must demonstrate meaningful use in the second payment year, see § 495.6 and § 495.8.

(iv) For hospitals participating in the Medicaid EHR incentive program, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, demonstrate meeting such criteria using the method approved by CMS.

(2) For FY 2012 and subsequent years must—

(i) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the eligible hospital or CAH used certified EHR and specify the technology used.

(ii) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the eligible hospital or CAH satisfied each of the applicable objectives and associated measures under § 495.6 except § 495.6(e)(2). The eligible hospital or CAH must specify the EHR reporting period and provide the result of each applicable measure, except for § 495.6(e)(2) "Report hospital quality measures to CMS or, in the case of Medicaid eligible hospitals, the States:"

(iii) For § 495.6(e)(2) "Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States," report electronically to CMS (or in the case of Medicaid eligible hospitals, the States), clinical quality measures in the form and manner specified by CMS.

(iv) For Medicaid hospitals if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, demonstrate meeting such criteria using the method approved by CMS.

(c) *Review of meaningful use.* (1) CMS may review an EP, eligible hospital or CAH's demonstration of meaningful use.

(2) EPs, eligible hospitals, and CAHs must keep documentation supporting their demonstration of meaningful use for 10 years.

§ 495.10 Participation requirements for EPs, eligible hospitals, and CAHs.

(a) An eligible hospital, CAH or EP must submit in a manner specified by CMS the following information in the first payment year:

(1) Name of the EP, eligible hospital or CAH.

(2) National Provider Identifier (NPI).

(3) Business address and phone number.

(b) In addition to the information submitted under paragraph (a) of this section, an eligible hospital or CAH, must, in the first payment year, submit in a manner specified by CMS its CMS Certification Number (CCN) and its Taxpayer Identification Number (TIN).

(c) Subject to paragraph (f) of this section, in addition to the information submitted under paragraph (a) of this section, an EP must submit in a manner specified by CMS, the Taxpayer Identification Number (TIN) to which the EP's incentive payment should be made.

(d) In the event the information specified in paragraphs (a) through (c) of this section as previously submitted to CMS is no longer accurate, the EP or

eligible hospital must provide updated information to CMS or the State on a timely basis in the manner specified by CMS or the State.

(e) An EP that qualifies as both a Medicaid EP and Medicare EP—

(1) Must notify CMS in the manner specified by CMS as to whether he or she elects to participate in the Medicare or the Medicaid EHR incentive program.

(2) Is limited to switching between programs one time, and only for payment years 2014 and before;

(3) Must, for each payment year, meet all of the Medicare or Medicaid applicable requirements, including applicable patient volume requirements, for the program he or she chooses to participate in;

(4) Is limited to receiving, in total, the maximum payments the EP would receive under the Medicaid EHR program, as described in subpart D of this part;

(5) Is placed in the payment year the EP would have been in, had the EP not switched programs. For example, an EP that begins receiving Medicaid incentive payments in 2011, and then switches to the Medicare program for 2012, is in his or her second payment year in 2012.

(f) Limitations on incentive payment reassignments. Section 1842(b)(6)(A) of the Act allows for the reassignment of payments under Medicare to an employer or entity with which the EP has a contractual arrangement allowing the employer or entity to bill and receive payment for the EP's covered professional services.

(1) EPs are permitted to reassign their incentive payments to their employer or to an entity with which they have a contractual arrangement, consistent with all rules governing reassignments including part 424, subpart F of this chapter.

(2) Each EP may only reassign the entire amount of the incentive payment to one employer or entity.

Subpart B—Requirements Specific to the Medicare Program

§ 495.100 Definitions.

In this subpart unless otherwise indicated—

Covered professional services means services furnished by an eligible professional for which payment is made under, or is based on, the Medicare physician fee schedule as provided in section 1848(k)(3) of the Act.

Eligible hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter, excluding those hospitals specified in § 412.23 of this chapter.

Eligible professional (EP) means a physician as defined in section 1861(r) of the Act, which includes all of the following types of professionals:

(1) A doctor of medicine or osteopathy.

(2) A doctor of dental surgery or medicine.

(3) A doctor of podiatric medicine.

(4) A doctor of optometry.

(5) A chiropractor.

Geographic health professional shortage area (HPSA) means an area that is designated by the Secretary under section 332(a)(1)(A) of the PHS Act as of December 31 of the year prior to the payment year as having a shortage of health professionals.

Qualifying CAH means a CAH that is a meaningful EHR user for the EHR reporting period for a cost reporting period beginning during a payment year.

Qualifying eligible professional (EP) means an EP who is a meaningful EHR user for the EHR reporting period for a payment year and who is not a hospital-based EP.

Qualifying hospital means an eligible hospital that is a meaningful EHR user for the EHR reporting period for a payment year.

§ 495.102 Incentive payments to EPs.

(a) *General rules.* (1) Subject to paragraph (b) of this section, in addition to the amount otherwise paid under section 1848 of the Act, there shall be paid to a qualifying eligible professional (or to an employer or entity in the cases described in section 1842(b)(6)(A) of the Act) for a payment year an amount equal 75 percent of the estimated allowed charges under the physician fee schedule (established under section 1848 of the Act) for the covered professional services furnished by the EP during the payment year.

(2) For purposes of this paragraph (a), the estimated allowed charges for the qualifying EP's covered professional services during the payment year are determined based on claims submitted no later than 2 months after the end of the payment year, and, in the case of a qualifying EP who furnishes covered professional services in more than one practice, are determined based on claims submitted for the EP's covered professional services across all such practices.

(b) *Limitations on amounts of incentive payments.*

(1) Except as otherwise provided in paragraph (b)(2) and paragraph (c) of this section, the amount of the incentive payment that a qualifying EP can receive for each payment year is limited to the following amounts:

(i) For the first payment year, $15,000 (or, if the first payment year for such qualifying eligible professional is 2011 or 2012, $18,000).

(ii) For the second payment year, $12,000.

(iii) For the third payment year, $8,000.

(iv) For the fourth payment year, $4,000.

(v) For the fifth payment year, $2,000.

(vi) For any succeeding payment year for such professional, $0.

(2)(i) If the first payment year for a qualifying eligible professional is 2014, then the amount for a payment year for a qualifying EP is the same as the amount specified for such payment year for a qualifying EP whose first payment year is 2013.

(ii) If the first payment year for a qualifying EP is after 2014, then the applicable amount specified in this paragraph for such professional for such year and any subsequent year must be $0.

(c) *Increase in incentive payment limit for EPs who predominantly furnish services in a geographic HPSA.* In the case of a qualifying eligible professional who in the year prior to the payment year furnishes more than 50 percent of his or her covered professional services in a geographic HPSA, the annual 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) Subject to paragraph (d)(3) of this section, beginning in 2015, for covered professional services furnished by an EP who is not a qualifying EP or a hospital-based EP for the year, the payment amount for such services is equal the product of the applicable percent specified in paragraph (d)(2) and the Medicare physician fee schedule amount for such services.

(2) *Applicable percent.* Applicable percent is as follows:

(i) For 2015, 99 percent if the eligible professional is not subject to the payment adjustment for an eligible professional who is not a successful electronic prescriber under section 1848(a)(5) of the Act, or 98 percent if the eligible professional is subject to the payment adjustment for an eligible professional who is not a successful electronic prescriber under section 1848(a)(5) of the Act).

(ii) For 2016, 98 percent.

(iii) For 2017 and each subsequent year, 97 percent.

(3) *Significant hardship exception.* The Secretary may, on a case-by-case basis, exempt an EP who is not a qualifying 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. The Secretary's determination to grant an EP an exemption under this paragraph (d)(3) may be renewed on an annual basis, provided that in no case may an EP be granted an exemption under this paragraph (d)(3) for more than 5 years.

§ 495.104 Incentive payments to eligible hospitals.

(a) *General rule.* A qualifying hospital (as defined in this subpart) shall receive the special incentive payment as determined under the formulas described in paragraph (c) of this section for the period specified in paragraph (b) of this section.

(b) *Transition periods.* Subject to the payment formula specified in paragraph (e) of this section, qualifying hospitals may receive incentive payments during transition periods which comprise the following fiscal years:

(1) Hospitals whose first payment year is FY 2011 may receive such payments for FYs 2011 through 2014.

(2) Hospitals whose first payment year is FY 2012 may receive such payments for FYs 2012 through 2015.

(3) Hospitals whose first payment year is FY 2013 may receive such payments for FYs 2013 through 2016.

(4) Hospitals whose first payment year is FY 2014 may receive such payments for FY 2014 through 2016.

(5) Hospitals whose first payment year is FY 2015 may receive such payments for FY 2015 through 2017.

(c) *Payment methodology.* (1) The incentive payment for each payment year is calculated as the product of the following:

(i) The initial amount determined under paragraph (c)(3) of this section;

(ii) The Medicare share fraction determined under paragraph (c)(4) of this section; and

(iii) The transition factor determined under paragraph (c)(5) of this section.

(2) *Interim and final payments.* CMS uses data on hospital discharges (as that term is defined in § 412.4(a) of this chapter), Medicare Part A inpatient-bed-days, Medicare Part C inpatient-bed-days, and total inpatient-bed-days, from the hospital cost report for the hospital fiscal year that ends during the Federal fiscal year prior to the fiscal year that serves as the payment year as the basis for making preliminary incentive payments. Final payments are determined at the time of settling the hospital cost report for the hospital fiscal year that ends during the payment year, and settled on the basis of data from that cost reporting period.

(3) *Initial amount.* The initial amount is equal to one of the following:

(i) For each hospital with 1,149 discharges or fewer during the fiscal year prior to the payment year, $2,000,000.

(ii) For each hospital with at least 1,150 but no more 23,000 discharges during the payment year, $2,000,000 + [$200 × (n − 1,149)], where n is the number of discharges for the hospital during the fiscal year prior to the payment year.

(iii) For each hospital with more than 23,000 discharges for the fiscal year prior to the payment year, $6,370,400.

(4) *Medicare share fraction*— (i) *General.* (A) CMS determines the Medicare share fraction by using the number of Medicare Part A, Medicare Part C, and total inpatient-bed-days using data from the Medicare cost report as specified by CMS.

(B) CMS computes the denominator of the Medicare share fraction using the charity care charges reported on the hospital's Medicare cost report.

(ii) The Medicare share fraction is the ratio of—

(A) A numerator which is the sum of—

(*1*) The number of inpatient-bed-days during the period which are attributable to individuals with respect to whom payment may be made under Part A; and

(*2*) The number of inpatient-bed-days during the period which are attributable to individuals who are enrolled with a Medicare Advantage organization (as defined in § 422.2 of this chapter).

(iii) A denominator which is the product of—

(A) The total number of inpatient-bed-days during the period; and

(B) The total amount of the eligible hospital's charges during the period, not including any charges that are attributable to charity care divided by the estimated total amount of the hospitals charges during the period.

(5) *Transition factor.* For purposes of the payment formula, the transition factor is as follows:

(i) For hospitals whose first payment year is FY 2011—

(A) 1 for FY 2011;

(B) ¾ for FY 2012;

(C) ½ for FY 2013; and

(D) ¼ for FY 2014.

(ii) Hospitals whose first payment year is FY 2012—

(A) 1 for FY 2012;

(B) ¾ for FY 2013;

(C) ½ for FY 2014; and

(D) ¼ for FY 2015;

(iii) Hospitals whose first payment year is FY 2013—

(A) 1 for FY 2013;

(B) ¾ for FY 2014;

(C) ½ for FY 2015; and

(D) ¼ for FY 2016.

(iv) Hospitals whose first payment year is FY 2014—

(A) ¾ for FY 2014;

(B) ½ for FY 2015; and

(C) ¼ for FY 2016.

(v) Hospitals whose first payment year is FY 2015—

(A) ½ for FY 2015; and

(B) ¼ for FY 2016.

§ 495.106 Incentive payments to CAHs.

(a) *Definitions.* In this section, unless otherwise indicated—

Payment year means a Federal fiscal year beginning after FY 2010 but before FY 2016.

Qualifying CAH means a CAH that would meet the definition of a meaningful EHR user at § 495.4, if it were an eligible hospital.

Reasonable costs incurred for the purchase of certified EHR technology for a qualifying CAH means the reasonable acquisition costs incurred for the purchase of depreciable assets as described in part 413 subpart G of this chapter, such as computers and associated hardware and software, necessary to administer certified EHR technology as defined in § 495.4, excluding any depreciation and interest expenses associated with the acquisition.

(b) *General rule.* A qualifying CAH receives an incentive payment for its reasonable costs incurred for the purchase of certified EHR technology, as defined in paragraph (a) of this section, in the manner described in paragraph (c) of this section for a cost reporting period beginning during a payment year as defined in paragraph (a) of this section.

(c) *Payment methodology*— (1) *Payment amount.* A qualifying CAH receives an incentive payment amount equal to the product of its reasonable costs incurred for the purchase of certified EHR technology and the Medicare share percentage.

(2) *Calculation of reasonable costs.* CMS or its Medicare contractor computes a qualifying CAH's reasonable costs incurred for the purchase of certified EHR technology, as defined in paragraph (a) of this section, as the sum of—

(i) The reasonable costs incurred for the purchase of certified EHR technology during the cost reporting period that begins in a payment year; and

(ii) Any reasonable costs incurred for the purchase of certified EHR technology in cost reporting periods beginning in years prior to the payment

year which have not been fully depreciated as of the cost reporting period beginning in the payment year.

(3) *Medicare share percentage.* Notwithstanding the percentage applicable under § 413.70(a)(1) of this chapter, the Medicare share percentage equals the lesser of—

(i) 100 percent; or

(ii) The sum of the Medicare share fraction for the CAH as calculated under § 495.104(c)(3) of this subpart and 20 percentage points.

(d) *Incentive payments made to CAHs.* (1) The amount of the incentive payment made to a qualifying CAH under this section represents the expensing and payment of the reasonable costs computed in paragraph (c) of this section in a single payment year and, as specified in § 413.70(a)(5) of this chapter, such payment is made in lieu of payment that would have been made under § 413.70(a)(1) of this chapter for the reasonable costs of the purchase of certified EHR technology including depreciation and interest expenses associated with the acquisition.

(2) The amount of the incentive payment made to a qualifying CAH under this section is paid through a prompt interim payment for the applicable payment year after—

(i) The CAH submits the necessary documentation, as specified by CMS or its Medicare contractors, to support the computation of the incentive payment amount under this section; and

(ii) CMS or its Medicare contractor reviews such documentation and determines the interim amount of the incentive payment.

(3) The interim incentive payment made under this paragraph is subject to a reconciliation process as specified by CMS and the final incentive payment as determined by CMS or its Medicare contractor is considered payment in full for the reasonable costs incurred for the purchase of certified EHR technology in a single payment year.

(4) In no case may an incentive payment be made with respect to a cost reporting period beginning during a payment year before FY 2011 or after FY 2015 and in no case may a CAH receive an incentive payment under this section with respect to more than 4 consecutive payment years.

(e) Reductions in payment to CAHs. For cost reporting periods beginning in FY 2015, if a CAH is not a qualifying CAH for a payment year, then the payment for inpatient services furnished by a CAH under § 413.70(a) of this chapter is adjusted by the applicable percentage described in § 413.70(a)(6) of this chapter unless otherwise exempt from such adjustment.

(f) *Administrative or judicial review.* There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the —

(1) Methodology and standards for determining the amount of payment, the reasonable cost, and adjustments described in this section including selection of periods for determining, and making estimates or using proxies of, inpatient-bed-days, hospital charges, charity charges, and the Medicare share percentage as described in this section;

(2) Methodology and standards for determining if a CAH is a qualified CAH under this section;

(3) Specification of EHR reporting periods, cost reporting periods, payment years, and fiscal years used to compute the CAH incentive payment as specified in this section; and

(4) Identification of the reasonable costs used to compute the CAH incentive payment under paragraph (c) of this section including any reconciliation of the CAH incentive payment amount made under paragraph (d) of this section.

§ 495.108 Posting of required information.

(a) CMS posts, on its Internet Web site, the following information regarding EPs, eligible hospitals, and CAHs receiving an incentive payment under subparts B and C of this part:

(1) Name.

(2) Business addresses.

(3) Business phone number.

(b) CMS posts, on its Internet Web site, the following information for qualifying MA organizations that receive an incentive payment under subpart C of this part—

(1) The information specified in paragraph (a) of this section for each of the qualifying MA organization's MA plan information; and

(2) The information specified in paragraph (a) of this section for each of the qualifying MA organization's MA EPs and MA-affiliated eligible hospitals.

Subpart C—Requirements Specific to Medicare Advantage (MA) Organizations

§ 495.200 Definitions.

As used in this subpart:

First payment year means with respect to—

(1) Covered professional services furnished by a qualifying MA EP, the first calendar year for which an incentive payment is made for such services under this subsection to a qualifying MA organization.

(2) Qualifying MA-affiliated eligible hospitals, the first fiscal year for which an incentive payment is made for qualifying MA-affiliated eligible hospitals under this subsection to a qualifying MA organization.

Inpatient-bed-days is defined in the same manner and is used in the same manner as that term is defined and used for purposes of implementing section 4201(a) of the American Recovery and Reinvestment Act of 2009 with respect to the Medicare FFS hospital EHR incentive program in § 495.104 of this part.

Patient care services means health care services for which payment would be made under, or for which payment would be based on, the fee schedule established under Medicare Part B if they were furnished by an EP.

Payment year means –

(1) For a qualifying MA EP, a calendar year beginning with CY 2011 and ending with CY 2016; and

(2) For an eligible hospital, a Federal fiscal year beginning with FY 2011 and ending with FY 2016.

Qualifying MA-affiliated eligible hospital means an eligible hospital under section 1886(n)(6) of the Act that is under common corporate governance with a qualifying MA organization and that of the Medicare beneficiaries it serves, more than two-thirds are Medicare individuals enrolled under MA plans, and that is a meaningful user of certified EHR technology as defined by § 495.4 of this part. In the case of a hospital for which at least one-third of whose Medicare bed-days for the year are covered under Part A rather than Part C, payment for that payment year is only be made under section 1886(n) of the Act and not under this section.

Qualifying MA EP means all of the following:

(1) A physician (as described in section 1861(r) of the Act), including a doctor of medicine or osteopathy who is either of the following:

(i) Employed by a qualifying MA organization.

(ii) Employed by, or is a partner of, an entity that through a contract with a qualifying MA organization furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of such organization.

(2) Furnishes at least 80 percent of his or her professional services covered under Title XVIII to enrollees of the qualifying MA organization.

(3) Furnishes, on average, at least 20 hours per week of patient care services to enrollees of the qualifying MA organization during the EHR reporting period.

(4) Is a meaningful user of certified EHR technology in accordance with § 495.4 of this part.

Qualifying MA organization means a MA organization that is organized as a health maintenance organization (HMO) as defined in section 2791(b)(3) of the Public Health Service (PHS) Act which includes a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as an HMO.

Second, third, fourth, and fifth payment year means with respect to incentive payments for qualifying—

(1) MA EPs to a qualifying MA organization, each successive calendar year immediately following the first payment year for the qualifying MA organization. The first payment year and each successive year immediately following the first payment year, for the qualifying MA organizations, through 2016, is the same for all qualifying MA EPs with respect to any specific qualifying MA organization.

(2) MA-affiliated eligible hospitals to a qualifying MA organization, each successive fiscal year immediately following the first payment year for the qualifying MA organization.

Under common corporate governance means that a qualifying MA organization and a qualifying MA-affiliated eligible hospital have a common parent corporation, that one is a subsidiary of the other, or that the organization and the hospital have a common board of directors.

§ 495.202 Identification of qualifying MA organizations, MA–EPs and MA-affiliated eligible hospitals.

(a) *Identification of qualifying MA organizations.* (1) Beginning with bids due in June 2010 (for plan year 2011), MA organizations seeking reimbursement for qualifying MA EPs and qualifying MA-affiliated eligible hospitals under the MA EHR incentive program are required to identify themselves to CMS in a form and manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act.

(2) Qualifying MA organizations offering MA HMO plans, absent evidence to the contrary, are deemed to meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3)–section 2791(b)(3) of the PHS Act.

(3) Qualifying MA organizations offering MA plan types other than HMOs, must attest to the fact that they meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3)–section 2791(b)(3) of the PHS Act.

(4) Beginning with bids due in June 2014 (for plan year 2015), all MA organizations with potentially qualifying MA EPs or potentially qualifying MA-affiliated eligible hospitals under the MA EHR incentive program must identify themselves to CMS in a form and manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act.

(b) *Identification of qualifying MA EPs and qualifying MA-affiliated eligible hospitals.*

(1) A qualifying MA organization, as part of its initial bid starting with plan year 2011, must make a preliminary identification of potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals for which the organization is seeking incentive payments.

(2) A qualifying MA organization must provide CMS with the following for each MA EP or eligible hospital:

(i) The MA EP's or MA-affiliated eligible hospital's name.

(ii) The address of the MA EP's practice or MA-affiliated eligible hospital's location.

(iii) NPI.

(iv) An attestation by MA organization specifying that the MA EP or MA-affiliated eligible hospital meets the eligibility criteria.

(3) Final identification of potentially qualifying MA EP or MA-affiliated eligible hospital must be made by the end of the payment year as defined in § 495.200 for which MA EHR incentive payments are being sought.

(4) Beginning plan year 2015 and for subsequent plan years, all qualifying MA organizations, as part of their initial bids in June for the following plan year must—

(i) Identify potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals;

(ii) Include information specified in paragraph (b)(2)(i)(A) through (C) of this section for each professional and hospital.

(iii) Include an attestation that each professional and hospital either meets or does not meet the EHR incentive payment eligibility criteria.

§ 495.204 Incentive payments to qualifying MA organizations for MA–EPs and hospitals.

(a) *General rule.* A qualifying MA organization receives an incentive payment for its qualifying MA–EPs and its qualifying MA-eligible hospitals. The incentive payment amount paid to a qualifying MA organization for a—

(1) Qualifying MA–EP is the amount determined under paragraph (b) of this section; and

(2) Qualifying MA-eligible hospital is the amount determined under paragraph (c) of this section.

(b) *Amount payable to qualifying MA organization for qualifying MA EPs.*

(1) CMS substitutes an amount determined to be equivalent to the amount computed under § 495.102 of this part.

(2) The qualifying MA organization must report to CMS within 30 days 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.

(3) CMS calculates the incentive amount for the MA organization for each qualifying MA EP as an amount equal to 75 percent of the reported annual revenue specified in paragraph (b)(2) of this section, up to the maximum amounts specified under 1848 (o)(1)(B) of the Act.

(4) For qualifying MA EPs who are compensated on a salaried basis, CMS requires the qualifying MA organization to develop a methodology for estimating the portion of each qualifying MA EP's salary 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 methodology—

(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 salaried qualifying MA EP.

(5) For qualifying MA EPs who are not salaried, qualifying MA organizations must obtain attestations from such qualifying MA EPs as to the amount of compensation received by such EPs for MA plan enrollees of the MA organization. The organizations must submit to CMS compensation information for each such MA EP based on such attestations.

(c) *Amount payable to qualifying MA organization for qualifying MA-affiliated eligible hospitals.*

(1) CMS substitutes an amount determined to be equivalent to the amount computed under § 495.104, to the extent data are not available to compute payments for qualifying MA-affiliated eligible hospitals under the Medicare FFS EHR hospital incentive program. CMS uses the same methodology and defines "inpatient-bed-days" and other terms as used under the Medicare FFS EHR hospital incentive program in § 495.104 of this part in computing amounts due qualifying MA organizations for MA-affiliated eligible hospitals.

(2) To the extent data are available, qualifying MA organizations must receive hospital incentive payments through their affiliated hospitals under the Medicare FFS EHR hospital incentive program, rather than through the MA EHR hospital incentive program.

(d) *Payment to qualifying MA organizations.* CMS makes payment to qualifying MA organizations for qualifying MA EPs only under the MA EHR incentive program and not under the Medicare FFS EHR incentive program to the extent an EP has earned less than the maximum incentive payment for the same period under the Medicare FFS EHR incentive program.

(e) *Payment review under MA.* To ensure the accuracy of the incentive payments, CMS conducts selected compliance reviews of qualifying MA organizations to ensure that EPs and eligible hospitals for which such qualifying organizations received incentive payments were meaningful users of certified EHR technology in accordance with § 422.504 of this chapter.

(1) The reviews include validation of the status of the organization as a qualifying MA organization, verification of meaningful use and review of data used to calculate incentive payments.

(2) MA organizations are required to maintain evidence of their qualification to receive incentive payments and the data necessary to accurately calculate incentive payments.

(3) Documents and records must be maintained for 10 years from the date such payments are made with respect to a given payment year.

(4) Payments that result from incorrect or fraudulent attestations, cost data, or any other submission required to establish eligibility or to qualify for such payment, will be recouped by CMS from the MA organization.

§ 495.206 Timeframe for payment to qualifying MA organizations.

(a) CMS makes payment to qualifying MA organizations for qualifying MA EPs under the MA EHR incentive program after computing incentive payments due under the Medicare FFS EHR incentive program according to § 495.102.

(b) Payments to qualifying MA organizations for qualifying MA-affiliated eligible hospitals under common corporate governance are made under the Medicare FFS EHR incentive program, following the timeline in specified in § 495.104 of this part. To the extent sufficient data do not exist to pay qualifying MA-affiliated eligible hospitals under common corporate governance under the Medicare FFS EHR incentive program, payment is made under the MA EHR incentive program, following the same timeline in § 495.104 of this part.

§ 495.208 Avoiding duplicate payment.

(a) Unless a qualifying MA EP is entitled to a maximum payment for a year under the Medicare FFS EHR incentive program, payment for such an individual is only be made under the MA EHR incentive program to a qualifying MA organization.

(b) Payment to qualifying MA organizations for a qualifying MA-affiliated eligible hospital under common governance only occurs under the MA EHR incentive program to the extent that sufficient data does not exist to pay such hospital under the Medicare FFS hospital incentive program under § 495.104 of this part. In no event are EHR incentive payments made for a hospital for a payment year under this section to the extent they have been made for the same hospital for the same payment year under § 495.104 of this part.

(c) Each qualifying MA organization must ensure that all potentially qualifying MA EPs are enumerated through the NPI system and that other identifying information required under § 495.210(b) is provided to CMS.

§ 495.210 Meaningful user attestation.

(a) Qualifying MA organizations are required to attest, in a form and manner specified by CMS, that each qualifying MA EP and qualifying MA-affiliated eligible hospitals is a meaningful EHR user.

(b) Qualifying MA organizations are required to attest within 30 days 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 30 days after close of the FY whether each qualifying MA-affiliated eligible hospital is a meaningful user.

§ 495.212 Limitation on review.

(a) There is no administrative or judicial review under section 1869 or 1878 of the Act, or otherwise of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR EP incentive program. This includes provisions related to duplication of payment avoidance and rules developed related to the fixed schedule for application of limitation on incentive payments for all qualifying MA EPs related to a specific qualifying MA organization. It also includes the methodology and standards developed for determining qualifying MA EPs and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures.

(b) There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR hospital incentive program. This includes provisions related to duplication of payment avoidance. It also includes the methodology and standards developed for determining qualifying MA-affiliated eligible hospitals and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures.

Subpart D—Requirements Specific to the Medicaid Program

§ 495.300 Basis and purpose.

This subpart implements section 4201 of the American Reinvestment and Recovery Act of 2009 and sections 1903(a)(3)(F) and 1903(t) of the Act which authorizes States, at their option, to provide for incentive payments to Medicaid providers for adopting, implementing, or upgrading certified electronic health record technology or for meaningful use of such technology. This subpart also provides enhanced Federal financial participation (FFP) to States to administer these incentive payments.

§ 495.302 Definitions.

As used in this subpart—

Acceptance documents mean written evidence of satisfactory completion of an approved phase of work or contract and acceptance thereof by the State agency.

Acquisition means to acquire health information technology (HIT) equipment or services for the purpose of implementation and administration under this Part from commercial sources or from State or local government resources.

Acute care hospital means a health care facility—

(1) Where the average length of patient stay is 25 days or fewer; and

(2) With a CMS certification number (previously known as the Medicare provider number) that has the last four digits in the series 0001—0879

Adopt, implement or upgrade means—

(1) Install or commence utilization of certified EHR technology capable of

meeting meaningful use requirements; or

(2) Expand the available functionality of certified EHR technology capable of meeting meaningful use requirements at the practice site, including staffing, maintenance, and training.

Children's hospital means a separately certified children's hospital, either freestanding or hospital-within-hospital that—

(1) Has a CMS certification number, (previously known as the Medicare provider number), that has the last 4 digits in the series 3300–3399; and

(2) Predominantly treats individuals under 21 years of age.

Entities promoting the adoption of certified electronic health record technology means the State-designated entities that are promoting the adoption of certified EHR technology by enabling oversight of the business, operational and legal issues involved in the adoption and implementation of EHR or by enabling the exchange and use of electronic clinical and administrative data between participating providers, in a secure manner, including maintaining the physical and organizational relationship integral to the adoption of certified EHR technology by EPs.

Health information technology planning advance planning document (HIT PAPD) means a plan of action that requests FFP and approval to accomplish the planning necessary for a State agency to determine the need for and plan the acquisition of HIT equipment or services or both and to acquire information necessary to prepare a HIT implementation advanced planning document or request for proposal to implement the State Medicaid HIT plan.

HIT implementation advance planning document (HIT IAPD) means a plan of action that requests FFP and approval to acquire and implement the proposed State Medicaid HIT plan services or equipment or both.

Medicaid information technology architecture (MITA) is both an initiative and a framework. It is a national framework to support improved systems development and health care management for the Medicaid enterprise. It is an initiative to establish national guidelines for technologies and processes that enable improved program administration for the Medicaid enterprise. The MITA initiative includes an architecture framework, models, processes, and planning guidelines for enabling State Medicaid enterprises to meet common objectives with the framework while supporting unique local needs.

Medicaid management information system (MMIS) means a mechanized claims processing and information retrieval system—referred to as Medicaid Management Information Systems (MMIS)—that meets specified requirements and that the Department has found (among other things) is compatible with the claims processing and information retrieval systems used in the administration of the Medicare program. The objectives of the MMIS are to include claims processing and retrieval of utilization and management information necessary for program administration and audit and must coordinate with other mechanized systems and subsystems that perform other functions, such as eligibility determination.

Needy individuals mean individuals that meet one of following:

(1) Received medical assistance from Medicaid or the Children's Health Insurance Program.

(2) Were furnished uncompensated care by the provider.

(3) Were furnished services at either no cost or reduced cost based on a sliding scale determined by the individuals' ability to pay.

Patient volume means the minimum participation threshold where the numerator is the total number of Medicaid patients or needy individuals treated in any 90-day period in the most recent calendar year preceding the reporting and the denominator is all patient encounters in the same 90-day period. Represented as follows:

[Total (Medicaid) treated in any 90-day period in the most recent calendar year preceding the reporting/Total patients in same 90-day period] * 100; or

[Total (Needy Individuals) treated in any 90-day period in the most recent calendar year preceding the reporting/ Total patients in same 90-day period] * 100.

Practices predominantly means an EP for whom the clinical location for over 50 percent of his or her total patient encounters over a period of 6 months in the most recent calendar year occurs at a federally qualified health center or rural health clinic.

Service oriented architecture or service component based architecture means organizing and developing information technology capabilities as collaborating services that interact with each other based on open standards.

State Medicaid health information technology plan (SMHP) means a document that describes the State's current and future HIT activities.

State self-assessment means a process that a State uses to review its strategic goals and objectives, measure its current business processes and capabilities against the (MITA) business capabilities and ultimately develops target capabilities to transform its Medicaid enterprise to be consistent with the MITA principles.

§ 495.304 Medicaid provider scope and eligibility.

(a) *General rule.* The following Medicaid providers are eligible to participate in the HIT incentives program:

(1) Medicaid EPs.

(2) Acute care hospitals.

(3) Children's hospitals.

(b) *Medicaid EP.* The Medicaid professional eligible for a EHR incentive payment is limited to the following:

(1) A physician.

(2) A dentist.

(3) A certified nurse-midwife.

(4) A nurse practitioner.

(5) A physician assistant practicing in a Federally Qualified Health Center or Rural Health Clinic, which is so led by a physician assistant.

(c) *Additional requirements for the Medicaid EP.* To qualify for an EHR incentive payment, a Medicaid EP must not be hospital-based as defined § 495.4 of this subpart and meet one of the following criteria for each year for which the EP seeks an EHR incentive payment:

(1) Have a minimum 30 percent patient volume attributable to individuals receiving Medicaid.

(2) Have a minimum 20 percent patient volume attributable to individuals receiving Medicaid, and be a pediatrician.

(3) Practice predominantly in a FQHC or RHC and have a minimum 30 percent patient volume attributable to needy individuals, as defined at § 495.302.

(d) *Exception.* The hospital-based exclusion in paragraph (c) does not apply to the Medicaid-EP qualifying based on practicing predominantly at a FQHC or RHC.

(e) *Additional requirement for the eligible hospital.* To be eligible for an EHR incentive payment for each year for which the eligible hospital seeks an EHR incentive payment the eligible hospital must meet the following criteria:

(1) An acute care hospital must have at least a 10 percent Medicaid patient volume for each year for which the hospital seeks an EHR incentive payment.

(2) A children's hospital is exempt from meeting a patient volume threshold.

§ 495.306 Establishing patient volume.

(a) A Medicaid provider must annually meet one of the following to establish patient volume:

(1)(i) *General rule for a professional.* Except as specified in paragraph (a)(1)(ii) of this section, a Medicaid EP must attest that a minimum of 30 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid.

(ii) *Optional exception.* (A) A pediatrician must attest that a minimum of 20 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid.

(B) A Medicaid EP practicing predominantly in a Federally Qualified Health Center or Rural Health Clinic must attest that a minimum of 30 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was with needy individuals as defined in § 495.302 of this subpart.

(2) *General rule for an acute care hospital.* An acute care hospital must attest that a minimum of 10 percent of all patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid.

(b) If a State has an alternative approach to the established timeframe for measuring patient volume, the State must submit the approach to CMS for review and prior approval. CMS determines if it is an acceptable alternative.

(1) To be considered for approval, the alternative approach must be justified and have a verifiable data source.

(2) If CMS approves the State's alternative approach to the established timeframe for measuring patient volume, such timeframe would apply to Medicaid EPs and eligible hospitals, instead of the 90-day timeframe described in paragraph (a) of this section.

(c) To establish patient volume for an EP who practices predominantly in a Federally Qualified Health Center or Rural Health Clinic by use of uncompensated care data, an adjustment to the uncompensated care data must be completed so that it is an appropriate proxy for charity care, including a downward adjustment to eliminate bad debt data from uncompensated care.

(d) An individual enrolled in a managed care organization, pre-paid inpatient health plan, or pre-paid ambulatory health plan under part 438 of this chapter must be included in the calculation to establish patient volume.

§ 495.308 Net average allowable costs as the basis for determining the incentive payment.

(a) *The first year of payment.* (1) The incentive is intended to offset the costs associated with the initial adoption of certified electronic health records technology.

(2) The maximum net average allowable costs for the first year are $25,000.

(b) *Subsequent payment years.* (1) The incentive is intended to offset maintenance and operation of certified EHR technology.

(2) The maximum net average allowable costs for each subsequent year are $10,000.

§ 495.310 Medicaid provider incentive payments.

(a) *General rule for a Medicaid EP.* The Medicaid EP's incentive payments are subject to the following limitations:

(1) First payment year. A first year payment may not exceed 85 percent of the maximum threshold of $25,000, which equals $21,250.

(2) *Subsequent annual payment years.* A subsequent annual payment may not exceed 85 percent of the maximum threshold of $10,000, which equals $8,500.

(i) Payments after the first year may continue for a maximum of 5 years.

(ii) Medicaid EPs may participate for a total of 6 years and may not begin receiving payments any later than CY 2016.

(3) *Maximum incentives.* In no case will the maximum incentive over a 6-year period exceed $63,750.

(4) *Limitation.* For a Medicaid EP who is a pediatrician described in paragraph (b) of this section is as follows:

(i) The maximum payment in the first year is further reduced to two-thirds, which equals $14,167.

(ii) The maximum payment in subsequent years is further reduced to two-thirds, which equals $5,667.

(iii) In no case will the maximum incentive payment to a pediatrician under this limitation exceed $42,500 over a 6-year period.

(b) *Optional exception for pediatricians.* A pediatrician described in this paragraph is a Medicaid EP who does not meet the 30 percent patient volume requirements described in § 495.304 and § 495.306, but who meets the 20 percent patient volume requirements described in such sections.

(c) *General rule for EPs.* An EP may only receive an incentive payment from either Medicare or Medicaid but not both.

(d) *Optional exception for EPs.* An EP may change his or her EHR incentive payment program election once, consistent with § 495.10 of this part but such change in election must occur for payments by occurring before CY 2015.

(e) *General rule for Medicaid EPs and hospitals.* An Medicaid EP or hospital may receive an incentive payment from only one State in a payment year.

(f) *Incentive payments to hospitals.* Incentive payments to an eligible hospital under this subpart are subject to all of the following conditions:

(1) The payment is provided over a minimum of a 3-year period and maximum of a 6-year period.

(2) The total incentive payment received over all payment years of the program is not greater than the aggregate EHR incentive amount, as calculated under paragraph (g) of this section.

(3) No single incentive payment for a payment year may exceed 50 percent of the aggregate EHR hospital incentive amount calculated under paragraph (g) of this section for an individual hospital.

(4) No incentive payments over a 2-year period may exceed 90 percent of the aggregate EHR hospital incentive amount calculated under paragraph (g) of this section for an individual hospital.

(5) No hospital may begin receiving incentive payments for any year after 2016.

(6) A multi-site hospital with one CMS Certification Number is considered one hospital for purposes of calculating payment.

(g) *Calculation of the aggregate EHR hospital incentive amount.* The aggregate EHR hospital incentive amount is calculated as the product of the (overall EHR amount) times (the Medicaid Share).

(1) *Overall EHR amount.* The overall EHR amount for an eligible hospital is based upon a theoretical 4 years of payment the hospital would receive based, for each of such 4 years, upon the product of the following:

(i) *Initial amount.* The initial amount is equal to the sum of—

(A) The base amount which is set at $2,000,000 for each of the theoretical 4 years; plus

(B) The discharge related amount for a 12-month period selected by the State but with the Federal fiscal year before the hospital's fiscal year that serves as the payment year. The discharge related amount is the sum of the following, with discharges over the 12-month period and based upon the total discharges for the eligible hospital (regardless of any source of payment):

(*1*) For the first through 1,149th discharge, $0.

(*2*) For the 1,150th through the 23,000th discharge, $200.

(*3*) For any discharge greater than the 23,000th, $0.

(C) For purposes of calculating the discharge-related amount under paragraph (g)(1)(i)(B) of this section, for the last 3 of the theoretical 4 years of payment, discharges are assumed to increase by the provider's average annual rate of growth for the most recent 3 years for which data are available per year. Negative rates of growth must be applied as such.

(ii) *Medicare share.* The Medicare share, which equals 1.

(iii) *Transition factor.* The transition factor which equals as follows:

(A) For the first of the theoretical 4 years, 1.

(B) For the second of the theoretical 4 years, ¾.

(C) For the third of the theoretical 4 years, ½.

(D) For the fourth of the theoretical 4 years, ¼.

(2) Medicaid share. The Medicaid share specified under this paragraph for an eligible hospital is equal to a fraction—

(i) The numerator of which is the sum (for the 12 month period selected by the State and with respect to the eligible hospital) of—

(A) The estimated number of inpatient-bed-days which are attributable to Medicaid individuals; and

(B) The estimated number of inpatient-bed-days which are attributable to individuals who are enrolled in a managed care organization, a pre-paid inpatient health plan, or a pre-paid ambulatory health plan under part 438 of this chapter; and

(ii) The denominator of which is the product of—

(A) The estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and

(B) The estimated total amount of the eligible hospital's charges during such period, not including any charges that are attributable to charity care, divided by the estimated total amount of the hospital's charges during such period.

(iii) In computing inpatient-bed-days under the previous sentence, a State may not include estimated inpatient-bed-days attributable to individuals with respect to whom payment may be made under Medicare Part A, or inpatient-bed-days attributable to individuals who are enrolled with a Medicare Advantage organization under Medicare Part C.

(h) *Approximate proxy for charity care.* If the State determines that an eligible hospital's data are not available on charity care necessary to calculate the portion of the formula specified in paragraph (g)(2)(ii)(B) of this section, the State may use that provider's data on uncompensated care to determine an appropriate proxy for charity care, but must include a downward adjustment to eliminate bad debt from uncompensated care data. The State must use auditable data sources.

(i) *Deeming.* In the absence of the data necessary, with respect to an eligible hospital the amount described in paragraph (g)(2)(ii)(B) must be deemed to be 1. In the absence of data, with respect to an eligible hospital, necessary to compute the amount described in paragraph (g)(2)(i)(B) of this section, the amount under such clause must be deemed to be 0.

(j) *Dual eligibility for incentives payments.* A hospital may receive incentive payments from both Medicare and Medicaid if it meets all eligibility criteria.

(k) *Payments to State-designated entities.* Payments to entities promoting the adoption of certified EHR technology as designated by the State must meet the following requirements:

(1) A Medicaid EP may designate his or her incentive payment to an entity promoting the adoption of certified EHR technology, as defined in § 495.302, and as designated by the State, only under the following conditions:

(i) The State has established a method to designate entities promoting the adoption of EHR technology that comports with the Federal definition in § 495.302.

(ii) The State publishes and makes available to all EPs a voluntary mechanism for designating annual payments and includes information about the verification mechanism the State will use to ensure that the assignment is voluntary and that no more than 5 percent of the annual payment is retained by the entity for costs not related to certified EHR technology.

(2) [Reserved]

§ 495.312 Process for payments.

(a) *General rule.* States must have a process for making payments consistent with the requirements in subparts A and D of this part.

(b) *Reporting data consistent with this subpart.* In order to receive a payment under this part, a provider must report the required data under subpart A and this subpart within the EHR reporting period described in § 495.4.

(c) *State role.* The State determines the provider's eligibility for the EHR incentive payment under subpart A and this subpart and approves, processes, and makes timely payments using a process approved by CMS.

(d) *State disbursement.* The State disburses an incentive payment to the provider based on the criteria described in subpart A and this subpart.

(e) *Timeframes.* Payments are disbursed consistent with the following timeframes for each type of Medicaid eligible provider:

(1) *Medicaid EPs.* States disburse payments consistent with the calendar year on a rolling basis following the end of the EHR reporting period for the payment year.

(2) *Medicaid eligible hospitals.* States disburse payments consistent with the Federal fiscal year on a rolling basis following the end of the EHR reporting period for the payment year.

§ 495.314 Activities required to receive an incentive payment.

(a) *First payment year.* (1) In the first payment year, to receive an incentive payment, the Medicaid EP or eligible hospital must meet one of the following:

(i) Demonstrate that during the EHR reporting period for a payment year, it has adopted, implemented, or upgraded certified EHR technology, as defined in § 495.302; or

(ii) Demonstrate that during the EHR reporting period for a payment year, it is a meaningful EHR user as defined in § 495.4.

(2) A provider may notify the State of its non-binding intention to participate in the incentives program prior to having fulfilled all of the eligibility criteria.

(b) *Subsequent payment years.* (1) In the second, third, fourth, fifth, and sixth payment years, to receive an incentive payment, the Medicaid EP or eligible hospital must demonstrate that during the EHR reporting period for the applicable payment year, it is a meaningful EHR user, as defined in § 495.4.

(2) The automated reporting of the clinical quality measures will be accomplished using certified EHR technology interoperable with the system designated by the State to receive the data.

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

(a) Subject to § 495.332 the State is responsible for tracking and verifying the activities necessary for a Medicaid EP or eligible hospital to receive an incentive payment for each payment year, as described in § 495.314.

(b) Subject to § 495.332, the State must submit a State Medicaid HIT Plan to CMS that includes:

(1) A detailed plan for monitoring, verifying and periodic auditing of the requirements for receiving incentive payments, as described in § 495.314; and

(2) A description of the how the State will collect and report on provider meaningful use of certified EHR technology.

(c) Subject to § 495.332 and § 495.350, the State is required to submit to CMS annual reports on the following:

(1) Provider adoption, implementation, or upgrade of certified EHR technology activities and payments; and

(2) Aggregated, de-identified meaningful use data.

(d)(1) The annual report described in paragraph (c) of this section must include, but is not limited to the following:

(i) The number, type, and practice location(s) of providers who qualified for an incentive payment on the basis of having adopted, implemented, or upgraded certified EHR technology;

(ii) Aggregated data tables representing the provider adoption, implementation, and upgrade of certified EHR technology;

(iii) The number, type, and practice location(s) of providers who qualified for an incentive payment on the basis of meaningful use of certified EHR technology;

(iv) Aggregated data tables representing the provider's clinical quality measures data; and

(v) A description and quantitative data on how its incentive payment program addressed individuals with unique needs such as children.

(2) The State may propose additional, not substitute, measures for meaningful use of certified EHR technology, subject to CMS prior approval.

(e) State failure to submit the required reports to CMS may result in discontinued or disallowed funding.

§ 495.318 State responsibilities for receiving FFP.

In order to be provided FFP under section 1903(a)(3)(F) of the Act, a State must demonstrate to the satisfaction of the Department, that the State is—

(a) Using the funds provided for the purposes of administering incentive payments to providers under this program, including tracking of meaningful use by Medicaid providers of EHR technology;

(b) Conducting adequate oversight of the program, including routine tracking of meaningful use attestations and reporting mechanisms; and

(c) Pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information, subject to applicable laws and regulations governing such exchange.

§ 495.320 FFP for payments to Medicaid providers.

Subject to the requirements outlined in this Subpart, FFP is available at 100 percent of State expenditures for payments to Medicaid eligible providers to encourage the adoption and meaningful use of certified EHR technology.

§ 495.322 FFP for reasonable administrative expenses.

Subject to prior approval conditions at § 495.324 of this subpart, FFP is available at 90 percent in State expenditures for administrative activities in support of implementing incentive payments to Medicaid eligible providers.

§ 495.324 Prior approval conditions.

(a) A State must obtain prior written approval as specified in paragraph (b) of this section, when the State plans to initiate planning and implementation activities in support of Medicaid provider incentive payments encouraging the adoption and use of certified EHR technology with proposed Federal financial participation.

(b) To receive 90 percent match, each State must receive prior approval for all of the following:

(1) The HIT planning advance planning document and the implementation advance planning document.

(2) A request for proposal and any contract that a State may utilize to complete activities under this subpart, unless specifically exempted by the Department, prior to release of the request for proposal or prior to execution of a contract.

(3) For contract amendments, unless specifically exempted by the Department, before execution of the contract amendment, involving contract cost increases exceeding $100,000 or contract time extensions of more than 60 days.

(c) Failure to submit any of the information specified in paragraph (b) of this section to the satisfaction of the Department may result in disapproval or suspension of project funding.

(d) A State must obtain prior written approval from the Department of its justification for a sole source acquisition, when it plans to acquire non-competitively from a nongovernmental source HIT equipment or services, with proposed FFP under this subpart if the total State and Federal acquisition cost is more than $100,000.

§ 495.326 Disallowance of Federal financial participation (FFP).

If the Department finds that any acquisition approved or modified under the provisions of this subpart fails to comply with the criteria, requirements, and other undertakings described in the approved HIT planning advance planning document and HIT implementation advance planning document to the detriment of the proper and efficient operation of the Medicaid program, payment of FFP may be disallowed. In the case of a suspension of approval of a HIT planning advance planning document and HIT implementation advance planning document, see 45 CFR 205.37(c) and 307.40(a).

§ 495.328 Request for reconsideration of adverse determination.

If CMS disapproves a State request for any elements of a State's advance planning document or State Medicaid HIT Plan under this subpart, or determines that requirements are met for approval on a date later than the date requested, the decision notice includes the following:

(a) The finding of fact upon which the determination was made.

(b) The procedures for appeal of the determination in the form of a request for reconsideration.

§ 495.330 Termination of Federal financial participation (FFP) for failure to provide access to information.

(a) The Department terminates FFP at any time if the Medicaid agency fails to provide State and Federal representatives with full access to records relating to HIT planning and implementation efforts, and the systems used to interoperate with electronic HIT, including on-site inspection.

(b) The Department may request such access at any time to determine whether the conditions in this subpart are being met.

§ 495.332 State Medicaid (HIT) plan requirements.

Each State Medicaid HIT plan must include all of the following elements:

(a) *State systems.* For State systems, interoperability, and the current and future visions:

(1) A baseline assessment of the current HIT landscape environment in the State including the inventory of existing HIT in the State. The assessment must include a comprehensive—

(i) Description of the HIT "as-is" landscape;

(ii) Description of the HIT "to-be" landscape; and

(iii) HIT roadmap and strategic plan for the next 5 years.

(2) A description of how the State Medicaid HIT plan will be planned, designed, developed and implemented, including how it will be implemented in accordance with the Medicaid Information Technology Architecture (MITA) principles as described in the Medicaid Information Technology Framework 2.0. The MITA initiative—

(i) Establishes national guidelines for technologies and processes that enable improved program administration for the Medicaid enterprise;

(ii) Includes business, information and technology architectures that provide an overall framework for interoperability, as well as processes and planning guidelines for enabling State Medicaid enterprises to meet common objectives within the framework while supporting unique local needs; and

(iii) Is important to the design and development of State EHR incentive payment systems.

(3) A description of how intrastate systems, including the Medicaid Management Information System (MMIS) and other automated mechanized claims processing and information retrieval systems—

(i) Have been considered in developing a HIT solution; and

(ii) A plan that incorporates the design, development, and implementation phases for interoperability of such State systems with a description of how any planned systems enhancements support overall State and Medicaid goals.

(4) A description of data-sharing components of HIT solutions.

(5) A description of how each State will promote secure data exchange, where permissible under the Health Insurance Portability and Accountability Act (HIPAA). HIPAA and other requirements included in the Recovery Act.

(6) A description of how each State will promote the use of data and technical standards to enhance data consistency and data sharing through common data-access mechanisms.

(7) A description of how each State will support integration of clinical and administrative data.

(8) A description of the process in place for ensuring improvements in health outcomes, clinical quality, or efficiency resulting from the adoption of certified EHR technology by recipients of Medicaid incentive payments and a methodology for verifying such information.

(9) A description of the process in place for ensuring that any certified EHR technology used as the basis for a payment incentive to Medicaid providers is compatible with State or Federal administrative management systems, including the MMIS or other automated claims processing system or information retrieval system and a methodology for verifying such information.

(10) A description of how each State will adopt national data standards for health and data exchange and open standards for technical solutions as they become available.

(11) A description of how the State intends to address the needs of underserved and vulnerable populations such as children, individuals with chronic conditions, Title IV–E foster care children, individuals in long-term care settings and the aged, blind, and disabled. This description must address the following:

(i) Person centered goals and objectives and shared decision-making.

(ii) Coordination of care across multiple service providers, funding sources, settings, and patient conditions.

(iii) Universal design to ensure access by people with disabilities and older Americans.

(iv) Self-direction including budget development and expenditure tracking.

(v) Institutional discharge planning and diversion activities that are tied to community based service availability.

(b) *Eligibility.* For eligibility, a description of the process in place for all of the following:

(1) For ensuring that each EP and eligible hospital meets all provider enrollment eligibility criteria upon enrollment and re-enrollment to the Medicaid EHR payment incentive program.

(2) For ensuring patient volume consistent with the criteria in § 495.304 and § 495.306 for each EP who practices predominantly in a FQHC or RHC and for each Medicaid EP who is a physician, pediatrician, nurse practitioner, certified nurse midwife or dentist and a methodology in place used to verify such information.

(3) For ensuring that the EP is a provider who meets patient volume consistent with the criteria in § 495.304 and a methodology in place used to verify such information.

(4) For ensuring that each Medicaid EP is not hospital-based and a methodology in place used to verify such information.

(5) To ensure that a hospital eligible for incentive payments has demonstrated an average length of stay of 25 days or less and that a methodology for verifying such information is available.

(c) *Monitoring and validation.* For monitoring and validation of information, States must include the following:

(1) A description of the process in place for ensuring that, because of CMS' and the States' oversight responsibilities, all provider information for attestations and any information added to the CMS Single Provider Repository including all information related to patient volume, NPI, Tax identification number (TIN), meaningful use, efforts to adopt, implement, or upgrade are all true and accurate and that any concealment or falsification of a material fact related to the attestation may result in prosecution under Federal and State laws and a methodology in place used to verify such information.

(2) A description of the process in place for ensuring that the EP or eligible hospital is eligible to receive an incentive payment consistent with the criteria outlined in § 495.314 and a methodology in place used to verify such information.

(3) A description of the process in place for capturing attestations from each EP or eligible hospital that they have meaningfully used certified EHR technology during the reporting period, and that they have adopted, implemented, or upgraded certified EHR technology during the reporting period and a description of the methodology in place used to verify such information.

(4) A description of the process in place for capturing clinical quality data from each EP or eligible hospital and a description of the methodology in place used to verify such information.

(5) A description of the process in place for monitoring the compliance of providers coming onto the program with different requirements depending upon the year and a methodology for verifying such information.

(6) A list of the specific actions planned to implement the HIT EHR incentive program, including a description and organizational charts for workgroups within State government including external partners.

(7) A description of the process in place to ensure that no amounts higher than 100 percent of FFP will be claimed for reimbursement of expenditures for State payments to Medicaid eligible providers for the certified EHR technology incentive payment program

and a methodology for verifying such information is available.

(8) A description of the process in place to ensure that no amounts higher than 90 percent of FFP will be claimed for administrative expenses in administering the certified EHR technology incentive payment program and a methodology for verifying such information is available.

(9) A description of the process and methodology for ensuring and verifying such information that includes the following:

(i) Amounts received under section 1903(a)(3)(F) of the Act with respect to payments to a Medicaid EP or eligible hospital are paid directly to such provider (or to an employer or facility to which such provider has assigned payments) without any deduction or rebate.

(ii) All assignments to an entity promoting the adoption of certified EHR technology, as designated by the State, are voluntary for the Medicaid EP involved.

(iii) Entities promoting the adoption of certified EHR technology do not retain more than 5 percent of such payments for costs not related to certified EHR technology (and support services including maintenance and training) that is for, or is necessary for the operation of, such technology.

(10) A description of the process in place for ensuring that each Medicaid EP or eligible hospital that collects an EHR payment incentive has collected a payment incentive from only one State even if the provider is licensed to practice in multiple States and a methodology for verifying such information.

(11)(i) A description of the process in place for ensuring that each EEP or eligible hospital that wishes to participate in the EHR incentive payment program will receive a NPI; and

(ii) A description of how the NPI will be used to coordinate with the CMS so that the EP will choose only one program from which to receive the incentive payment and the hospital payments are tracked accordingly.

(12) A description of the process in place for ensuring that each EP or eligible hospital who wishes to participate in the EHR incentive payment program will provide a TIN to the State for purposes of the incentive payment.

(d) *Payments.* Payments must provide descriptions of the following processes that are in place:

(1) The process in place for ensuring that there is no duplication of Medicare and Medicaid incentive payments to EPs and a methodology for verifying such information.

(2) The process in place to ensure that any existing fiscal relationships with providers to disburse the incentive payments through Medicaid managed care plans does not result in payments that exceed 105 percent of the capitation rate, in order to comply with the Medicaid managed care incentive payment rules at § 438.6(v)(5)(iii) of this chapter and a methodology for verifying such information.

(3) The process in place to ensure that only appropriate funding sources are used to make Medicaid EHR incentive payments and that a methodology for verifying such information is available.

(4) The process in place to ensure that Medicaid EHR incentive payments are made for no more than 6 years and that no EP or eligible hospital begins receiving payments after 2016 and that a methodology for verifying such information is available.

(5) 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 and the yearly maximum allowable payment thresholds and a methodology for verifying such information is available.

(6) The process in place to ensure that all hospital calculations and hospital payment incentives are made consistent with the requirements of this part and a methodology for verifying such information is available.

(7) The process in place to provide for the timely and accurate payment of incentive payments to EPs and eligible hospitals, including the time frame specified by the State to meet the timely payment requirement.

(8) The process in place and a methodology for verifying such information to provide that any monies that have been paid inappropriately as an improper payment or otherwise not in compliance with this subpart will be recouped and FFP will be repaid.

(e) *For combating fraud and abuse and for provider appeals.* (1) A description of the process in place for a provider to appeal consistent with the criteria described in § 495.370 and a methodology for verifying the following related to the EHR incentives payment program:

(i) Incentive payments.

(ii) Provider eligibility determinations.

(iii) Demonstration of efforts to adopt, implement or upgrade and meaningful use eligibility for incentive payments under this part.

(2) A description of the process in place, and a methodology for verifying such information, to address Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(f) *Optional—proposed alternatives.* A State may choose to propose any of the following, but they must be included as an element in the State Medicaid HIT Plan for review and approval:

(1) An alternative methodology for measuring patient volume, consistent with § 495.306(b).

(2) (i) Additional requirements for qualifying a Medicaid provider as a meaningful user of certified EHR technology consistent with § 495.4 and § 495.316(e) of this part.

(ii) A State may propose additional meaningful use objectives beyond the Federal standards at § 495.6, if they do not require additional functionality beyond that of certified electronic health record technology. See also § 495.316(e).

(3) A plan for early implementation of incentive payments for a provider who adopts, implements, or upgrades certified EHR technology consistent with the § 495.302 and § 495.314.

(i) An approvable plan must include mechanisms for making timely and accurate payments.

(ii) A State will require a provider to attest that they are not receiving a payment in any other State.

§ 495.334 State self-assessment requirements.

Each State must prepare a State self-assessment that meets the following requirements:

(a) List and prioritize the State's goals and objectives for HIT.

(b) Define the State's current business model and map to the Medicaid information technology architecture business process model.

(c) Assess the State's current capabilities.

(d) Determine the State's target capabilities.

§ 495.336 Health information technology planning advance planning document requirements (HIT PAPD).

Each State's HIT PAPD must contain the following:

(a) A statement of need and objective which clearly state the purpose and objectives of the project to be accomplished and the necessity for the project.

(b) A project management plan which addresses the following:

(1) The planning project organization.

(2) Planning activities and deliverables.

(3) State and contractor resource needs.

(4) Planning project procurement activities and schedule.

(c) A specific budget for the planning of the project.

(d) An estimated total project cost and a prospective State and Federal cost distribution, including planning and implementation.

(e) A commitment to submit a HIT implementation advance planning document.

(f) A commitment to conduct and complete activities which will result in the production of the State Medicaid HIT plan that includes conduct of the following activities:

(1) A statewide HIT environmental baseline self-assessment.

(2) An assessment of desired HIT future environment.

(3) Development of benchmarks and transition strategies to move from the current environment to the desired future environment.

(g) A commitment to submit the plan to CMS for approval.

§ 495.338 Health information technology implementation advance planning document requirements (HIT IAPD).

Each State's HIT IAPD must contain the following:

(a) The results of the activities conducted as a result of the HIT planning advance planning document, including the approved state Medicaid HIT plan.

(b) A statement of needs and objectives.

(c) A statement of alternative considerations.

(d) A personnel resource statement indicating availability of qualified and adequate staff, including a project director to accomplish the project objectives.

(e) A detailed description of the nature and scope of the activities to be undertaken and the methods to be used to accomplish the project.

(f) The proposed activity schedule for the project.

(g) A proposed budget including a consideration of all HIT implementation advance planning document activity costs, including but not limited to the following:

(1) The cost to implement and administer incentive payments.

(2) Procurement or acquisition.

(3) State personnel.

(4) Contractor services.

(5) Hardware, software, and licensing.

(6) Equipment and supplies.

(7) Training and outreach.

(8) Travel.

(9) Administrative operations.

(10) Miscellaneous expenses for the project.

(h) An estimate of prospective cost distribution to the various State and Federal funding sources and the proposed procedures for distributing costs.

(i) A detailed payment listing file that—

(1) Is in an electronic format that may be a field delimited ASCII text file, a commonly used spreadsheet file, or a commonly used database file; and

(2) Shows each EP and eligible hospital for which the State will provide for the payment of incentive payments, including the—

(i) Name of the provider;

(ii) National provider identifier of the provider;

(iii) Type of provider as specified in § 495.304;

(iv) Planned annual payment amounts;

(v) Total of planned payment amounts; and

(vi) Calendar year of each planned annual payment amount.

(j) A statement setting forth the security and interface requirements to be employed for all State HIT systems, and related systems, and the system failure and disaster recovery procedures available.

§ 495.340 As-needed HIT PAPD update and as-needed HIT IAPD update requirements.

Each State must submit a HIT PAPD update or a HIT IAPD no later than 60 days after the occurrence of project changes including but not limited to any of the following:

(a) A projected cost increase of $100,000 or more.

(b) A schedule extension of more than 60 days for major milestones.

(c) A significant change in planning approach or implementation approach, or scope of activities beyond that approved in the HIT planning advance planning document or the HIT implementation advance planning document.

(d) A change in implementation concept or a change to the scope of the project.

(e) A change to the approved cost allocation methodology.

§ 495.342 Annual HIT IAPD requirements.

Each State's annual HIT IAPD is due 60 days from the HIT IAPD approved anniversary date and must contain the following:

(a) A reference to the approved HIT PAPD/IAPD and all approved changes.

(b) A project activity status which reports the status of the past year's major project tasks and milestones, addressing the degree of completion and tasks/milestones remaining to be completed and discusses past and anticipated problems or delays in meeting target dates in the approved HIT technology PAPD/IAPD and approved changes to it.

(c) A report of all project deliverables completed in the past year and degree of completion for unfinished products.

(d) A project activity schedule for the remainder of the project.

(e) A project expenditure status which consists of a detailed accounting of all expenditures for project development over the past year and an explanation of the differences between projected expenses in the approved HIT PAPD/IAPD and actual expenditures for the past year.

(f) A report of any approved or anticipated changes to the allocation basis in the advance planning document's approved cost methodology.

(g) An updated detailed payment listing file in an electronic format.

§ 495.344 Approval of the State Medicaid HIT plan, the HIT PAPD and update, the HIT IAPD and update, and the annual HIT IAPD.

The Department does not approve any of these documents that do not include all information required under this subpart.

§ 495.346 Access to systems and records.

The State agency must allow the Department access to all records and systems operated by the State in support of this program, including cost records associated with approved administrative funding and incentive payments to Medicaid providers. State records related to contractors employed for the purpose of assisting with implementation or oversight activities or providing assistance, at such intervals as are deemed necessary by the Department to determine whether the conditions for approval are being met and to determine the efficiency, economy, and effectiveness of the program.

§ 495.348 Procurement standards.

(a) *General rule.* Procurements of HIT equipment and services are subject to the following procurement standards in paragraphs (b) through (f) of this section regardless of any conditions for prior approval. These standards—

(1) Include a requirement for maximum practical open and free competition regardless of whether the procurement is formally advertised or negotiated.

(2) Are established to ensure that such materials and services are obtained in a

cost effective manner and in compliance with the provisions of applicable Federal statutes and executive orders.

(3) Apply when the cost of the procurement is treated as a direct cost of an award.

(b) *Grantee responsibilities.* The standards contained in this section do not relieve the Grantee of the contractual responsibilities arising under its contract(s).

(1) The grantee is the responsible authority, without recourse to the Departmental awarding agency, regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into in support of an award or other agreement. This includes disputes, claims, and protests of award, source evaluation or other matters of a contractual nature.

(2) Matters concerning violation of statute are to be referred to such Federal, State or local authority as may have proper jurisdiction.

(c) *Codes of conduct.* The grantee must maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts.

(1) No employee, officer, or agent must participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved.

(2) Such a conflict would arise when the employee, officer, or agent, or any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for an award.

(3) The officers, employees, and agents of the grantee must neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or parties to subagreements.

(4) Grantees may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value.

(5) The standards of conduct provide for disciplinary actions to be applied for violations of such standards by officers, employers, or agents of the grantees.

(d) *Competition.* All procurement transactions must be conducted in a manner to provide, to the maximum extent practical, open and free competition.

(1) The grantee must be alert to organizational conflicts of interest as well as noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade.

(2) In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft grant applications, or contract specifications, requirements, statements of work, invitations for bids and requests for proposals must be excluded from competing for such procurements.

(3) Awards must be made to the bidder or offeror whose bid or offer is responsive to the solicitation and is most advantageous to the grantee, price, quality, and other factors considered.

(4) Solicitations must clearly set forth all requirements that the bidder or offeror must fulfill in order for the bid or offer to be evaluated by the grantee.

(5) Any and all bids or offers may be rejected when it is in the grantee's interest to do so.

(e) *Procurement procedures.* All grantees must establish written procurement procedures. These procedures must provide, at a minimum, the following:

(1) Grantees avoid purchasing unnecessary items.

(2) When appropriate, an analysis is made of lease and purchase alternatives to determine which would be the most economical and practical procurement for the grantee and the Federal government.

(3) Solicitations for goods and services provide for all of the following:

(i) A clear and accurate description of the technical requirements for the material, product or service to be procured. In competitive procurements, such a description must not contain features which unduly restrict competition.

(ii) Requirements which the bidder or offer must fulfill and all other factors to be used in evaluating bids or proposals.

(iii) A description, whenever practicable, of technical requirements in terms of functions to be performed or performance required, including the range of acceptable characteristics or minimum acceptable standards.

(iv) The specific features of brand name or equal descriptions that bidders are required to meet when such items are included in the solicitation.

(v) The acceptance, to the extent practicable and economically feasible, of products and services dimensioned in the metric system of measurement.

(vi) Preference, to the extent practicable and economically feasible, for products and services that conserve natural resources and protect the environment and are energy efficient.

(4) Positive efforts must be made by grantees to utilize small businesses, minority-owned firms, and women's business enterprises, whenever possible. Grantees of Departmental awards must take all of the following steps to further this goal:

(i) Ensure that small businesses, minority-owned firms, and women's business enterprises are used to the fullest extent practicable.

(ii) Make information on forthcoming opportunities available and arrange time frames for purchases and contracts to encourage and facilitate participation by small businesses, minority-owned firms, and women's business enterprises.

(iii) Consider in the contract process whether firms competing for larger contracts intend to subcontract with small businesses, minority-owned firms, and women's business enterprises.

(iv) Encourage contracting with consortia of small businesses, minority-owned firms and women's business enterprises when a contract is too large for one of these firms to handle individually.

(v) Use the services and assistance, as appropriate, of such organizations as the Small Business Administration and the Department of Commerce's Minority Business Development Agency in the solicitation and utilization of small businesses, minority-owned firms and women's business enterprises.

(5) The type of procuring instruments used (for example, fixed price contracts, cost reimbursable contracts, purchase orders, and incentive contracts) must be determined by the grantee but must be appropriate for the particular procurement and for promoting the best interest of the program or project involved.

(6) The "cost-plus-a-percentage-of-cost" or "percentage of construction cost" methods of contracting must not be used.

(7) Contracts must be made only with responsible contractors who possess the potential ability to perform successfully under the terms and conditions of the proposed procurement.

(8) Consideration must be given to such matters as contractor integrity, record of past performance, financial and technical resources or accessibility to other necessary resources.

(9) In certain circumstances, contracts with certain parties are restricted by agencies' implementation of Executive Orders 12549 and 12689, "Debarment and Suspension" as described in 45 CFR part 76.

(10) Some form of cost or price analysis must be made and documented in the procurement files in connection with every procurement action.

(11) Price analysis may be accomplished in various ways, including the comparison of price quotations submitted, market prices,

and similar indicia, together with discounts.

(12) Cost analysis is the review and evaluation of each element of cost to determine reasonableness, allocability, and allowability.

(13) Procurement records and files for purchases in excess of the simplified acquisition threshold must include the following at a minimum:

(i) Basis for contractor selection.

(ii) Justification for lack of competition when competitive bids or offers are not obtained.

(iii) Basis for award cost or price.

(f) *Contract administration.* A system for contract administration must be maintained to ensure contractor conformance with the terms, conditions and specifications of the contract and to ensure adequate and timely follow-up of all purchases. Grantees must evaluate contractor performance and document, as appropriate, whether contractors have met the terms, conditions, and specifications of the contract.

(g) *Additional contract requirements.* The grantee must include, in addition to provisions to define a sound and complete agreement, the following provisions in all contracts, which must also be applied to subcontracts:

(1) Contracts in excess of the simplified acquisition threshold must contain contractual provisions or conditions that allow for administrative, contractual, or legal remedies in instances in which a contractor violates or breaches the contract terms, and provide for such remedial actions as may be appropriate.

(2) All contracts in excess of the simplified acquisition threshold (currently $100,000) must contain suitable provisions for termination by the grantee, including the manner by which termination must be effected and the basis for settlement.

(h) *Conditions for default or termination.* Such contracts must describe conditions under which the contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor.

(i) *Access to contract materials and staff.* All negotiated contracts (except those for less than the simplified acquisition threshold) awarded by grantees must include a provision to the effect that the grantee, the Departmental awarding agency, the U.S. Comptroller General, or any of their duly authorized representatives, must have access to any books, documents, papers and records and staff of the contractor which are directly pertinent to a specific program for the purpose of making audits, examinations, excerpts and transcriptions.

§ 495.350 State Medicaid agency attestations.

(a) The State must provide assurances to the Department that amounts received with respect to sums expended that are attributable to payments to a Medicaid provider for the adoption of EHR are paid directly to such provider, or to an employer or facility to which such provider has assigned payments, without any deduction or rebate.

(b) State Medicaid agency attestations must be provided in accordance with § 433.74 of this chapter.

§ 495.352 Reporting requirements.

Each State must submit to the Department on a quarterly basis a progress report documenting specific implementation and oversight activities performed during the quarter, including progress in implementing the State's approved Medicaid HIT plan.

§ 495.354 Rules for charging equipment.

Equipment acquired under this subpart is subject to the public assistance program requirements concerning the computation of claims for Federal financial participation in accordance with the provisions of 45 CFR part 95, subpart G.

§ 495.356 Nondiscrimination requirements.

State agencies and any other recipients or subrecipients of Federal financial assistance provided under this subpart are subject to the nondiscrimination requirements in 45 CFR parts 80, 84, and 91.

(a) These regulations in 45 CFR parts 80, 84, and 91 prohibit individuals from being excluded from participation in, being denied the benefits of, or being otherwise subjected to discrimination under any program or activity which received Federal financial assistance.

(b) Specifically, 45 part 80 prohibits discrimination on the basis of race, color, or national origin; 45 CFR part 84 prohibits discrimination on the basis of disability; and 45 CFR part 91 prohibits discrimination on the basis of age.

§ 495.358 Cost allocation plans.

State agencies that acquire HIT equipment and services under this subpart are subject to cost allocation plan requirements in 45 CFR part 95.

§ 495.360 Software and ownership rights.

(a) *General rule.* The State or local government must include a clause in all procurement instruments that provides that the State or local government will have all ownership rights in software or modifications thereof and associated documentation designed, developed or installed with FFP under this Subpart.

(b) *Federal license.* The Department reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use and to authorize others to use for Federal government purposes, such software, modifications, and documentation.

(c) *Proprietary software.* Proprietary operating/vendor software packages such as software that is owned and licensed for use by third parties, which are provided at established catalog or market prices and sold or leased to the general public must not be subject to the ownership provisions in paragraphs (a) and (b) of this section.

(d) *Limitation.* Federal financial participation is not available for proprietary applications software developed specifically for the public assistance programs covered under this subpart.

§ 495.362 Retroactive approval of FFP with an effective date of February 18, 2009.

For administrative activities performed by a State, without obtaining prior approval, which are in support of planning for incentive payments to providers, a State may request consideration of FFP by recorded request in a HIT advance planning document or implementation advance planning document update. In such a consideration, the agency takes into consideration overall Federal interests which may include any of the following:

(a) The acquisition must not be before February 18, 2009.

(b) The acquisition must be reasonable, useful, and necessary.

(c) The acquisition must be attributable to payments for reasonable administrative expenses under section 1903(a)(3)(F)(ii) of the Act.

§ 495.364 Review and assessment of administrative activities and expenses of Medicaid provider health information technology adoption and operation.

(a) CMS conducts periodic reviews on an as needed basis to assess the State's progress described in its approved HIT planning advance planning document and health information technology implementation advance planning document.

(b) During planning, development, and implementation, these reviews will generally be limited to the overall progress, work performance, expenditure reports, project deliverables and supporting documentation.

(c) CMS assesses the State's overall compliance with the approved advance planning document and provide

technical assistance and information sharing from other State projects.

(d) CMS will, on a continuing basis, review, assess and inspect the planning, design, development, implementation, and operation of activities and payments for reasonable administrative expenses related to the administration of payment for Medicaid provider HIT adoption and operation payments to determine the extent to which such activities meet the following:

(1) All requirements of this subpart.

(2) The goals and objectives stated in the approved HIT implementation advance planning document and State Medicaid HIT plan.

(3) The schedule, budget, and other conditions of the approved HIT implementation advance planning document and State Medicaid HIT plan.

§ 495.366 Financial oversight and monitoring of expenditures.

(a) *General rule.* (1) The State must have a process in place to estimate expenditures for the Medicaid EHR payment incentive program using the Medicaid Budget Expenditure System.

(2) The State must have a process in place to report actual expenditures for the Medicaid EHR payment incentive program using the Medicaid Budget Expenditure System.

(3) The State must have an automated payment and information retrieval mechanized system (Medicaid Management Information System) to make EHR payment incentives, to ensure Medicaid provider eligibility, to ensure the accuracy of payment incentives, and to identify potential improper payments.

(b) *Provider eligibility as basis for making payment.* Subject to § 495.332, the State must do all of the following:

(1) Collect and verify basic information on Medicaid providers to assure provider enrollment eligibility upon enrollment or re-enrollment to the Medicaid EHR payment incentive program.

(2) Collect and verify basic information on Medicaid providers to assure patient volume.

(3) Collect and verify basic information on Medicaid providers to assure that EPs are not hospital-based including the determination that substantially all health care services are not furnished in a hospital setting, either inpatient or outpatient.

(4) Collect and verify basic information on Medicaid providers to assure that EPs are practicing predominantly in a Federally qualified health center or rural health clinic.

(5) Have a process in place to assure that Medicaid providers who wish to participate in the EHR incentive payment program has or will have a NPI and will choose only one program from which to receive the incentive payment using the NPI, a TIN, and CMS' national provider election database.

(c) *Meaningful use and efforts to adopt, implement, or upgrade to certified electronic health record technology to make payment.* Subject to §§ 495.354 and 495.374, the State must annually collect and verify information regarding the efforts to adopt, implement, or upgrade certified EHR technology and the meaningful use of said technology before making any payments to providers.

(d) *Claiming Federal reimbursement for State expenditures.* Subject to § 495.332, the State must do the following:

(1) Assure that State expenditures are claimed in accordance with, including but not limited to, applicable Federal laws, regulations, and policy guidance.

(2) Have a process in place to assure that expenditures for administering the Medicaid EHR incentive payment program will not be claimed at amounts higher than 90 percent of the cost of such administration.

(3) Have a process in place to assure that expenditures for payment of Medicaid EHR incentive payments will not be claimed at amounts higher than 100 percent of the cost of such payments to Medicaid providers.

(e) *Improper Medicaid electronic health record payment incentives.*

(1) Subject to § 495.332, the State must have a process in place to assure that no duplicate Medicaid EHR payment incentives are paid between the Medicare and Medicaid programs, or paid by more than one State even if the provider is licensed to practice in multiple States, or paid within more than one area of a State.

(2) Subject to § 495.332, the State must have a process in place to assure that Medicaid EHR incentive payments are made without reduction or rebate, have been paid directly to an eligible provider or to an employer, a facility, or an eligible third-party entity to which the Medicaid eligible provider has assigned payments.

(3) Subject to § 495.332, the State must have a process in place to assure that Medicaid EHR incentive payments are made for no more than 6 years or for any year starting after the year of 2015 unless the provider has been provided payment under paragraph (b)(1) of this section for the previous year.

(4) Subject to § 495.332, the State must have a process in place to assure that only appropriate funding sources are used to make Medicaid EHR incentive payments.

(5) Subject to § 495.332, the State must have a process in place to assure that Medicaid EHR incentive payments are not paid at amounts higher than 85 percent of the net average allowable cost of certified EHR technology and the yearly maximum allowable payment thresholds.

(6) Subject to § 495.332, the State must have a process in place to assure that for those entities promoting the adoption of EHR technology, the Medicaid EHR incentive payments are paid on a voluntary basis and that these entities do not retain more than 5 percent of such payments for costs not related to certified EHR technology.

(7) Subject to § 495.332, the State must have a process in place to assure that any existing fiscal relationships with providers to disburse the incentive through Medicaid managed care plans does not exceed 105 percent of the capitation rate, in order to comply with the Medicaid managed care incentive payment rules at § 438.6(c)(5)(iii) of this chapter and a methodology for verifying such information.

(8) The State must not request reimbursement for Federal financial participation unless all requirements of this subpart have been satisfied.

§ 495.368 Combating fraud and abuse.

(a) *General rule.* (1) The State must comply with Federal requirements to—

(i) Ensure the qualifications of the providers who request Medicaid EHR incentive payments;

(ii) Detect improper payments; and

(iii) In accordance with 42 CFR § 455.15 and § 455.21, refer suspected cases of fraud and abuse to the Medicaid Fraud Control Unit.

(2) The State must take corrective action in the case of improper EHR payment incentives to Medicaid providers.

(b) *Providers' statements regarding submission of documentation containing falsification or concealment of a material fact on EHR incentive payment documentation.* On any forms on which a provider submits information necessary to the determination of eligibility to receive EHR incentive payments, the State must obtain the statement that meet the following:

(1) Is signed by the provider and contains the following statement: "This is to certify that the foregoing information is true, accurate, and complete. I understand that Medicaid EHR incentive payments submitted under this provider number will be from

Federal funds, and that any falsification, or concealment of a material fact may be prosecuted under Federal and State laws."

(2) Appears directly above the claimant's signature, or if it is printed on the reverse of the form, a reference to the statements must appear immediately preceding the provider's signature.

(3) Is resubmitted upon a change in provider representative.

(4) Is updated as needed.

(c) *Overpayments.* States must repay to CMS all Federal financial participation received by providers identified as an overpayment regardless or recoupment from such providers, within 60 days of discovery of the overpayment, in accordance with sections 1903(a)(1), (d)(2), and (d)(3) of the Act and part 433 Subpart F of the regulations.

(d) *Complying with Federal laws and regulations.* States must comply with all Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

§ 495.370 Appeals process for a Medicaid provider receiving electronic health record incentive payments.

(a) The State must have a process in place consistent with the requirements established in § 447.253(e) of this chapter for a provider or entity to appeal the following issues related to the HIT incentives payment program:

(1) Incentive payments.

(2) Incentive payment amounts.

(3) Provider eligibility determinations.

(4) Demonstration of adopting, implementing, and upgrading, and meaningful use eligibility for incentives under this subpart.

(b) Subject to paragraph (a) of this section, the State's process must ensure the following:

(1) That the provider (whether an individual or an entity) has an opportunity to challenge the State's determination under this Part by submitting documents or data or both to support the provider's claim.

(2) That such process employs methods for conducting an appeal that are consistent with the State's Administrative Procedure law(s).

(c) The State must provide that the provider (whether individual or entity) is also given any additional appeals rights that would otherwise be available under procedures established by the State.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program, Program No. 93.778, Medical Assistance Program.)

Dated: November 13, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 28, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–31217 Filed 12–30–09; 4:15 pm]

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Part III

Department of Health and Human Services

45 CFR Part 170

Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991–AB58

Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Interim final rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this interim final rule with a request for comments to adopt an initial set of standards, implementation specifications, and certification criteria, as required by section 3004(b)(1) of the Public Health Service Act. This interim final rule represents the first step in an incremental approach to adopting standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health information technology and to support its meaningful use. The certification criteria adopted in this initial set establish the capabilities and related standards that certified electronic health record (EHR) technology will need to include in order to, at a minimum, support the achievement of the proposed meaningful use Stage 1 (beginning in 2011) by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs.

DATES: *Effective Date:* This interim final rule is effective February 12, 2010. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of February 12, 2010.

Comment Date: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on March 15, 2010.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments, identified by RIN 0991–AB58, by any of the following methods (please do not submit duplicate comments).

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word. *http://www.regulations.gov.*
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: HITECH Initial Set Interim Final Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201. Please submit one original and two copies.
- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: HITECH Initial Set Interim Final Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered to be proprietary. We will post all comments received before the close of the comment period at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Policy Analyst, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Acronyms

AHIC American Health Information Community
ANSI American National Standards Institute
ASP Application Service Provider
CAH Critical Access Hospital
CCD Continuity of Care Document
CCHIT Certification Commission for Health Information Technology
CCR Continuity of Care Record
CDA Clinical Document Architecture
CDC Centers for Disease Control and Prevention
CFR Code of Federal Regulations
CGD Certification Guidance Document
CMS Centers for Medicare & Medicaid Services
CPOE Computerized Provider Order Entry
EHR Electronic Health Record
FIPS Federal Information Processing Standards
GIPSE Geocoded Interoperable Population Summary Exchange
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
HITSP Healthcare Information Technology Standards Panel
HL7 Health Level Seven
ICD International Classification of Diseases
ICD–9–CM ICD, 9th Revision, Clinical Modifications
ICD–10–PCS ICD, 10th Revision, Procedure Coding System
ICD–10–CM ICD, 10th Revision, Related Health Problems
IHS Indian Health Service
LOINC Logical Observation Identifiers Names and Codes
MA Medicare Advantage
NCPDP National Council for Prescription Drug Programs
NCVHS National Committee on Vital and Health Statistics
NLM National Library of Medicine
NQF National Quality Forum
OASIS Organization for the Advancement of Structured Information Standards
OCR Office for Civil Rights
OIG Office of Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
PHSA Public Health Service Act
PQRI Physician Quality Reporting Initiative
REST Representational state transfer
RFA Regulatory Flexibility Act
SDOs Standards Development Organizations
SNOMED CT Systematized Nomenclature of Medicine Clinical Terms
SOAP Simple Object Access Protocol
UCUM Unified Code for Units of Measure
UMLS Unified Medical Language System
UNII Unique Ingredient Identifier
XML eXtensible Markup Language

Table of Contents

I. Background
A. ONC Background

B. Interdependencies With Other HITECH Provisions and Relationship to Other Regulatory Requirements and Related Activities
1. Medicare and Medicaid EHR Incentive Programs Proposed Rule
2. Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule Accounting of Disclosures Regulation
3. Previous Recognition of Certification Bodies and New Authority Under the HITECH Act
4. Other HHS Regulatory Actions
a. Health Insurance Portability and Accountability Act of 1996 (HIPAA) Transactions and Code Sets Standards
b. Electronic Prescribing Standards
C. Standards, Implementation Specifications, and Certification Criteria Processes Before and After the HITECH Act
1. ONC's Processes Prior to the HITECH Act
2. HITECH Act Requirements for the Adoption of Standards, Implementation Specifications, and Certification Criteria
D. Future Updates to Standards, Implementation Specifications, and Certification Criteria
II. Overview of the Interim Final Rule
III. Section-By-Section Description of the Interim Final Rule
A. Applicability
B. Definitions
1. Definition of Standard
2. Definition of Implementation Specification
3. Definition of Certification Criteria
4. Definition of Qualified Electronic Health Record (EHR)
5. Definition of EHR Module
6. Definition of Complete EHR
7. Definition of Certified EHR Technology
8. Definition of Disclosure
C. Initial Set of Standards, Implementation Specifications, and Certification Criteria
1. Adopted Certification Criteria
2. Adopted Standards
a. Transport Standards
b. Content Exchange and Vocabulary Standards
i. Patient Summary Record
ii. Drug Formulary Check
iii. Electronic Prescribing
iv. Administrative Transactions
v. Quality Reporting
vi. Submission of Lab Results to Public Health Agencies
vii. Submission to Public Health Agencies for Surveillance or Reporting
viii. Submission to Immunization Registries
ix. Table 2A
c. Privacy and Security Standards
3. Adopted Implementation Specifications
4. Additional Considerations, Clarifications, and Requests for Public Comments
a. Relationship to Other Federal Laws
b. Human Readable Format
c. Certification Criterion and Standard Regarding Accounting of Disclosures
d. Additional Requests for Public Comment
IV. Collection of Information Requirements
V. Regulatory Impact Analysis
A. Introduction
B. Why Is This Rule Needed?
C. Costs and Benefits
1. Costs
2. Benefits
D. Regulatory Flexibility Act Analysis
E. Executive Order 13132—Federalism
F. Unfunded Mandates Reform Act of 1995
Regulation Text

I. Background

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created "Title XXX—Health Information Technology and Quality" to improve health care quality, safety, and efficiency through the promotion of health information technology (HIT) and the electronic exchange of health information. Section 3004(b)(1) of the PHSA requires the Secretary of the Department of Health and Human Services (the Secretary) to adopt an initial set of standards, implementation specifications, and certification criteria by December 31, 2009 to enhance the interoperability, functionality, utility, and security of health information technology. It also permits the Secretary to adopt this initial set through an interim final rule.

The certification criteria adopted in this initial set establish the capabilities and related standards that certified electronic health record (EHR) technology (Certified EHR Technology) will need to include in order to, at a minimum, support the achievement of the proposed meaningful use Stage 1 by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs.

Throughout this interim final rule, we routinely refer to eligible professionals and eligible hospitals. This is done because we have closely aligned the initial set of standards, implementation specifications, and certification criteria adopted by this rule to focus on the capabilities that Certified EHR Technology must be able to provide in order to support the achievement of the proposed criteria for meaningful use Stage 1 by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs. This initial focus is not meant to limit or preclude health care providers who do not meet the definitions of eligible professional or eligible hospital from obtaining or adopting Certified EHR Technology. To the contrary, Certified EHR Technology will possess the capabilities that can assist any health care provider to improve the quality, safety and efficiency of the care they deliver.

We note that ordinarily we publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. As mentioned above, however, section 3004(b)(1) explicitly authorizes the Secretary to issue this rule on an interim final basis. Moreover, section 3004(b)(1) requires the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria by December 31, 2009. We have therefore decided to proceed directly with this interim final rule. Nevertheless, we are providing the public with a 60-day period following publication of this document to submit comments on the interim final rule.

The following discussion provides the background information relevant to the Secretary's adoption of an initial set of standards, implementation specifications, and certification criteria.

A. ONC Background

Executive Order 13335 (69 FR 24059) established the Office of the National Coordinator for Health Information Technology (ONC) on April 24, 2004. In an effort to "provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care," the President directed the Secretary to create within the Office of the Secretary the position of National Health Information Technology Coordinator (National Coordinator). The National Coordinator was charged with: Serving as the Secretary's principal advisor on the development, application, and use of HIT and directing the HHS HIT programs; ensuring that the HIT policy and programs of HHS were coordinated with those of relevant Executive Branch agencies; to the extent permitted by law, coordinating outreach and consultation by the relevant Executive Branch agencies with public and private parties of interest; and at the request of the Office of Management and Budget (OMB), providing comments and advice regarding specific Federal HIT programs. Additionally, the National Coordinator was required, to the extent permitted by law, to develop, maintain, and direct the implementation of a strategic plan to guide the nationwide implementation of interoperable HIT in

both the public and private health care sectors. Included in Executive Order 13335 as a strategic plan objective, was the goal to "advance the development, adoption, and implementation of health care information technology standards nationally through collaboration among public and private interests, and consistent with current efforts to set health information technology standards for use by the Federal Government."

Section 3001 of the PHSA establishes by statute the ONC within HHS and provides the National Coordinator with additional responsibilities and duties beyond those originally identified in Executive Order 13335. Specifically, the National Coordinator is charged with, among other duties: Reviewing and determining whether to endorse each standard, implementation specification, and certification criterion that is recommended by the HIT Standards Committee (a Federal advisory committee to the National Coordinator) and making such determinations and reporting them to the Secretary; reviewing Federal HIT investments to ensure they meet the objectives of the Federal HIT Strategic Plan; coordinating the HIT policy and programs of HHS with those of other relevant Federal agencies; serving as a leading member in the establishment and operations of the HIT Policy Committee and HIT Standards Committee; updating the Federal HIT Strategic Plan in consultation with other appropriate Federal agencies and through collaboration with public and private entities; keeping or recognizing a program or programs to certify EHR technology; conducting studies and reports; and establishing a governance mechanism for the Nationwide Health Information Network (NHIN).

B. Interdependencies With Other HITECH Provisions and Relationship to Other Regulatory Requirements and Related Activities

The HITECH Act creates multiple interdependencies between this interim final rule and other regulatory requirements, processes, and programs.

1. Medicare and Medicaid EHR Incentive Programs Proposed Rule

In writing the provisions of the HITECH Act, Congress fundamentally tied the standards, implementation specifications, and certification criteria adopted in this interim final rule to the incentives available under the Medicare and Medicaid EHR Incentive Programs by requiring the meaningful use of Certified EHR Technology. Congress outlined several goals for meaningful use one of which includes the "use of certified EHR technology in a meaningful manner." This means that to qualify for incentives, an eligible professional or eligible hospital must both adopt Certified EHR Technology and demonstrate meaningful use of this technology. Congress further specified that Certified EHR Technology must be certified as meeting the standards adopted by the Secretary, which we adopt in this rule. As referenced in the preamble to the Medicare and Medicaid EHR Incentives Program proposed rule the Medicare and/or Medicaid incentive payments are available to certain eligible professionals and eligible hospitals.

We have adopted standards, implementation specifications, and certification criteria in this interim final rule in part to assure that Certified EHR Technology is capable of supporting the achievement of meaningful use by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs. The certification criteria, adopted by the Secretary, must be used to test and certify that Complete EHRs or EHR Modules have properly implemented the capabilities required by the certification criteria and, where appropriate, the standards and implementation specifications adopted by the Secretary. ONC and the Centers for Medicare & Medicaid Services (CMS) have worked carefully to ensure that this interim final rule and the Medicare and Medicaid EHR Incentive Programs proposed rule are aligned.

To inform our collaborative rulemaking processes, ONC and CMS received input from hundreds of technical subject matter experts, health care providers, and other stakeholders who provided written comments to, testified before, and attended meetings held by three HHS Federal advisory committees: the National Committee on Vital and Health Statistics, the HIT Policy Committee, and the HIT Standards Committee. After several meetings of its workgroups and the full committee, the HIT Policy Committee presented and recommended to the National Coordinator at its July 16, 2009 meeting a matrix on meaningful use of Certified EHR Technology that contained: Overall health outcome policy priorities; health care goals; draft objectives for eligible professionals and eligible hospitals for 2011 (beginning of meaningful use Stage 1), 2013 (beginning of meaningful use Stage 2), and 2015 (beginning of meaningful use Stage 3); and specific measures for each of those years. With respect to this interim final rule's relationship to the Medicare and Medicaid EHR Incentive Programs proposed rule, we have adopted certification criteria that directly support CMS's proposed meaningful use Stage 1 objectives. The stages of meaningful use are described and have been proposed by CMS in the Medicare and Medicaid EHR Incentive Programs proposed rule as the following:

- Stage 1 (beginning in 2011): The proposed Stage 1 meaningful use criteria "focuses on electronically capturing health information in a coded 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); consistent with other provisions of Medicare and Medicaid law, implementing clinical decision support tools to facilitate disease and medication management; and reporting clinical quality measures and public health information."
- Stage 2 (beginning in 2013): CMS has proposed that its goals for the Stage 2 meaningful use criteria, "consistent with other provisions of Medicare and Medicaid law, expand upon the Stage 1 criteria to 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, such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results (such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, pulmonary function tests and other such data needed to diagnose and treat disease). Additionally we may consider applying the criteria more broadly to both the inpatient and outpatient hospital settings."
- Stage 3 (beginning in 2015): CMS has proposed that its goals for the Stage 3 meaningful use criteria are, "consistent with other provisions of Medicare and Medicaid law, to focus on promoting improvements in quality, safety and efficiency, focusing on decision support for national high priority conditions, patient access to self management tools, access to comprehensive patient data and improving population health."

2. Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule Accounting of Disclosures Regulation

Section 13405(c) of the HITECH Act requires the Secretary to promulgate regulations on what information shall be

collected about disclosures for treatment, payment, or health care operations made "through an electronic health record" by a HIPAA covered entity. These regulations, which will be issued by the Secretary through the HHS Office for Civil Rights, must be issued not later than 6 months after the date on which the Secretary adopts standards on accounting for disclosures described in the section 3002(b)(2)(B)(iv) of the PHSA. The certification criterion and standard associated with this requirement and included in this interim final rule are discussed in more detail below in section III.C.4.c.

3. Previous Recognition of Certification Bodies and New Authority Under the HITECH Act

Among other responsibilities, section 3001(c)(5) of the PHSA expressly requires the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, to "keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted" by the Secretary under section 3004. HHS's recognition of certain bodies to conduct HIT certification is not new as a result of the HITECH Act. In August 2006, HHS published two final rules in which CMS and the Office of Inspector General (OIG) promulgated an exception to the physician self-referral prohibition and a safe harbor under the anti-kickback statute, respectively, for certain arrangements involving the donation of interoperable EHR software to physicians and other health care practitioners or entities (71 FR 45140 and 71 FR 45110, respectively). The exception and safe harbor provide that EHR software will be "deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the [physician/recipient]." ONC published separately a Certification Guidance Document (CGD) (71 FR 44296) to explain the factors ONC would use to determine whether or not to recommend to the Secretary a body for recognized certification body status. The CGD serves as a guide for ONC to evaluate applications for recognized certification body status and provides the information a body would need to apply for and obtain such status. In section VI of the CGD, ONC notified the public and potential applicants that the recognition process would be formalized through notice and comment rulemaking.

After reviewing the new responsibilities assumed under the HITECH Act and the additional purpose to which the certification of the HIT is now tied (qualifying for incentive payments) in combination with ONC's current responsibilities under the CGD, we have decided to propose in a separate rulemaking, processes to replace the CGD and establish HIT certification programs as specified by section 3001(c)(5) of the PHSA. We have decided to proceed with a separate notice and comment rulemaking (which we anticipate publishing shortly after this interim final rule) to establish the policies for the certification of HIT and the process a certification body will need to follow to become an authorized certification body, as determined by the National Coordinator.

4. Other HHS Regulatory Actions

a. HIPAA Transactions and Code Sets Standards

The Secretary has previously adopted and modified transactions and code sets standards for HIPAA covered entities. Many of these same covered entities are now also eligible to qualify for incentive payments under the Medicare and Medicaid EHR Incentives Program. As a result, we want to assure that Certified EHR Technology positions these eligible professionals and eligible hospitals to qualify for incentive payments and comply with these transactions and code set standards. Most recently, in August 2008, HHS proposed through two rules (73 FR 49742 and 73 FR 49796) the updating of electronic transaction standards, new transaction standards, and the adoption of International Classification of Diseases (ICD), 10th Revision, Related Health Problems (ICD–10–CM) and ICD, 10th Revision, Procedure Coding System (ICD–10–PSC) code sets to replace the ICD, 9th Revision, Clinical Modifications (ICD–9–CM) Volumes 1 and 2, and the ICD–9–CM Volume 3 code sets, respectively. After reviewing and considering public comments on these proposals, in January 2009, HHS adopted in final rules published at 74 FR 3296 and 74 FR 3328 certain updated transaction standards, new transaction standards, and code sets.

The rules established a timeline for compliance with some of these updated standards and code sets. For example, all HIPAA covered entities are required to comply with ICD–10–CM and ICD–10–PSC on and after October 1, 2013.

In adopting an initial set of standards and implementation specifications as specified at section 3004(b)(1) of the PHSA, we have taken into account HIPAA transactions and code sets standards and their associated implementation timetables. We have ensured that our standards and implementation specifications are consistent with the previously adopted HIPAA transactions and code sets standards and with the established implementation timetable. Further, we intend for our future adoption of standards and implementation specifications for meaningful use Stage 2 and Stage 3 to continue to be consistent with the Secretary's adoption and modification of HIPAA transactions and code sets standards and their timeframes for compliance.

b. Electronic Prescribing Standards

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) provided for, among other things, the Voluntary Prescription Drug Benefit Program. Under that program, electronically transmitted prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals must be sent in a manner that complies with applicable standards that are adopted by the Secretary. The Secretary proposed the first of these standards in a February 2005 rulemaking (70 FR 6256). Subsequently, on June 23, 2006 (71 FR 36020), HHS published an interim final rule that maintained the National Council for Prescription Drug Programs (NCPDP) SCRIPT 5.0 as the adopted standard, but allowed for the voluntary use of a subsequent backward compatible version of the standard, NCPDP SCRIPT 8.1.

As a result of pilot testing of six "initial standards" that had been identified in 2005, the Secretary issued a notice of proposed rulemaking on November 16, 2007 (72 FR 64900) which proposed adoption of certain standards. The Secretary also used this proposed rule to solicit comments regarding the impact of adopting NCPDP SCRIPT 8.1 and retiring NCPDP SCRIPT 5.0. Based on the comments that were received, the Secretary issued a final rule (73 FR 18918) on April 7, 2008 that adopted NCPDP SCRIPT Version 8.1 and retired NCPDP SCRIPT Version 5.0. In adopting an initial set of standards to meet the requirement specified at section 3004(b)(1) of the PHSA, we have taken into account these electronic prescribing standards and ensured that our standards are consistent with them.

C. Standards, Implementation Specifications, and Certification Criteria Processes Before and After the HITECH Act

1. ONC's Processes Prior to the HITECH Act

Prior to the enactment of the HITECH Act, ONC's processes consisted of the "acceptance" and "recognition" of HIT standards, implementation specifications, and certification criteria for the electronic exchange of health information and electronic health records. This prior process and its participants are described in further detail below.

Chartered in 2005, the American Health Information Community (AHIC), a Federal advisory committee, was charged with making recommendations to the Secretary on how to accelerate the development and adoption of HIT. Until its sunset in November 2008, AHIC advanced to the Secretary several recommendations related to standards, implementation specifications, and certification criteria. To structure those recommendations, AHIC identified "use cases" to prioritize areas in need of harmonized standards and to enable ONC to guide the work of organizations with specific expertise in those priority areas. A use case provided a description of the activity of stakeholders, a sequence of their actions, and technical specifications for systems and technologies involved when the actors engage in responding to or participating in such activity.

Created in 2005 by the American National Standards Institute (ANSI) under a contract with HHS, the Healthcare Information Technology Standards Panel (HITSP)—a cooperative partnership of more than 500 public and private sector organizations—began its work to take into account AHIC identified use cases, as directed by ONC. HITSP was established for the purpose of harmonizing and integrating a widely accepted and useful set of standards to enable and support interoperability among healthcare software systems and the organizations and entities that utilize the systems. HITSP also became a primary forum for HIT standards harmonization after the Consolidated Health Informatics (CHI) initiative, which began in October 2001 as a collaborative effort to adopt Federal government-wide interoperability standards to be implemented by Federal agencies, was gradually phased out. The CHI initiative adopted several standards that were fed into and reused as part of HITSP's standards harmonization processes. As a result, over the course of its three-year existence, AHIC sought testimony from HITSP representatives several times on their standards harmonization work in order to inform potential recommendations for the Secretary. In many cases, after a presentation by HITSP, AHIC would make recommendations to the Secretary regarding standards and implementation specifications for recognition. The Secretary would subsequently review those recommendations and determine whether to recognize some or all of the recommended standards and implementation specifications.

Executive Order 13410 (71 FR 51089) acknowledged that the Secretary recognizes interoperability standards for use by certain Federal agencies.[1] This Executive Order also directed those Federal agencies, to the extent permitted by law, to require in their contracts and agreements with certain organizations the use, where available, of health information technology systems and products that meet recognized interoperability standards. Executive Order 13410 was issued on August 28, 2006, to, among other goals, ensure that health care programs administered or sponsored by the Federal government promoted quality and efficient delivery of health care through the use of health information technology. On March 1, 2007, January 23, 2008, and January 29, 2009, HHS published notices in the **Federal Register** (72 FR 9339, 73 FR 3973, 74 FR 3599, respectively) announcing either the Secretary's acceptance or recognition of certain standards and implementation specifications. In an effort to assist with the implementation and adoption challenges associated with recognized standards, the Secretary chose to first "accept" and then formally "recognize" one year after acceptance, specified standards and implementation specifications. This delay provided Federal agencies with additional time to prepare for Executive Order 13410's directive to "utilize, where available, health information technology systems and products that meet recognized interoperability standards" when they implemented, acquired, or upgraded "health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities."

The third participant besides AHIC and HITSP that played a role in ONC's prior processes was the Certification Commission for Health Information Technology (CCHIT). Founded in 2004, CCHIT established the first comprehensive process to test and certify EHR technology. After establishing a certification criteria development process that included diverse stakeholders and a voluntary, consensus-based approach, CCHIT began certifying ambulatory EHR technology in 2006. Since 2006, CCHIT has expanded its certification program to include inpatient EHR technology, emergency department EHR technology, as well as its certification criteria for EHR technology to meet specific needs of certain health care providers/specialists (*e.g.,* cardiovascular, child health). On May 16, 2006, CCHIT presented its 2006 ambulatory EHR certification criteria to AHIC and after considering the criteria, AHIC recommended that the Secretary recognize CCHIT-identified certification criteria for functionality, interoperability, and security.

This recommendation informed the Secretary's decision to recognize the 2006 ambulatory EHR certification criteria for use by recognized certification bodies in conjunction with published final rules for exceptions to the physician self-referral law and safe harbors to the anti-kickback statute for electronic prescribing and EHR software arrangements (71 FR 45140 and 71 FR 45110, respectively). The exception and safe harbor provide that EHR software will be "deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the [physician/recipient]." These provisions of the EHR exception and safe harbor anticipated that: (1) HHS would recognize one or more EHR certifying bodies, and (2) HHS would recognize criteria for the certification of EHRs. The **Federal Register** notice (71 FR 44295) describing the Secretary's recognition of these certification criteria was published on August 4, 2006.

Section 3004(b)(2) of the PHSA provides that in adopting an initial set of standards, implementation specifications, and certification criteria in accordance with section 3004(b)(1), the Secretary may adopt those standards, implementation specifications, and certification criteria

[1] Executive Order 13410 defines "agency" to mean "an agency of the Federal Government that administers or sponsors a Federal health care program." It also defines "Federal health care program" as including "the Federal Employees Health Benefit Program, the Medicare program, programs operated directly by the Indian Health Service, the TRICARE program for the Department of Defense and other uniformed services, and the health care program operated by the Department of Veterans Affairs." For purposes of the Executive Order, "Federal health care program" does not include "State operated or funded federally subsidized programs such as Medicaid, the State Children's Health Insurance Program, or services provided to Department of Veterans' Affairs beneficiaries under 38 U.S.C. 1703."

that went through the process established by ONC before the date of the enactment of the HITECH Act. We believe that in separately requiring the Secretary to adopt an "initial set" of standards, implementation specifications, and certification criteria under section 3004(b)(1) of the PHSA, Congress provided the Secretary with the discretion to adopt standards, implementation specifications, or certification criteria which had not gone through the prior process. As described above, while the prior process included a significant body of work it did not encompass the entirety of the areas Congress requested the Secretary to focus on in the HITECH Act, nor did it envision the policies and capabilities that would be necessary for Certified EHR Technology to meet the proposed definition of meaningful use Stage 1 included in the Medicare and Medicaid EHR Incentive Programs proposed rule. As a result, we have, after considering the input received through the recommendations of the HIT Policy Committee and HIT Standards Committee, adopted an initial set of standards, implementation specifications, and certification criteria to, at a minimum, support the achievement of what is being proposed for meaningful use Stage 1. We have noted in section III of this rule, where applicable, those standards and implementation specifications that were previously accepted or recognized by the Secretary under this prior process and those that were not. Due to our approach of aligning adopted certification criteria with the proposed definition of meaningful use Stage 1, the Secretary has decided not to adopt previously recognized certification criteria developed in 2006 as any of the certification criteria in this interim final rule.

2. HITECH Act Requirements for the Adoption of Standards, Implementation Specifications, and Certification Criteria

With the passage of the HITECH Act, two new Federal advisory committees, the HIT Policy Committee and the HIT Standards Committee, were established as specified in the new sections of the PHSA, 3002 and 3003, respectively. Both are responsible for advising the National Coordinator on different aspects of standards, implementation specifications, and certification criteria and consequently they both have the potential to impact how and when standards, implementation specifications, and certification criteria are adopted by the Secretary. The HIT Policy Committee is responsible for, among other duties, recommending priorities for standards, implementation specifications, and certification criteria while the HIT Standards Committee is responsible for recommending standards, implementation specifications, and certification criteria for adoption under section 3004 of the PHSA.

Section 3002 of the PHSA directs the HIT Policy Committee to "make policy recommendations to the National Coordinator relating to the implementation of a nationwide health information technology infrastructure." Section 3002(b) further specifies the type of policy recommendations expected of the HIT Policy Committee by requiring that the committee focus on "specific areas of standards development" and in so doing "recommend the areas in which standards, implementation specifications, and certification criteria are needed for the electronic exchange and use of health information for purposes of adoption under section 3004." Section 3002(b) also requires the HIT Policy Committee, after determining the areas where standards, implementation specifications, and certification criteria are needed (a process and analysis that are likely to occur on a periodic basis), to "recommend an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria among the areas so recommended." After receipt of a recommendation related to a priority order, the National Coordinator is expected to review the priorities identified by the HIT Policy Committee and generally will either accept them as submitted, request adjustments, or reject the priority order in whole or in part. Once the National Coordinator accepts a recommendation for the priority order of standards, implementation specifications, and certification criteria, such priorities will be communicated to the HIT Standards Committee to guide its work. The HIT Policy Committee is charged with making recommendations in at least the following eight areas as specified in section 3002(b)(2)(B) of the PHSA:

(1) Technologies that protect the privacy of health information and promote security in a qualified electronic health record, including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns, in accordance with applicable law, and for the use and disclosure of limited data sets of such information;

(2) A nationwide health information technology infrastructure that allows for the electronic use and accurate exchange of health information;

(3) The utilization of a certified electronic health record for each person in the United States by 2014;

(4) Technologies that as a part of a qualified electronic health record allow for an accounting of disclosures made by a covered entity (as defined for purposes of regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996) for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of such regulations);

(5) The use of certified electronic health records to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, by reducing medical errors, by improving population health, by reducing health disparities, by reducing chronic disease, and by advancing research and education;

(6) Technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in the nationwide health information network or physically transported outside of the secured, physical perimeter of a health care provider, health plan, or health care clearinghouse;

(7) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including, at a minimum, race, ethnicity, primary language, and gender information; and

(8) Technologies that address the needs of children and other vulnerable populations.

The HIT Policy Committee is also authorized at 3002(b)(2)(C) to consider other areas to make recommendations such as the "appropriate uses of a nationwide health information infrastructure, including [for] * * * collection of quality data and public reporting," "telemedicine," and "technologies that help reduce medical errors."

Section 3003 of the PHSA directs the HIT Standards Committee to "recommend to the National Coordinator standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption under section 3004." It also established that the HIT Standards Committee must recommend standards, implementation specifications, and certification criteria they have developed, harmonized, or recognized. We note that in section 3003(b)(2), the HIT Standards Committee is also expressly permitted to recognize harmonized or updated standards from other entities and as a result, we expect the HIT Standards Committee to, where appropriate, consider the standards, implementation specifications, and certification criteria from various

entities for recommendation to the National Coordinator. We expect that in determining whether to recognize harmonized or updated standards from other entities, the HIT Standards Committee will look to entities such as HITSP and the National Quality Forum (NQF). Additionally, section 3003(a) requires the HIT Standards Committee to focus on and make recommendations to the National Coordinator on the eight areas in section 3002(b)(2)(B) listed above. The HIT Standards Committee is required to update their recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B) of the PHSA.

Section 3004 of the PHSA redefines how the Secretary adopts standards, implementation specifications, and certification criteria.

- Section 3004(b)(1) of the PHSA requires a one-time action by the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria. This interim final rule has been published to meet the requirements in section 3004(b)(1).
- Section 3004(a) of the PHSA defines a process whereby an obligation is imposed on the Secretary to review standards, implementation specifications, and certification criteria and identifies the procedures for the Secretary to follow to determine whether to adopt any grouping of standards, implementation specifications, or certification criteria included within National Coordinator-endorsed recommendations. The specific elements of the process related to section 3004(a) will be described in greater detail below.
- Section 3004(b)(3) of the PHSA entitled "subsequent standards activity" states that the "Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent" with the schedule published by the HIT Standards Committee. While we intend to consistently seek the insights and recommendations of the HIT Standards Committee, we note that section 3004(b)(3) provides the Secretary with the authority and discretion to adopt standards, implementation specifications, and certification criteria without having first received a National Coordinator-endorsed HIT Standards Committee recommendation.

Under section 3004(a) when a recommendation regarding a standard, implementation specification, or certification criterion is made by the HIT Standards Committee to the National Coordinator, a time limited statutory process is triggered. First, after receiving a recommendation from the HIT Standards Committee, the National Coordinator must review and determine whether to endorse the recommendation as well as report such determination to the Secretary. Upon receipt of an "endorsed recommendation," the Secretary is required to consult with representatives of other relevant Federal agencies to review the standards, implementation specifications, or certification criteria and determine whether to propose their adoption. The Secretary is required to publish all determinations in the **Federal Register**. If the Secretary determines to propose the adoption of standards, implementation specifications, or certification criteria, the Secretary is permitted to adopt any grouping of standards, implementation specifications, or certification criteria. On the other hand, if the Secretary determines not to propose the adoption of any grouping of standards, implementation specifications, or certification criteria, the Secretary must notify the National Coordinator and the HIT Standards Committee in writing of such determination and the reasons for not proposing their adoption.

The HIT Standards Committee issued recommendations to the National Coordinator on August 20, 2009, and updated those recommendations on September 15, 2009. In fulfilling the duties under section 3001(c)(1)(A) and (B), the National Coordinator reviewed the recommendations made by the HIT Standards Committee and issued a determination endorsing several recommendations for the Secretary's consideration. As specified in section 3004(a)(3), this interim final rule also serves as the Secretary's formal publication of the determinations made regarding the National Coordinator-endorsed recommendations.

D. Future Updates to Standards, Implementation Specifications, and Certification Criteria

The initial set of standards, implementation specifications, and certification criteria adopted in this interim final rule marks the beginning of what we expect to be an iterative approach to enhancing the interoperability, functionality, utility, and security of HIT. A number of factors including maturity, prevalence in the market, and implementation complexity informed our adoption of the standards, implementation specifications, and certification criteria included in this interim final rule.

Our approach to the adoption of standards, implementation specifications, and certification criteria is pragmatic, but forward looking. While a high-level of interoperability nationwide will take time and be challenging, we believe that the HITECH Act has generated a significant amount of momentum and interest in meeting the challenges that lie ahead.

We recognize that interoperability and standardization can occur at many different levels. For example, one organization may use an information model to describe patient demographic information as (PatientAge, PatientSex, StreetAddress), while another may describe similar demographic information in a different way (DateOfBirth, Gender, City/State). To achieve interoperability at this information level, these information models would need to be harmonized into a consistent representation.

In other cases, organizations may use the same information model, but use different vocabularies or code sets (for example, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) or ICD9–CM) within those information models. To achieve interoperability at this level, standardizing vocabularies, or mapping between different vocabularies (using tools like Unified Medical Language System (UMLS)) may be necessary. For some levels, (such as the network transport protocol), an industry standard that is widely used (*e.g.*, Transmission Control Protocol (TCP) and the Internet Protocol (IP), (TCP/IP)) will likely be the most appropriate. Ultimately, to achieve semantic interoperability, we anticipate that multiple layers—network transportation protocols, data and services descriptions, information models, and vocabularies and code sets—will need to be standardized and/or harmonized to produce an inclusive, consistent representation of the interoperability requirements. We anticipate using a harmonization process that will integrate different representations of health care information into a consistent representation and maintain and update that consistent representation over time. For an information model, this process could include merging related concepts, adding new concepts, and mapping concepts from one representation of health care information to another. Similar processes to support standardization of data and services descriptions and vocabularies and codes sets may also be needed.

We also recognize that a sustainable and incremental approach to the adoption of standards will require

processes for harmonizing both current and future standards. This will allow us to incrementally update our initial set of standards, implementation specifications, and certification criteria and provide a framework to maintain them. Our decision to adopt such updates will be informed and guided by recommendations from the HIT Policy Committee, HIT Standards Committee, public comment, industry readiness, and future meaningful use goals and objectives established for the Medicare and Medicaid EHR Incentive Programs. As a result, we expect, unless otherwise necessary, to adopt standards, implementation specifications, and certification criteria synchronously with and to support a transition to the next stage of meaningful use in the Medicare and Medicaid EHR Incentive Programs. In doing so, we also anticipate increasing the level of specificity we provide related to standards, implementation specifications, and certification criteria as well as phasing out certain alternative standards that have been adopted in this initial set. Furthermore, we anticipate that the requirements for meaningful use will become more demanding over time, and consequently that Certified EHR Technology will need to include greater capabilities as well as the ability to exchange electronic health information in a variety of circumstances with many different types of health information technology. Finally, as will be discussed in more detail in the HIT Certification Programs proposed rule, it is possible that the certification programs established by the National Coordinator could certify other types of HIT, perhaps related to certain specialty products and personal health records. In order for that to occur, specific standards, implementation specifications, and certification criteria related to those types of HIT would need to be developed and adopted.

II. Overview of the Interim Final Rule

We are adding a new part, part 170, to title 45 of the Code of Federal Regulations (CFR) to adopt the initial set of standards, implementation specifications, and certification criteria required by section 3004(b)(1) of the PHSA. We describe the standards, implementation specifications, and certification criteria adopted by the Secretary and the factors that contributed to their adoption. We anticipate that adopted standards, implementation specifications, and certification criteria will be used to prepare Complete EHRs and EHR Modules for testing and certification. In turn, eligible professionals and eligible hospitals that wish to position themselves to achieve the requirements of meaningful use Stage 1, once finalized, could adopt and implement Certified EHR Technology. In drafting this interim final rule, we considered the input of the National Committee on Vital and Health Statistics, the HIT Policy Committee, and the HIT Standards Committee and the public comments received by each committee. We invite public comment on this interim final rule and have posed several questions on topics for which we are interested in receiving specific public comment.

III. Section-By-Section Description of the Interim Final Rule

A. Applicability—§ 170.101

This part establishes the applicable standards, implementation specifications, and certification criteria that must be used to test and certify HIT.

B. Definitions—§ 170.102

1. Definition of Standard

The term *standard* is used in many different contexts and for many different purposes. The HITECH Act did not define or provide a description of the term, standard, or how it should be used in relation to HIT. As a result, we looked to other sources to inform our definition for the term.

As specified in the HIPAA Rules, standard is defined at 45 CFR 160.103 to mean "a rule, condition, or requirement: (1) Describing the following information for products, systems, services or practices: (i) Classification of components. (ii) Specification of materials, performance, or operations; or (iii) Delineation of procedures; or (2) With respect to the privacy of individually identifiable health information." This definition includes important concepts that we believe are applicable and appropriate for this interim final rule and we have included these concepts in our definition of standard. Other definitions or descriptions of the term standard include "an established policy on a particular practice or method;" "a set of instructions for performing operations or functions;" or "a published statement on a topic specifying the characteristics, usually measurable, that must be satisfied or achieved to comply with the standard." [2]

We believe the types of standards envisioned by Congress in the HITECH Act that would be most applicable to HIT are standards that are technical, functional, or performance-based. For example, a technical standard could specify that the structure of a message containing a patient's blood test results must include a header, the type of test performed, and the results, and further, that message must always be put in that sequence and be 128 bits long; a functional standard could specify certain actions that must be consistently accomplished by HIT such as recording the date and time when an electronic prescription is transmitted; and a performance standard could specify certain operational requirements for HIT such as being able to properly identify a drug-allergy contraindication 99.99% of the time for patient safety purposes. With this in mind, we have chosen to define standard to mean: a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, characteristics, or actions.

2. Definition of Implementation Specification

The term *implementation specification* is defined at 45 CFR 160.103 of the HIPAA Rules as "specific requirements or instructions for implementing a standard." We believe that this definition conveys accurately the meaning of the term as used in the HITECH Act, which seeks consistency between these implementation specifications and those adopted under HIPAA. Moreover, the concept it applies complements the definition of standard adopted in this interim final rule. Additionally, this definition is straightforward, easy to understand, and is otherwise consistent with our goals. We have therefore adopted the HIPAA regulatory definition of implementation specification without modification.

3. Definition of Certification Criteria

The term *certification criteria* is described at section 3001(c)(5)(B) of the PHSA to mean "with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications." We have incorporated this description into our definition of certification criteria described below and expanded it to also address how the term is used in various parts of the HITECH Act. The definition consequently encompasses more than just certification criteria that establish technology meets "standards and implementation specifications." In support of meaningful use, for instance, there are many other capabilities

[2] This last definition is referenced in Federal Information Processing Standards 201.

Certified EHR Technology will need to provide under the HITECH Act even though such capabilities do not require a particular standard or implementation specification. As a result, we believe that it is critical for these capabilities to be tested and certified too. To do otherwise would potentially make it difficult for eligible professionals and eligible hospitals to know whether the Certified EHR Technology they have adopted and implemented will support their achievement of meaningful use. For example, if we did not require a certification criterion for medication reconciliation, a proposed meaningful use Stage 1 objective, Certified EHR Technology under this scenario would not provide any assurance to an eligible professional or eligible hospital that the proposed meaningful use Stage 1 requirement could be met. On the other hand, by adopting a certification criterion for medication reconciliation in this interim final rule, eligible professionals and eligible hospitals can be assured that once they adopt and implement Certified EHR Technology, it includes, at a minimum, the medication reconciliation capabilities required to support their achievement of the proposed meaningful use Stage 1 requirement.

For these reasons we have defined the term certification criteria to encompass both the statutory description and the statutory use of the term. The definition consequently also includes other certification criteria that are not directly tied to establishing that health information technology has met a standard or implementation specification. We have therefore defined certification criteria to mean: criteria: (1) To establish that health information technology meets applicable standards and implementation specifications adopted by the Secretary; or (2) that are used to test and certify that health information technology includes required capabilities.

4. Definition of Qualified Electronic Health Record (EHR)

Qualified EHR is defined at section 3000(13) of the PHSA as "an electronic record of health-related information on an individual that: (A) Includes patient demographic and clinical health information, such as medical history and problem lists; and (B) 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; and (iv) to exchange electronic health information with, and integrate such information from other sources." We have adopted the statutory definition of Qualified EHR without modification.

5. Definition of EHR Module

We have defined the term *EHR Module* to mean any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary. Examples of EHR Modules include, but are not limited to, the following:

- An interface or other software program that provides the capability to exchange electronic health information;
- An open source software program that enables individuals online access to certain health information maintained by EHR technology;
- A clinical decision support rules engine;
- A software program used to submit public health information to public health authorities; and
- A quality measure reporting service or software program.

While the use of EHR Modules may enable an eligible professional or eligible hospital to create a combination of products and services that, taken together, meets the definition of Certified EHR Technology, this approach carries with it a responsibility on the part of the eligible professional or eligible hospital to perform additional diligence to ensure that the certified EHR Modules selected are capable of working together to support the achievement of meaningful use. In other words, two certified EHR Modules may provide the additional capabilities necessary to meet the definition of Certified EHR Technology, but may not integrate well with each other or with the other EHR technology they were added to. As a result, eligible professionals and eligible hospitals that elect to adopt and implement certified EHR Modules should take care to ensure that the certified EHR Modules they select are interoperable and can properly perform in their expected operational environment.

6. Definition of Complete EHR

The term *Complete EHR* is used to mean EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary. We believe this definition helps to create a clear distinction between a Complete EHR, an EHR Module, and Certified EHR Technology. The term Complete EHR is not meant to limit the capabilities that a Complete EHR can include. Rather, it is meant to encompass EHR technology that can perform all of the applicable capabilities required by certification criteria adopted by the Secretary and distinguish it from EHR technology that cannot perform those capabilities. We fully expect some Complete EHRs to have capabilities beyond those addressed by certification criteria adopted by the Secretary.

7. Definition of Certified EHR Technology

Certified EHR Technology is defined at section 3000(1) of the PHSA as "a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved." In this interim final rule, we have slightly revised the definition of Certified EHR Technology to make it more consistent with the initial standards, implementation specifications, and certification criteria that are being adopted. Certification criteria focus on the capabilities of Complete EHRs or EHR Modules and consequently, Certified EHR Technology should be defined in accordance with that approach. We believe defining Certified EHR Technology in that manner will provide greater clarity and meaning for this interim final rule.

We have defined Certified EHR Technology to mean:

A Complete EHR or a combination of EHR Modules, each of which:

(1) Meets the requirements included in the definition of a Qualified EHR; and

(2) 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.

To clarify the meaning of "applicable certification criteria" in this definition's second part, we note that Congress indicated their expectation that different types of HIT would be certified. Congress elaborated on this expectation with a parenthetical in the statutory definition, which references two examples, "an ambulatory electronic health record for office-based physicians" and "an inpatient hospital electronic health record for hospitals." For a variety of reasons, including that certain proposed meaningful use Stage 1 objectives only apply to an eligible professional or eligible hospital and that these two types of health care providers require different capabilities from Certified EHR Technology, we have adopted specific certification criteria that are only "applicable" to Complete EHRs or EHR Modules designed for use in an ambulatory setting (*e.g.*, by eligible professionals) or an inpatient setting (*e.g.*, by eligible hospitals). We indicate in Table 1, and in the regulation text below, which certification criteria apply

solely to Complete EHRs or EHR Modules designed for use in an ambulatory setting or an inpatient setting. For example, we do not expect Certified EHR Technology that is adopted and implemented by an eligible professional to include the capability to create an electronic copy of discharge instructions. We do, however, expect Certified EHR Technology that is adopted and implemented by an eligible hospital to include this capability.

We believe that by adding the word "technology" after "EHR," Congress intended to convey an expectation that rather than adopt a complete, all-in-one solution, eligible professionals and eligible hospitals would likely adopt and implement some number of technological components or EHR Modules to extend the useful life of their legacy EHR technology or other HIT that may not provide all of the capabilities necessary to achieve meaningful use.

In the early stages of the Medicare and Medicaid EHR Incentive Programs, we expect most eligible professionals and many eligible hospitals to opt for a Complete EHR that has met the definition of Certified EHR Technology. However, with the future in mind, and to address those eligible providers and eligible hospitals that may decide to implement their own Complete EHRs or EHR Modules, we have adopted a definition of Certified EHR Technology that we believe is flexible enough to account for innovations in an industry that continues to rapidly evolve. Additionally, we believe this definition of Certified EHR Technology will lead to a more competitive marketplace and allow those who adopt HIT to choose from a variety of offerings ranging from subscription services, to vendor-based products, to open source products. An innovative and competitive HIT marketplace needs to exist much like the marketplace for consumer electronics, where, for the purpose of setting up a home theater, a television, DVD player, and stereo system can be purchased from three different manufacturers, from a single manufacturer, or as a complete system from one manufacturer.

To that end, we believe that it will be common in the near future for Certified EHR Technology to be assembled from several replaceable and swappable EHR Modules. For example, an EHR Module specifically designed to enable electronic health information exchange may be implemented for the purposes of interoperability and participation in a health information organization, regional health information organization, or some other consortium whose purpose is to enable the electronic exchange of health information. As another example, a subscription to an application service provider (ASP) for electronic prescribing could be an EHR Module and used to help meet the definition of Certified EHR Technology provided that the electronic prescribing capability the ASP enables has been tested and certified.

As long as each EHR Module has been separately tested and certified in accordance with the certification program established by the National Coordinator (which will be discussed in a future rulemaking) to all of the applicable certification criteria adopted by the Secretary, a proper combination of certified EHR Modules could meet the definition of Certified EHR Technology. To clarify, we are not requiring the certification of combinations of certified EHR Modules, just that the individual EHR Modules combined have each been certified to all applicable certification criteria in order for such a "combination" to meet the definition of Certified EHR Technology.

The following are examples of Certified EHR Technology:

- A complete EHR that is tested and certified to all applicable certification criteria.
- The combination of three certified EHR modules that include all of the capabilities required by all applicable certification criteria. (We note that in this circumstance it is the user's responsibility to determine whether the combination of these three certified EHR Modules would meet all of the applicable certification criteria necessary to meet the definition of Certified EHR Technology.)

The following are examples of what would not meet the definition of Certified EHR Technology:

- Complete EHRs that have not been tested and certified in accordance with the certification program established by the National Coordinator even though it may be claimed that such technology provides the same capabilities as those required by adopted certification criteria.
- The combination of three certified EHR modules that do not include all of the capabilities required by all applicable certification criteria. That is, if these three certified EHR modules were purchased by an eligible professional and none of them included the capability to electronically prescribe, the combination of these three modules would not be a proper combination of certified EHR Modules and would not meet the definition of Certified EHR Technology.

It is important to note that the capabilities included in the definition of Qualified EHR set the floor for the capabilities that Certified EHR Technology must include. For example, the definition of Qualified EHR does not require capabilities related to privacy and security; however, the Secretary has adopted certification criteria for privacy and security. Therefore, where the Secretary has adopted certification criteria that require capabilities beyond those specified in the definition of a Qualified EHR, a Complete EHR or EHR Module will need to be tested and certified to those adopted certification criteria in order for the definition of Certified EHR Technology to be met.

8. Definition of Disclosure

We define *disclosure* in this interim final rule to have the same meaning specified at 45 CFR 160.103—"the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information." As previously mentioned, once the Secretary adopts a standard on accounting for disclosures described in section 3002(b)(2)(B)(iv) of the PHSA, the Secretary through the HHS Office for Civil Rights, is required to modify (no later than 6 months after the date on which the Secretary adopts standards on accounting for disclosures) the HIPAA Privacy Rule at 45 CFR 164.528 to require that HIPAA covered entities account for disclosures related to treatment, payment, and health care operations made through an electronic health record and to identify in the regulations the information that shall be collected about each of the disclosures.

C. Initial Set of Standards, Implementation Specifications, and Certification Criteria §§ 170.202, 170.205, 170.210, 170.302, 170.304, 170.306

The sections below describe the initial set of standards, implementation specifications, and certification criteria adopted by the Secretary to support, in part, the achievement of meaningful use Stage 1 (which begins in 2011). The standards, implementation specifications, and certification criteria adopted are meant to serve as the basis for the testing and certification of Complete EHRs and EHR Modules and they should in no way be misconstrued as additional detailed requirements for meaningful use Stage 1 itself. In order to prevent confusion, we believe it is necessary to make clear that the standards, implementation specifications, and certification criteria adopted by the Secretary in this interim final rule apply to, and establish the

required capabilities for, Certified EHR Technology. These criteria do not establish requirements for health care providers, such as eligible professionals or eligible hospitals to follow. Because certification criteria describe both the required capabilities Certified EHR Technology must include and, where applicable, the standard(s) that must be used by those capabilities, we discuss adopted certification criteria first. Table 1 below displays the certification criteria we have adopted. Next we discuss adopted standards and the purposes for their use. Tables 2A and 2B include the standards referenced by adopted certification criteria for a particular exchange or privacy or security purpose. Lastly we discuss our approach to implementation specifications.

To guide our approach to adopting the standards, implementation specifications, and certification criteria below, we established the following goals:

- Promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability;
- Support the evolution and timely maintenance of adopted standards;
- Promote technical innovation using adopted standards;
- Encourage participation and adoption by all vendors, including small businesses;
- Keep implementation costs as low as reasonably possible;
- Consider best practices, experiences, policies, frameworks, and the input of the HIT Policy Committee and HIT Standards Committee in current and future standards;
- Enable mechanisms such as the NHIN to serve as a test-bed for innovation and as an open-source reference implementation of best practices; and
- To the extent possible, adopt standards that are modular and not interdependent. For example, an adopted vocabulary standard would not be tied to a particular content exchange standard (*e.g.,* the adoption of Current Procedural Terminology (CPT®) Fourth Edition (CPT–4) codes would not require or preclude the use of a particular patient summary record standard such as the continuity of care document (CCD) or continuity of care record (CCR)).

1. Adopted Certification Criteria

At its July 16, 2009 and August 14, 2009 meetings, the HIT Policy Committee made recommendations to the National Coordinator on policies for meaningful use and the certification of HIT, which the National Coordinator has considered. For the purposes of this interim final rule and the adoption of an initial set of certification criteria, we believe that the meaningful use matrix recommended by the HIT Policy Committee as modified in the Medicare and Medicaid EHR Incentive Programs proposed rule provides a logical way to structure our presentation of adopted certification criteria. Furthermore, we found the following recommendations on certification from the HIT Policy Committee to be particularly informative for the scope of this interim final rule and our approach to adopting certification criteria—that certification should focus on meaningful use and be leveraged to improve security, privacy, and interoperability. We agree that for this initial set of certification criteria, supporting the achievement of meaningful use Stage 1, as proposed in the Medicare and Medicaid EHR Incentive Programs proposed rule, is a foremost priority. As a result, we have adopted, based in part on the HIT Policy Committee's recommendation, an initial set of certification criteria to support the achievement by eligible professionals and eligible hospitals of meaningful use Stage 1, as proposed in the Medicare and Medicaid EHR Incentive Programs proposed rule.

The meaningful use matrix recommended by the HIT Policy Committee, a revised form of which CMS has included in the Medicare and Medicaid EHR Incentive Programs proposed rule, includes overall health outcome policy priorities and health care goals that are the same for eligible professionals and eligible hospitals. The health outcome policy priorities identified in the Medicare and Medicaid EHR Incentive Programs proposed rule are: "Improving quality, safety, efficiency, and reducing health disparities; engage patients and families in their health care; improve care coordination; improve population and public health; and ensure adequate privacy and security protections for personal health information." For each policy priority, there are also associated health care goals which are described in more detail in the Medicare and Medicaid EHR Incentive Programs proposed rule.

The health care goals served as the bases for the proposed specific meaningful use Stage 1 objectives for eligible professionals and eligible hospitals set forth in the Medicare and Medicaid EHR Incentive Programs proposed rule. We have consequently used the proposed objectives in the Medicare and Medicaid EHR Incentive Programs proposed rule to identify the initial set of certification criteria adopted in this interim final rule and have linked the certification criteria to these objectives.

Many of the proposed meaningful use Stage 1 objectives are exactly the same for eligible professionals and eligible hospitals. Where proposed meaningful use Stage 1 objectives were identical for eligible professionals and eligible hospitals, we adopted identical certification criteria for Complete EHRs or EHR Modules. However, there are instances where proposed meaningful use Stage 1 objective and corresponding meaningful use measure are specifically aimed at an eligible professional (*e.g.,* electronic prescribing) or eligible hospital (*e.g.,* provision of an electronic copy of discharge instructions). Where the proposed meaningful use Stage 1 objectives were worded differently or only applied to an eligible professional or eligible hospital, we have adopted specific certification criteria to assure that Certified EHR Technology includes the capabilities necessary to meet that objective.

Additionally, CMS describes in the Medicare and Medicaid EHR Incentive Programs proposed rule a number of the terms referenced in this table, specifically those in the first column which align directly with the proposed meaningful use Stage 1 objectives. For example, one of the proposed meaningful use Stage 1 objectives is to "perform medication reconciliation at relevant encounters and each transition of care." We have adopted a certification criterion to assure that a Complete EHR or EHR Module is capable of performing medication reconciliation. However, it is not within the scope of this interim final rule to specify when or how often this needs to occur. Rather, the proposed meaningful use Stage 1 measure for this proposed objective dictates the frequency, and the preamble of the Medicare and Medicaid EHR Incentive Programs proposed rule provides descriptions for what is meant by "relevant encounters" and "each transition of care." We encourage any reader seeking the meaning or further explanation of a particular term in the objectives to review the Medicare and Medicaid EHR Incentive Programs proposed rule.

To improve the readability of Table 1 and illustrate the linkage between adopted certification criteria and proposed meaningful use Stage 1 objectives, in instances where the proposed meaningful use Stage 1 objective was the same in concept for eligible professionals and eligible hospitals but differed slightly with

respect to wording, we provided a combined objective and referenced the full proposed objective in a footnote. All certification criteria are prefaced with the statement "A Complete EHR or EHR Module must include the capability to:" in order to create uniformity in the way each certification criterion is read.

Finally, we understand that certain types of standards, specifically code sets, must be maintained and frequently updated to serve their intended purpose effectively. Code sets are typically used for encoding data elements, such as medical terms, medical concepts, diagnoses, and medical procedures. As new medical procedures, technologies, treatments, or diagnostic methods are developed or discovered, additional codes must be added or existing codes must be revised. In some cases, new codes are necessary to reflect the most recent changes in medical practice, involving perhaps revised medication dosage, updated treatment procedures, or the discovery of new diseases. In many cases, the new codes must be disseminated and implemented quickly for patient safety and significant public health purposes.

To address this need and accommodate industry practice, we have in this interim final rule indicated that certain types of standards will be considered a floor for certification. We have implemented this approach by preceding references to specific adopted standards with the phrase, "at a minimum." In those instances, the certification criterion requires compliance with the version of the code set that has been adopted through incorporation by reference, or any subsequently released version of the code set. This approach will permit Complete EHRs and EHR Modules to be tested and certified, to, "at a minimum," the version of the standard that has been adopted or a more current or subsequently released version. This will also enable Certified EHR Technology to be updated from an older, "minimum," adopted version of a code set to a more current version without adversely affecting Certified EHR Technology's "certified status." We intend to elaborate in the upcoming HIT Certification Programs proposed rule on how testing and certification would be conducted using standards we have adopted and designated as "minimums" in certain certification criteria.

Because we expect to adopt additional code set standards in the future, we believe this approach is necessary. Moreover, we believe the certification of Complete EHRs and EHR Modules should be flexible enough to accommodate current code sets that are regularly maintained and updated. We also believe that this approach will enable and encourage eligible professionals and eligible hospitals to adopt Certified EHR Technology and keep it current, which will promote patient safety, public health safety, and more broadly, improve health care quality.

That being said, we understand that this approach has certain limitations. In some cases, for instance, rather than simply maintaining, correcting, or slightly revising a code set, a code set maintaining organization will modify the structure or framework of a code set to meet developing industry needs. We would consider this type of significant revision to a code set to be a "modification," rather than maintenance or a minor update of the code set. An example of a code set "modification" would be if a hypothetical XYZ code set version 1 were to use 7-digit numeric codes to represent health information while XYZ code set version 2 used 9-digit alphanumeric codes to represent health information. In such cases, interoperability would likely be reduced among Complete EHRs and EHR Modules that have adopted different versions of the structurally divergent code sets. If a code set that we have adopted through incorporation by reference is modified significantly, we will update the incorporation by reference of the adopted version with the more recent version of the code set prior to requiring or permitting certification according to the newer version.

The following provides an example of how our approach will work. A proposed meaningful use Stage 1 objective specifies the capability to submit electronic data to immunization registries and, accordingly, we have adopted a certification criterion to assure that a Complete EHR or EHR Module is capable of electronically recording, retrieving, and transmitting immunization information to immunization registries in accordance with the standards specified in Table 2A row 8. Table 2A row 8 references, as a vocabulary standard (code set), the CDC maintained HL7 standard code set CVX-Vaccines Administered. The current version of the CVX code set was published July 30, 2009, and includes new vaccine codes related to the "Novel Influenza-H1N1." Continuing our CVX example, if the CDC were to publish a new version of CVX on February 1, 2010, we would permit a Complete EHR or EHR Module to be tested and certified according to the minimum adopted version of the standard, the July 30, 2009, version of CVX or the February 1, 2010 version that was subsequently issued as part of the code set's maintenance.

For certain certification criteria in Table 1 below, we include a percent symbol "%" superscript to indicate instances where the version of an adopted standard (specified in the regulation text) will be "at a minimum" the version to which a Complete EHR or EHR Module must be tested and certified in order to be considered compliant with the adopted standard.

TABLE 1—CERTIFICATION CRITERIA

Proposed meaningful use Stage 1 objectives	Certification criteria to support the achievement of meaningful use Stage 1 by eligible professionals	Certification criteria to support the achievement of meaningful use Stage 1 by eligible hospital
	A Complete EHR or EHR Module must include the capability to:	
Use Computerized Provider Order Entry (CPOE)[3].	Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: 1. Medications; 2. Laboratory; 3. Radiology/imaging; and	Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: 1. Medications; 2. Laboratory; 3. Radiology/imaging;

TABLE 1—CERTIFICATION CRITERIA—Continued

Proposed meaningful use Stage 1 objectives	Certification criteria to support the achievement of meaningful use Stage 1 by eligible professionals	Certification criteria to support the achievement of meaningful use Stage 1 by eligible hospital
	4. Provider referrals.	4. Blood bank; 5. Physical therapy; 6. Occupational therapy; 7. Respiratory therapy; 8. Rehabilitation therapy; 9. Dialysis; 10. Provider consults; and 11. Discharge and transfer.
Implement drug-drug, drug-allergy, drug-formulary checks.	1. Automatically and electronically generate and indicate (*e.g.,* pop-up message or sound) in real-time, alerts at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, age, and CPOE. 2. Enable a user to electronically check if drugs are in a formulary or preferred drug list in accordance with the standard specified in Table 2A row 2. 3. Provide certain users with administrator rights to deactivate, modify, and add rules for drug-drug and drug-allergy checking. 4. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.	
Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT®.	Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care (*i.e.,* over multiple office visits) in accordance with the applicable standards% specified in Table 2A row 1.	
Generate and transmit permissible prescriptions electronically (eRx).	Enable a user to electronically transmit medication orders (prescriptions) for patients in accordance with the standards specified in Table 2A row 3.	No Associated Proposed Meaningful Use Stage 1 Objective.
Maintain active medication list	Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care (*i.e.,* over multiple office visits) in accordance with the applicable standard specified in Table 2A row 1.	
Maintain active medication allergy list	Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care (*i.e.,* over multiple office visits).	
Record demographics [4 5]	Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, and date of birth.	Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, date of birth, and date and cause of death in the event of mortality.
Record and chart changes in vital signs: • Height • Weight • Blood pressure • Calculate and display: BMI • Plot and display growth charts for children 2–20 years, including BMI.	1. Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, the height, weight, blood pressure, temperature, and pulse. 2. Automatically calculate and display body mass index (BMI) based on a patient's height and weight. 3. Plot and electronically display, upon request, growth charts (height, weight, and BMI) for patients 2–20 years old.	
Record smoking status for patients 13 years old or older.	Enable a user to electronically record, modify, and retrieve the smoking status of a patient to: current smoker, former smoker, or never smoked.	
Incorporate clinical lab-test results into EHR as structured data.	1. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format. 2. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes. 3. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).[6] 4. Enable a user to electronically update a patient's record based upon received laboratory test results.	
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach.	Enable a user to electronically select, sort, retrieve, and output a list of patients and patients' clinical information, based on user-defined demographic data, medication list, and specific conditions.	
Report quality measures to CMS or the States [7 8].	1. Calculate and electronically display quality measure results as specified by CMS or states. 2. Enable a user to electronically submit calculated quality measures in accordance with the standard specified in Table 2A row 5.	

TABLE 1—CERTIFICATION CRITERIA—Continued

Proposed meaningful use Stage 1 objectives	Certification criteria to support the achievement of meaningful use Stage 1 by eligible professionals	Certification criteria to support the achievement of meaningful use Stage 1 by eligible hospital
Send reminders to patients per patient preference for preventive/follow up care.	Electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient preferences based on demographic data, specific conditions, and/or medication list.	No Associated Proposed Meaningful Use Stage 1 Objective.
Implement 5 clinical decision support rules [9 10]	1. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to specialty or clinical priorities that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list. 2. Automatically and electronically generate and indicate (*e.g.,* pop-up message or sound) in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade. 3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.	1. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to a high priority hospital condition that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list. 2. Automatically and electronically generate and indicate (*e.g.,* pop-up message or sound) in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade. 3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.
Check insurance eligibility electronically from public and private payers.	Enable a user to electronically record and display patients' insurance eligibility, and submit insurance eligibility queries to public or private payers and receive an eligibility response in accordance with the applicable standards specified in Table 2A row 4.	
Submit claims electronically to public and private payers.	Enable a user to electronically submit claims to public or private payers in accordance with the applicable standards specified in Table 2A row 4.	
Provide patients with an electronic copy of their health information upon request [11 12].	Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in: (1) Human readable format; and (2) accordance with the standards% specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.	Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, discharge summary, and procedures in: (1) Human readable format; and (2) accordance with the standards% specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.
Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.	No Associated Proposed Meaningful Use Stage 1 Objective.	Enable a user to create an electronic copy of the discharge instructions and procedures for a patient, in human readable format, at the time of discharge to provide to a patient on electronic media, or through some other electronic means.
Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the eligible professional.	Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, medication allergy list, immunizations, and procedures.	No Associated Proposed Meaningful Use Stage 1 Objective.
Provide clinical summaries for patients for each office visit.	1. Enable a user to provide clinical summaries to patients (in paper or electronic form) for each office visit that include, at a minimum, diagnostic test results, medication list, medication allergy list, procedures, problem list, and immunizations. 2. If the clinical summary is provided electronically (*i.e.,* not printed), it must be provided in: (1) Human readable format; and (2) accordance with the standards% specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.	No Associated Proposed Meaningful Use Stage 1 Objective.

TABLE 1—CERTIFICATION CRITERIA—Continued

Proposed meaningful use Stage 1 objectives	Certification criteria to support the achievement of meaningful use Stage 1 by eligible professionals	Certification criteria to support the achievement of meaningful use Stage 1 by eligible hospital
Capability to exchange key clinical information among providers of care and patient authorized entities electronically [13] [14]. Provide summary care record for each transition of care and referral.	1. Electronically receive a patient summary record, from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures and upon receipt of a patient summary record formatted in an alternative standard specified in Table 2A row 1, displaying it in human readable format. 2. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with the standards% specified in Table 2A row 1.	1. Electronically receive a patient summary record, from other providers and organizations including, at a minimum, discharge summary, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures and upon receipt of a patient summary record formatted in an alternative standard specified in Table 2A row 1, displaying it in human readable format. 2. Enable a user to electronically transmit a patient summary record, to other providers and organizations including, at a minimum, discharge summary, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with the standards% specified in Table 2A row 1.
Perform medication reconciliation at relevant encounters and each transition of care. Capability to submit electronic data to immunization registries and actual submission where required and accepted.	Electronically complete medication reconciliation of two or more medication lists (compare and merge) into a single medication list that can be electronically displayed in real-time. Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with the standards% specified in Table 2A row 8 or in accordance with the applicable state-designated standard format.	
Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received.	No Associated Proposed Meaningful Use Stage 1 Objective.	Electronically record, retrieve, and transmit reportable clinical lab results to public health agencies in accordance with the standards% specified in Table 2A row 6.
Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice. Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.	Electronically record, retrieve, and transmit syndrome-based (*e.g.,* influenza like illness) public health surveillance information to public health agencies in accordance with the standards specified in Table 2A row 7. 1. Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information. 2. Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency. 3. Terminate an electronic session after a predetermined time of inactivity. 4. Encrypt and decrypt electronic health information according to user-defined preferences (*e.g.,* backups, removable media, at log-on/off) in accordance with the standard specified in Table 2B row 1. 5. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in Table 2B row 2. 6. Record actions (*e.g.,* deletion) related to electronic health information in accordance with the standard specified in Table 2B row 3 (*i.e.,* audit log), provide alerts based on user-defined events, and electronically display and print all or a specified set of recorded information upon request or at a set period of time. 7. Verify that electronic health information has not been altered in transit and detect the alteration and deletion of electronic health information and audit logs in accordance with the standard specified in Table 2B row 4. 8. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information. 9. Verify that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in Table 2B row 5. 10. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in Table 2B row 6.	

We reiterate that adopted certification criteria identify the required capabilities for a Complete EHR or EHR Module to be certified. Adopted certification criteria do not apply to, or require actions by, eligible professionals or eligible hospitals. For example, to be certified, a Complete EHR or EHR Module must be capable of plotting and displaying growth charts for patients. By

[3] For eligible hospitals the full proposed meaningful use Stage 1 objective is: "Use CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP)."

[4] For eligible professionals the full proposed meaningful use Stage 1 objective is: "record demographics: preferred language, insurance type, gender, race, ethnicity, date of birth."

[5] For eligible hospitals the full proposed meaningful use Stage 1 objective is: "record demographics: preferred language, insurance type, gender, race, ethnicity, date of birth, date and cause of death in the event of mortality."

[6] 42 CFR 493.1291(b) specifies that "[t]he test report information maintained as part of the

being tested and certified, a Complete EHR or EHR Module will have demonstrated that this capability is available for an eligible professional or eligible hospital to use.

In adopting these certification criteria, we attempted to balance specificity with flexibility and the opportunity for innovation. However, in taking this approach we recognize that certain tradeoffs exist. On one hand, we anticipate that flexibility will allow Complete EHRs and EHR Modules to evolve over time to meet these criteria in increasingly efficient, useable, and innovative ways. On the other hand, any lack of specificity concerning the capabilities Complete EHRs or EHR Modules must include risks the possibility that Certified EHR Technology may inadequately support an eligible professional or eligible hospital's attempt to achieve meaningful use Stage 1, once finalized. Therefore, we request public comment on whether any of the adopted certification criteria above are insufficiently specific to be used to test and certify Complete EHRs or EHR Modules with reasonable assurance that the technology will effectively support the delivery of health care as well as the achievement of meaningful use Stage 1, once finalized.

2. Adopted Standards

In fulfilling the Secretary's responsibility under section 3004(b)(1), the following initial set of standards and implementation specifications have been adopted [15] for use in Certified EHR Technology to support proposed meaningful use Stage 1 and to enable increased interoperability and privacy and security. We have organized adopted standards into the same four categories recommended by the HIT Standards Committee.

- Vocabulary Standards (*i.e.,* standardized nomenclatures and code sets used to describe clinical problems and procedures, medications, and allergies);
- Content Exchange Standards (*i.e.,* standards used to share clinical information such as clinical summaries, prescriptions, and structured electronic documents);
- Transport Standards (*i.e.,* standards used to establish a common, predictable, secure communication protocol between systems); and
- Privacy and Security Standards (*e.g.,* authentication, access control, transmission security) which relate to and span across all of the other types of standards.

As demonstrated by the adopted certification criteria, we expect Certified EHR Technology to be tested and certified as being capable of complying with adopted standards. We note that there are not standards required for every certification criterion adopted by this interim final rule. However, we have required standards as part of certain certification criteria when their adoption could lead to increased interoperability and privacy and security. We agree with the HIT Policy Committee's recommendation to focus on these two areas and believe they are the most important to emphasize for this initial set of standards. We discuss the adopted interoperability standards directly below and the adopted privacy and security standards in section III.C.2.c.

With respect to interoperability standards we have, after considering the recommendations of the HIT Standards Committee, chosen to adopt alternative standards for certain purposes. Also, at the recommendation of the HIT Standards Committee, we have limited the adoption of specific vocabulary standards in this initial set to a few, important instances.

Presently, we have only adopted a limited number of certification criteria that require Certified EHR Technology to be capable of using a specific vocabulary or code set. In certain instances, because of other HHS regulatory requirements, we have adopted those vocabularies and code sets with which the regulated community is already required to comply. We expect future stages of meaningful use will require Certified EHR Technology to provide additional capabilities as well as an increased capacity to exchange electronic health information according to specific vocabularies and code sets. To enhance interoperability, we believe it will be essential to adopt specific standards, vocabularies, and code sets in the future. We look forward to receiving recommendations from the HIT Standards Committee related to specific vocabularies and code sets to support future stages of meaningful use.

The initial set of standards and implementation specifications in this interim final rule was adopted to support the proposed requirements for meaningful use Stage 1. We have added a column in Table 2A to illustrate the standards that we believe Certified EHR Technology should most likely be capable of to support meaningful use Stage 2 (although as explained in the Medicare and Medicaid EHR Incentives Program proposed rule, CMS intends to engage in rulemaking to adopt Stage 2 criteria for meaningful use and ONC would adopt standards consistent with this effort). We developed this list of candidate Stage 2 standards by considering the recommendations made by the HIT Standards Committee related to standards to support meaningful use Stage 2 and developing our own estimates of what it would take to advance interoperability. We have added a column in Table 2A to illustrate the standards that we believe should be included in Certified EHR Technology to support meaningful use Stage 2. With the exception of standards that are tied to other HHS regulatory requirements, this additional column represents our best estimate and does not in any way imply the Secretary's adoption of these standards or limit the Secretary's discretion to adopt different standards in the future. We look forward to receiving recommendations from the HIT Standards Committee to advance interoperability in line with these estimates and welcome comments on

patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request." 42 CFR 493.1291(c) specifies the required test report information.

[7] For eligible professionals the full proposed meaningful use Stage 1 objective is "Report ambulatory quality measures to CMS or the States."

[8] For eligible hospitals the full proposed meaningful use Stage 1 objective is "Report hospital quality measures to CMS or the States."

[9] For eligible professionals the full proposed meaningful use Stage 1 objective is "Implement 5 clinical decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules"

[10] For eligible hospitals the full proposed meaningful use Stage 1 objective is "Implement 5 clinical decision support rules related to a high priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules"

[11] For eligible professionals the full proposed meaningful use Stage 1 objective is "Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies), upon request"

[12] For eligible hospitals the full proposed meaningful use Stage 1 objective is "Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request"

[13] For eligible professionals the full proposed meaningful use Stage 1 objective is "Capability to exchange key clinical information (for example problem list, medication list, allergies, diagnostic test results) among providers of care and patient authorized entities electronically."

[14] For eligible hospitals the full proposed meaningful use Stage 1 objective is "Capability to exchange key clinical information (for example discharge summary, procedures, problem list, medication list, allergies, diagnostic test results) among providers of care and patient authorized entities electronically."

[15] Per section 3004(b)(1), we believe the standards adopted address all applicable "areas required for consideration" under section 3002(b)(2)(B)—the HIT Policy Committee required areas described above in Section I of this interim final rule.

the industry's ability to implement these candidate standards in time to support meaningful use Stage 2 (which is proposed to begin in 2013).

As an example of our future expectations, currently adopted certification criteria do not require the use of the vocabulary standard, RxNorm. However, RxNorm maintains links from the RxNorm concept unique identifier (CUI) to the corresponding drug codes in other vocabularies. While we have not adopted RxNorm as a standard in this initial set, we have adopted as a standard for medication information the use of a vocabulary the National Library of Medicine has identified as an RxNorm drug data source provider with a complete data set integrated within RxNorm (additional detail regarding this standard is provided below). We believe this standard will establish an important bridge to full RxNorm adoption and will help facilitate this transition over time. We anticipate adopting certification criteria that requires Certified EHR Technology be capable of using the RxNorm superset in its entirety to support meaningful use Stage 2 and look forward to HIT Standards Committee recommendations in this regard.

As another example, we have adopted a certification criterion that requires Certified EHR Technology to be capable of receiving a message with Logical Observation Identifiers Names and Codes (LOINC®) codes from a laboratory, retaining those LOINC® codes, and using LOINC® codes to populate a patient summary record. We do not require Certified EHR Technology to be capable of mapping all laboratory orders or tests to LOINC® codes. Rather, we require that Certified EHR Technology be capable of using LOINC® codes that are received and retained to populate a patient summary record. Moreover, having LOINC® codes used internally for meaningful use Stage 1 will prepare Certified EHR Technology for any future potential meaningful use Stage 2 requirements. We believe the use of LOINC®, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), and other vocabulary standards will accelerate the adoption and use of clinical decision support. Requiring LOINC® as a vocabulary standard that Certified EHR Technology must have the capability to support for meaningful use Stage 1 provides an incremental approach to achieving these future goals.

A final example would be, if an eligible professional uses Certified EHR Technology that has implemented the continuity of care document (CCD) standard for the exchange of a patient summary record and receives a patient summary record formatted in the continuity of care record (CCR) standard, their Certified EHR Technology must be capable of interpreting the information within the CCR message and displaying it in human readable format. We do not expressly state how this should be accomplished or in what format human readable information should be displayed (*e.g.,* information in a CCR message could be converted to a text file or PDF). We only require that Certified EHR Technology must be capable of performing this function. We believe this requirement is critical and have included it to allow flexibility in the marketplace during meaningful use Stage 1 and to prevent good faith efforts to exchange information from going to waste (*i.e.,* information is exchanged, but is unreadable to both Certified EHR Technology (machine readable) and humans).

We discuss in more detail below the four categories identified above and the standards adopted for each. At the end of this section we provide in Table 2A the standards adopted for certain exchange purposes to support meaningful use Stage 1, as proposed in the Medicare and Medicaid EHR Incentive Programs proposed rule, as well as those candidate standards we believe should be adopted and required in certification criteria to support meaningful use Stage 2.

Finally, and consistent with the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 3701 *et seq.*) and OMB Circular A–119 [16] (the circular), we have adopted voluntary consensus standards wherever practical. We have noted with a superscript "+" (plus sign) those standards that are not voluntary consensus standards. Both the NTTAA and the Circular require Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities. Federal agencies, however, are not required to use such standards if doing so would be "inconsistent with applicable law or otherwise impractical." In those instances in which we have not used voluntary consensus standards, we determined that to do so would be impractical for two principal reasons. First, in most cases a voluntary consensus standard that could meet the requisite technical goals was simply unavailable. Second, to the extent that a potentially equivalent voluntary consensus standard was available, the standard was too limiting and did not meet our policy goals, including allowing for greater innovation by the marketplace. We solicit comment on our approach and the availability of voluntary consensus standards that may be viable alternatives to any of the non-voluntary consensus standards we have adopted.

a. Transport Standards

With respect to transport standards, we have adopted Simple Object Access Protocol (SOAP) version 1.2 and Representational state transfer (REST) to provide standard ways for systems to interact with each other. SOAP and REST are discussed in more detail below. These standards are widely used and implemented by the HIT industry and were also recommended by the HIT Standards Committee. We understand that the industry is already exploring other standards beyond SOAP and REST, and we look forward to receiving recommendations from the HIT Standards Committee in this regard to help enable innovation in the marketplace rather than constrain it.

We recognize, out of the four categories of standards identified above, that the term "transport standard" may be used by others to refer to what we have called a "content exchange standard." In the interest of retaining the categories recommended by the HIT Standards Committee and to avoid further confusion, we have chosen this categorization and believe the following distinction can be made to clarify the meaning of the two terms in this interim final rule. Transport standards are not domain specific while content exchange standards are. That is, SOAP and REST can be used by other industries to exchange information while the CCD, for example, is specifically designed for the exchange of health information.

SOAP, originally defined as "Simple Object Access Protocol", is a protocol specification for exchanging structured information in the implementation of Web Services in computer networks. It relies on Extensible Markup Language (XML) as its message format, and usually relies on other Application Layer protocols (most notably Remote Procedure Call (RPC) and HyperText Transfer Protocol (HTTP)) for message negotiation and transmission. SOAP can form the foundation layer of a web services protocol stack, providing a basic messaging framework upon which web services can be built. The SOAP architecture consists of several layers of

[16] *http://www.whitehouse.gov/omb/circulars_a119.*

specifications for message format, message exchange patterns (MEP), underlying transport protocol bindings, message processing models, and protocol extensibility. SOAP was adopted because it is widely used and versatile enough to allow for the use of different transport protocols, is platform independent, and is language independent.

REST is a style of software architecture for distributed hypermedia systems such as the Internet. Systems which follow REST principles are often referred to as "RESTful". An important concept in REST is the existence of Web resources (sources of specific information), each of which is referenced with a global identifier (*e.g.,* a Uniform Resource Identifier or URI in HTTP). In order to manipulate these resources, "components" of the network (user agents and origin servers) communicate via a standardized interface (*e.g.,* HTTP) and exchange "representations" of these resources (the actual documents conveying the information). A RESTful web service is a simple web service implemented using HTTP and the principles of REST.

b. Content Exchange and Vocabulary Standards

i. Patient Summary Record

With respect to meaningful use Stage 1, Certified EHR Technology will be required to be certified as being capable of (1) using the Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2 (R2) Level 2 CCD or ASTM CCR to electronically exchange a patient summary record; and 2) upon receipt of a patient summary record formatted in an alternative standard, displaying it in human readable format. An HL7 CCD Level 2 allows the body of the CCD to be either structured XML text, or unstructured text, and provides backward compatibility to CCD Level 1 documents as well as a migration path to the more complex HL7 Version 3 reference information model (RIM) based information found in CCD Level 3.

For the purposes of industry readiness and to further interoperability in a stepwise fashion, we have decided to adopt these two content exchange standards as alternatives. We firmly believe one patient summary record standard should be adopted to support meaningful use Stage 2 and beyond. We believe that this is necessary to improve patient care and access to health information as well as interoperability in general. We expect the industry to move toward a single standard for patient summary records in the near future and potentially in time to support meaningful use Stage 2. We welcome public comments regarding these alternatives and specifically comments that can address the HIT industry's readiness to move to a single standard. We also look forward to receiving recommendations from the HIT Standards Committee in this regard.

With respect to the vocabulary standards for use within a patient summary record, and in support of proposed meaningful Stage 1 objectives, we expect the following fields to be populated: problem list; medication list; medication allergy list; procedures; vital signs; units of measure; lab orders and results; and, where appropriate, discharge summary. At this time, the Secretary has only adopted standards related to the use of International Classification of Diseases, 9th Revision, Clinical Modifications (ICD–9–CM) or SNOMED CT® to populate a problem list and ICD–9–CM or American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT–4) to populate information related to procedures. For medication lists, we have adopted a standard that requires the use of codes from a drug vocabulary the National Library of Medicine has identified as an RxNorm drug data source provider with a complete data set integrated within RxNorm.[17] For lab results, we have adopted a standard that requires the use of LOINC® to populate information in a patient summary record related to lab orders and results when LOINC® codes have been received from a laboratory and are retained and subsequently available to Certified EHR Technology. In instances where LOINC® codes have not been received from a laboratory, the use of any local or proprietary code is permitted (*i.e.,* we do not require these local or proprietary codes to be converted to LOINC® codes in order to populate a patient summary record). Apart from the standards specified above, we do not specify the types of vocabularies or code sets that could potentially be used to populate the remaining fields of a patient summary record. As shown in Table 2A, we anticipate adopting vocabulary standards for many of the fields above to support meaningful use Stage 2. For example, we have not identified any code sets for medication allergies, but we believe there is value to integrating both medication and non-medication related allergies using a common standard, and in providing ingredient-based medication allergies. These requirements would be satisfied through the use of the UNII standard (referenced as a candidate Stage 2 standard in Table 2A). We request public comment on the standard we have adopted to populate medication list information.

ii. Drug Formulary Check

For the purposes of performing a drug formulary check, Certified EHR Technology must be capable of using NCPDP Formulary & Benefits Standard 1.0 adopted by HHS (73 FR 18918) in order to ensure in circumstances where an eligible professional or eligible hospital electronically prescribes a Part D drug for a Medicare Part D eligible individual, he/she can maintain compliance with applicable law. We are adopting this standard also to meet one of the proposed meaningful use Stage 1 objectives, which seeks to have an automated formulary check as a capability provided by Certified EHR Technology so that formulary and benefit information can be readily provided to advise an eligible professional or eligible hospital's decisions in prescribing drugs to a patient.

iii. Electronic Prescribing

For the purposes of electronic prescribing, Certified EHR Technology must be capable of using NCPDP SCRIPT 8.1 or NCPDP SCRIPT 8.1 and 10.6. SCRIPT 8.1 is the current standard adopted by HHS for specified transactions involving the communication of a prescription or prescription-related information between prescribers and dispensers in the Medicare Part D electronic prescribing drug program. While it is not recognized as such at this time, we expect that SCRIPT 10.6 will be a permitted backwards compatible alternative by the start of meaningful use Stage 1. Moreover, if SCRIPT 10.6 is permitted, prior to any modification of the provisions of this interim final rule in response to public comment, we

[17] According to the most recent *RxNorm Release Documentation File Full Release* (11/2/09) published by the National Library of Medicine, the following RxNorm drug data source providers with a complete data set integrated within RxNorm are identified at the end of section 11.1 located at *http://www.nlm.nih.gov/research/umls/rxnorm/docs/2009/rxnorm_doco_full11022009.html* GS—10/01/2009 (Gold Standard Alchemy); MDDB—10/07/2009 (Master Drug Data Base. Medi-Span, a division of Wolters Kluwer Health); MMSL—10/01/2009 (Multum MediSource Lexicon); MMX—09/28/2009 (Micromedex DRUGDEX); MSH—08/17/2009 (Medical Subject Headings (MeSH)); MTHFDA—8/28/2009 (FDA National Drug Code Directory); MTHSPL—10/28/2009 (FDA Structured Product Labels); NDDF—10/02/2009 (First DataBank NDDF Plus Source Vocabulary); SNOMED CT—07/31/2009 (SNOMED Clinical Terms (drug information) SNOMED International); VANDF—10/07/2009 (Veterans Health Administration National Drug File). We note that FDA Unique Ingredient Identifiers (UNII) are a component of RxNorm.

would expect to change our requirement to simply permit either SCRIPT 8.1 or SCRIPT 10.6. Again, with respect to a vocabulary standard, we have adopted a standard that requires the use of codes from a drug vocabulary currently integrated into the RxNorm (see detailed description above). We believe that adopting RxNorm in the future will lead to improved interoperability and look forward to receiving recommendations from the HIT Standards Committee in this regard.

iv. Administrative Transactions

For the purposes of conducting certain administrative transactions, Certified EHR Technology must be capable of using applicable HIPAA transaction standards and Medicare Part D standards adopted by the Secretary. This includes at least the following Accredited Standards Committee (ASC) X12N Subcommittee standards or NCPDP standards for the relevant covered transactions. Because the HIPAA transactions standards regulations reference the transaction standards together with the "implementation guides," which are comprised of implementation specifications, we have chosen to identify the adopted standards and implementation specifications associated with these HIPAA transaction standards together rather than separately in section III.C.3 below. In adopting these standards and the implementation specifications, we have referenced the CFR locations where they have been adopted for the relevant HIPAA transactions, and as a result the certification criteria will track the adopted HIPAA transactions standards requirements. Consequently, as the HIPAA transaction standards are updated or modified, Complete EHRs or EHR Modules will be certified consistently with the current HIPAA transaction standards requirements. We intend, to the extent possible, to assure that Certified EHR Technology will enable covered entities to conduct HIPAA covered transactions as "standard transactions," as that term is defined in 45 CFR 162.103.

However, in pursuing this approach we note that in accordance with 45 CFR 162.1102 and 45 CFR 162.1202, the Secretary currently permits the use of two versions of ASC X12N and NCPDP standards (Versions 4010/4010A and 5010 and Versions 5.1 and D.0, respectively) until December 31, 2011, at which point only the most recently adopted HIPAA transaction standards will be permitted (74 FR 3296). Unlike the effective date for ICD–10–CM and ICD–10–PCS which is set for October 1, 2013, placing compliance within meaningful use Stage 2, the 5010 and D.0 HIPAA transaction standards are required to be used in the second year of meaningful use Stage 1. Consequently, in order for eligible professionals and eligible hospitals that adopt Certified EHR Technology to remain in compliance with the law for conducting certain administrative transactions, Certified EHR Technology must be capable of using both versions of applicable adopted HIPAA transaction standards.

- For retail pharmacy drugs and dental, professional, and institutional health care eligibility benefit inquiry and response transactions (as defined at 45 CFR 162.1201) Certified EHR must be capable of using the following standards:
  - NCPDP Telecommunications Standards Implementation Guide, Version 5, Release 1 (Version 5.1), and Version D, Release 0 (Version D.0) equivalent NCPDP Batch Standards Batch Implementation Guide, Versions 1.1 and 1.2; and
  - ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010 (004010X092) and Addenda to Health Care Eligibility Benefit Inquiry and Response (004010X092A1) as well as ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, Version 5010 (ASC X12N/005010X279).
- For retail pharmacy drugs and dental, professional, and institutional health care claims or equivalent encounter information transaction (as defined at 45 CFR 162.1101):
  - NCPDP Telecommunications Standards Implementation Guide, Version 5, Release 1 (Version 5.1), and Version D, Release 0 (Version D.0) equivalent NCPDP Batch Standards Batch Implementation Guide, Versions 1.1 and 1.2; and
  - ASC X12N 837—Health Care Claim: Dental—Version 4010 (004010X097) and Addenda to Health Care Claim: Dental, Version 4010 (004010X097A1) as well as ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), (ASC X12N/005010X224), and Type 1 Errata to Health Care Claim: Dental (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, (ASC X12N/005010X224A1); and
  - ASC X12N 837—Health Care Claims: Professional, Volumes 1 and 2, Version 4010 (004010X098) and Addenda to Health Care Claims: Professional, Volumes 1 and 2, Version 4010, (004010x098A1), as well as ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), (ASC X12N/005010X222); and
  - The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, (004010X096) and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, (004010X096A1) as well as ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), (ASC X12N/005010X223), and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 (ASC X12N/005010X223A1).
- To perform eligibility inquiry and response transactions between dispensers and Part D sponsors for Part D prescription drugs.
  - NCPDP Telecommunications Standards Implementation Guide, Version, 5, Release 1 (Version 5.1), and equivalent NCPDP Batch Standards Batch Implementation Guide, Version 1.1.

v. Quality Reporting

For the purposes of electronically submitting calculated quality measures required by CMS or by States, Certified EHR Technology must be capable of using the CMS PQRI 2008 Registry XML Specification. We recognize that CMS has discussed in the Medicare and Medicaid EHR Incentive Programs proposed rule potential approaches to quality reporting requirements for future years of meaningful use and we anticipate adopting standards as necessary and in consultation with CMS to support future quality reporting requirements. We also understand that for the purposes of electronically submitting quality measures an upcoming standard for Complete EHRs and EHR modules may be the HL7 Quality Reporting Document Architecture (QRDA) Implementation Guide based on HL7 CDA Release 2 and we request public comment on whether this standard is mature enough to be used in Complete EHRs and EHR Modules during meaningful use Stage 1.

vi. Submission of Lab Results to Public Health Agencies

For the purposes of submitting lab results to public health agencies, Certified EHR Technology must be capable of using HL7 2.5.1. With respect to vocabulary standards for the submission of lab results to public health agencies, we have adopted the same standard for populating lab results as we do for the patient summary record above. We believe that enabling the use

of UCUM and SNOMED CT® for this exchange in the future would lead to improved interoperability.

vii. Submission to Public Health Agencies for Surveillance or Reporting

For the purposes of electronically submitting information to public health agencies for surveillance and reporting, Certified EHR Technology must be capable of using HL7 2.3.1 or HL7 2.5.1 as a content exchange standard. This requirement is not meant to include adverse event reporting. At this time, we have not adopted a specific vocabulary standard for submitting information to public health agencies for surveillance and reporting, and believe that such standards will be determined in large part by the applicable public health agency receiving such information. We look forward to receiving recommendations from the HIT Standards Committee regarding additional standards that should be adopted to facilitate the electronic submission of information to public health agencies for surveillance and reporting purposes.

viii. Submission to Immunization Registries

For the purposes of electronically submitting information to immunization registries Certified EHR Technology must be capable of using HL7 2.3.1 or HL7 2.5.1 as a content exchange standard and the CDC maintained HL7 standard code set CVX—Vaccines Administered [18] as the vocabulary standard.

ix. Table 2A

Table 2A below displays the applicable adopted standards for each exchange purpose specified. We have used "Cx" and "V" as shorthand for "content exchange" and "vocabulary," respectively, to identify which standard category applies to the exchange purpose. Where a cell in table 2A includes the reference "no standard adopted at this time" it means that a Complete EHR or EHR Module would not be required to be tested and certified as including a particular standard. As a result, any local or proprietary standard could be used as well as the standard(s) listed as candidate meaningful use Stage 2 standards. Unless marked with the following superscripts, all of the adopted standards are from the ONC process that took place prior to the enactment of the HITECH Act or are required by other HHS regulations.

- A number sign "#" indicates that the HIT Standards Committee recommended this standard to the National Coordinator but it was not part of the prior ONC process.
- An asterisk "*" indicates that the standard was neither recommended by the HIT Standards Committee nor part of the prior ONC process.
- A plus sign "+" as mentioned above indicates a standard that is not a voluntary consensus standard.

TABLE 2A—ADOPTED CONTENT EXCHANGE AND VOCABULARY STANDARDS

Row No.	*Purpose*	*Category*	*Adopted standard(s) to support meaningful use stage 1*	*Candidate standard(s) to support meaningful use stage 2*
1	*Patient Summary Record*	Cx	HL7 CDA R2 CCD Level 2 or ASTM CCR.	Alternatives expected to be narrowed based on HIT Standards Committee recommendations.
	• Problem List	V	Applicable HIPAA code set required by law (i.e., ICD–9–CM); or SNOMED CT®.	Applicable HIPAA code set required by law (*e.g.,* ICD–10–CM) or SNOMED CT®.
	• Medication List	V	Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm+.	RxNorm.
	• Medication Allergy List	V	No standard adopted at this time	UNII.
	• Procedures	V	Applicable HIPAA code sets required by law (i.e., ICD–9–CM or CPT–4®).	Applicable HIPAA code sets required by law (*i.e.,* ICD–10–PCS or CPT–4®).
	• Vital Signs	V	No standard adopted at this time	CDA template.
	• Units of Measure	V	No standard adopted at this time	UCUM.
	• Lab Orders and Results	V	LOINC® when LOINC® codes have been received from a laboratory.	LOINC®.
2	*Drug Formulary Check*	Cx	Applicable Part D standard required by law (i.e., NCPDP Formulary & Benefits Standard 1.0).	Applicable Part D standard required by law.
3	*Electronic Prescribing*	Cx	Applicable Part D standard required by law (e.g., NCPDP SCRIPT 8.1) or NCPDP SCRIPT 8.1 and NCPDP SCRIPT 10.6.	NCPDP SCRIPT 10.6.
		V	Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm+.	RxNorm.
4	*Administrative Transactions*	Cx	Applicable HIPAA transaction standards required by law.	Applicable HIPAA transaction standards required by law.
5	*Quality Reporting*	Cx	CMS PQRI 2008 Registry XML Specification#,+.	Potentially newer version(s) or standards based on HIT Standards Committee Input.

[18] The CDC's National Center of Immunization and Respiratory Diseases (NCIRD) maintains the HL7 external code set CVX *http://www.cdc.gov/vaccines/programs/iis/stds/cvx.htm.*

TABLE 2A—ADOPTED CONTENT EXCHANGE AND VOCABULARY STANDARDS—Continued

Row No.	Purpose	Category	Adopted standard(s) to support meaningful use stage 1	Candidate standard(s) to support meaningful use stage 2
6	*Submission of Lab Results to Public Health Agencies.*	Cx	HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Recommendations.
		V	LOINC® when LOINC® codes have been received from a laboratory.	LOINC®, UCUM, and SNOMED CT® or Applicable Public Health Agency Requirements.
7	*Submission to Public Health Agencies for Surveillance or Reporting (excluding adverse event reporting).*	Cx	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Input.
		V	According to Applicable Public Health Agency Requirements.	GIPSE or According to Applicable Public Health Agency Requirements.
8	*Submission to Immunization Registries.*	Cx	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Recommendations.
		V	CVX*,+	CVX.

c. Privacy and Security Standards

We believe it is necessary for Certified EHR Technology to provide certain privacy and security capabilities. In that regard, we have aligned adopted certification criteria to applicable HIPAA Security Rule requirements and believe that in doing so, such capabilities may assist eligible professionals and eligible hospitals to improve their overall approach to privacy and security. In addition, some may find that the capabilities provided by Certified EHR Technology may facilitate and streamline compliance with Federal and state privacy and security laws. We believe that the HIPAA Security Rule serves as an appropriate starting point for establishing the capabilities for Certified EHR Technology. That being said, the HITECH Act directs the HIT Policy Committee, the HIT Standards Committee, and ONC to look at capabilities beyond those explicitly specified in the HIPAA Security Rule. We intend to work with both of these Committees to explore these areas and where possible to adopt new certification criteria and standards in the future to improve the capabilities Certified EHR Technology can provide to protect health information.

The adopted certification criteria in Table 1 assure that Certified EHR Technology is capable of supporting eligible professionals and eligible hospitals comply with HIPAA requirements to protect electronic health information residing within Certified EHR Technology and, where appropriate, when such information is exchanged. For certain capabilities, we have adopted, after considering the recommendations of the HIT Standards Committee, specific standards to be used in Certified EHR Technology. These standards and their purposes are displayed in Table 2B. For other capabilities, we have not adopted specific standards because such capabilities can be appropriately addressed through different approaches, and we did not want to preclude innovation. For example, while we have adopted a certification criterion related to access control, we have not adopted a specific standard for access control because we believe that the industry will continue to innovate at a rapid pace in this area and better methods to implement this capability will be available faster than we would be able to adopt them via regulation. On the other hand, we have adopted certification criteria and standards for encryption because specific industry best practices and requirements exist with respect to encryption and the strength of encryption algorithms. HHS previously articulated in guidance entitled "Guidance Specifying the Technologies and Methodologies That Render Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals" (74 FR 42741) that encryption is an effective method to "render protected health information unusable, unreadable, or indecipherable to unauthorized individuals," and one that can exempt a HIPAA covered entity from having to report a breach. To further support this determination, we believe a logical and practical next step and one that will provide eligible professionals and eligible hospitals with a capability they may not have had in the past is to require Certified EHR Technology to be capable of encryption.

It is important to note, under 45 CFR 164.312(a)(2)(iv) and (e)(2)(ii), a HIPAA covered entity must assess whether encryption as a method for safeguarding electronic protected health information is a reasonable and appropriate safeguard in its environment. Consequently, a HIPAA covered entity could be in compliance with the HIPAA Security Rule if it determines that encryption is not reasonable and appropriate in its environment and it documents its rationale and implements an equivalent alternative measure if reasonable and appropriate. We hope that by requiring Certified EHR Technology to include this capability, that the use of encryption will become more prevalent. Of the certification criteria and associated standards we have adopted related to encryption, the first is for encryption in general while the second is specific to when electronic health information is exchanged. The first certification criterion and standard will assure that Certified EHR Technology is capable of using encryption according to user-defined preferences. There are several industry best practices in this regard and we expect that with the availability of the capability to perform encryption, eligible professionals and hospitals will follow suit and enhance how they protect electronic health information. We anticipate that this capability could be used by eligible professionals and eligible hospitals to encrypt backup hard drives or tapes, removable media, or portable devices. Finally, we expect other functions or services such as domain name service, directory access, and consistent time (*e.g.,* for audit logs) to support and further enable some of the standards in Table 2B. However, due to the fact these functions or services may be part of an overall implementation of Certified EHR Technology (*e.g.,* operating system, network time server) rather than a specific capability Certified EHR

Technology should be tested and certified as including, we chose not to adopt certification criteria or standards. We request public comment on whether the previously mentioned functions or services or any other function or service should be considered for adoption by the Secretary as a necessary capability for Certified EHR Technology to include.

After considering the written and oral public comments provided to both the HIT Policy and HIT Standards Committees, we would like to clarify the applicability of the privacy and security certification criteria and standards adopted in this interim final rule. This interim final rule strictly focuses on the capabilities of Certified EHR Technology and does not change existing HIPAA Privacy Rule or Security Rule requirements, guarantee compliance with those requirements, or absolve an eligible professional, eligible hospital, or other health care provider who adopts Certified EHR Technology from having to comply with any applicable provision of the HIPAA Privacy or Security Rules. While the capabilities provided by Certified EHR Technology may assist an eligible professional or eligible hospital in improving their technical safeguards in order to meet some or all of the HIPAA Security Rule's requirements or influence their risk analysis, the use of Certified EHR Technology alone does not equate to compliance with the HIPAA Privacy or Security Rules. The capabilities provided by Certified EHR Technology do not affect in any way the analysis a HIPAA covered entity is responsible for performing specified at 45 CFR 164.306(b) and (d). Unless there are specific meaningful use measures for privacy and security that require the use of a particular capability, an eligible professional or eligible hospital may find that its security practices exceed these capabilities and nothing in this rule precludes the use or implementation of more protective privacy and security measures.

TABLE 2B—ADOPTED PRIVACY AND SECURITY STANDARDS

Row No.	*Purpose*	*Adopted standard*
1	*General Encryption and Decryption of Electronic Health Information.*	A symmetric 128 bit fixed-block cipher algorithm capable of using a 128, 192, or 256 bit encryption key must be used (*e.g.,* FIPS 197 Advanced Encryption Standard, (AES), Nov 2001). +
2	*Encryption and Decryption of Electronic Health Information for Exchange.*	An encrypted and integrity protected link must be implemented (*e.g.,* TLS, IPv6, IPv4 with IPsec). +
3	*Record Actions Related to Electronic Health Information (i.e., audit log).*	The date, time, patient identification (name or number), and user identification (name or number) must be recorded when electronic health information is created, modified, deleted, or printed. An indication of which action(s) occurred must also be recorded (*e.g.,* modification). +
4	*Verification that Electronic Health Information has not been Altered in Transit.*	A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit. The secure hash algorithm used must be SHA–1 or higher (*e.g.,* Federal Information Processing Standards (FIPS) Publication (PUB) Secure Hash Standard (SHS) FIPS PUB 180–3). +
5	*Cross-Enterprise Authentication*	Use of a cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails (*e.g.,* IHE Cross Enterprise User Assertion (XUA) with SAML identity assertions). +
6	*Record Treatment, Payment, and Health Care Operations Disclosures.*	The date, time, patient identification (name or number), user identification (name or number), and a description of the disclosure must be recorded. +

3. Adopted Implementation Specifications

Pursuant to section 3004 of the PHSA, the Secretary is required to adopt implementation specifications in addition to standards and certification criteria. Implementation specifications, which for HIPAA covered transaction standards are found in implementation guides, provide specific configuration instructions and constraints for implementing a particular standard or set of standards. Because some standards can be implemented in several different ways, these specifications are critical in some cases to make interoperability a reality—simply using a standard does not necessarily guarantee interoperability.

Standards Development Organizations (SDOs), HITSP, and others have developed implementation specifications with varying degrees of specificity, which in turn have resulted in varying degrees of interoperability. In some cases, the standards used in the NHIN, for example, have been constrained even further and resulted in a narrow and unique set of implementation specifications, designed for a specific architecture and well-defined exchange. Based on input from HIT Standards Committee, we understand that very few implementation specifications are widely used and most are immature or too architecturally specific for adoption by large segments of the HIT industry before meaningful use Stage 2.

Given the importance of implementation specifications and the analyses and field testing necessary to refine them, we do not believe, with the exception of the few mentioned below, that there are mature implementation specifications ready to adopt to support meaningful use Stage 1. We seek public comment on whether there are in fact implementation specifications that are industry-tested and would not present a significant burden if they were adopted. We believe that certain exchange purposes such as electronic prescribing and laboratory test results, already have available some of the most mature implementation specifications. We will consider adopting implementation specifications, though, for any or all adopted standards provided that there is convincing evidence submitted in public comment of the specifications' maturity and widespread usage.

We have adopted a certification criterion requiring that Certified EHR Technology be capable of using the standard, CMS PQRI 2008 Registry XML Specification, for quality reporting. We have also adopted as the implementation specifications for this standard, the Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry. Additionally, as we noted above we have adopted standards that require Certified EHR Technology to be capable of using applicable HIPAA transaction standards adopted by HHS for eligibility for health plan

transactions and for health care claims or equivalent encounter information transactions. In so doing, the specific HIPAA standards and "implementation specifications" associated with these covered transactions have also been adopted. As a supporting implementation specification for the eligibility for health plan transactions HIPAA transaction standard we have also adopted the requirements of Phase 1 of the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE). We request public comment on the HIT industry's experience using CAQH CORE Phase 1 with adopted HIPAA transactions standards.

Finally, in preparing to adopt future implementation specifications to support meaningful use Stage 2, ONC plans to work with the HIT industry and solicit input from relevant Federal advisory committees to obtain further specificity in the area of implementation specifications. We also encourage SDOs to make widely available implementation specifications that can be tested and adopted by the Secretary in the future.

4. Additional Considerations, Clarifications, and Requests for Public Comments

a. Relationship to Other Federal Laws

Nothing required by this interim final rule should be construed as affecting existing legal requirements under other Federal laws. While the capabilities provided by Certified EHR Technology may assist in the compliance with certain legal requirements, they do not in any way remove or alter those requirements. For example, Certified EHR Technology may be able to assist health care providers required to comply with the Confidentiality of Alcohol and Drug Abuse Patient Records Regulation, 42 CFR Part 2, but it may not provide, from a technical perspective, all of the capabilities necessary to comply with these regulations. As another example, in providing patients with access to their online health information, it is important to note that the accessibility requirements of the Americans with Disabilities Act of 1990 and Section 504 of the Rehabilitation Act of 1973 still apply to entities covered by these Federal civil rights laws. Additionally, Title VI of the Civil Rights Act of 1964 and its implementing regulations protect persons from unlawful discrimination on the basis of race, color and national origin. Under Title VI and its implementing regulations, recipients of Federal financial assistance must take reasonable steps to ensure meaningful access to their programs, services, and activities by eligible limited English proficient persons.

b. Human Readable Format

As acknowledged in prior sections of this interim final rule, the initial set of adopted standards, implementation specifications, and certification criteria are only the beginning of what we expect will be an incremental approach to enhance the interoperability, functionality, and utility of health information technology. We believe that in order to recognize the enormous potential of HIT, greater standardization in future years is necessary. In that regard, we recognize that more advanced interoperability requires health information to be represented by specific vocabularies and code sets that can be interpreted by EHR technology as well as converted and presented in a readable format to the users of such technology. At the present time we recognize that implementing certain vocabularies and code sets in EHR technology is a difficult, technical undertaking. For that reason, we have not adopted specific vocabularies and code sets for a number of the exchange purposes identified above in Table 2A. We have, however, as a transitional step, adopted certification criteria that require Certified EHR Technology to be capable of presenting health information received in human readable format. By human readable format, we mean a format that enables a human to read and easily comprehend the information presented to them regardless of the method of presentation (*e.g.,* computer screen, handheld device, electronic document). This would likely require information in coded or machine readable format to be converted to, for example, its narrative English language description. In an effort to further the transition to, and prevalence of, more specific vocabularies and code sets, we are interested in public comment regarding industry readiness if we were to adopt certification criteria requiring the use of additional vocabularies and code sets in parallel with meaningful use Stage 2. Such certification criteria could include not only that Certified EHR Technology be capable of presenting information in human readable format but also that it be capable of automatically incorporating certain vocabulary or code sets (*i.e.,* machine readable information).

c. Certification Criterion and Standard Regarding Accounting of Disclosures

Section 3004(b)(1) of the PHSA requires the Secretary to adopt a standard and certification criterion in this interim final rule that are consistent with section 3002(b)(2)(B)(iv) (pertaining to technologies that, as part of a Qualified EHR, allow for an accounting of disclosures made by a HIPAA covered entity for purposes of treatment, payment, and health care operations). This requirement is parallel to section 13405(c) of the HITECH Act, which requires the Secretary to modify (no later than 6 months after the date on which the Secretary adopts standards on accounting for disclosures) the HIPAA Privacy Rule at 45 CFR 164.528 to now require that HIPAA covered entities account for disclosures related to treatment, payment, and health care operations made through an electronic health record and to identify in the regulations the information that shall be collected about each of the disclosures. In promulgating these regulations, the Secretary is instructed to "only require such information to be collected through an electronic health record in a manner that takes into account the interests of the individuals in learning the circumstances under which their protected health information is being disclosed and takes into account the administrative burden of accounting for such disclosures." Unless modified by the Secretary, the effective date [19] for HIPAA covered entities that have acquired an electronic health record after January 1, 2009, is January 1, 2011, or anytime after this date when they acquire an electronic health record.

We intend for our adoption of a basic certification criterion and standard to account for disclosures (§ 170.302(v) and § 170.210(e), respectively) to provide a technical foundation for the information that the Secretary will subsequently determine should be collected for treatment, payment and health care operations disclosures. We have adopted a basic certification criterion that requires the capability to record disclosures (as defined by the HIPAA Privacy Rule) made for treatment, payment, and health care operations in accordance with the standard we have adopted. The standard specified in Table 2B above stipulates a functional requirement that a recorded disclosure for treatment, payment, or health care operations must include:

[19] See HITECH Act section 13405(c)(4), which also provides that the effective date for HIPAA covered entities that are current users of EHRs (*i.e.,* acquired EHRs as of January 1, 2009) January 1, 2014, unless modified by the Secretary.

The date, time, patient identification (name or number), user identification (name or number), and a description of the disclosure. We believe date, time, patient identification, and user identification are all readily available data because it is the same information required in the standard for an audit log. We have also included the requirement that a "description of the disclosure" must be recorded; however, we have not required any additional specificity for what should be included in the "description," because the Secretary has not yet weighed the interests of individuals with the administrative burden associated with accounting for such disclosures to determine what information shall be collected. The certification criterion and standard in this interim final rule are limited to disclosures for treatment, payment, and health care operations, as those terms are defined at 45 CFR 164.501. This interim final rule does not address the capability of Certified EHR Technology to account for other types of disclosures. We note that a HIPAA covered entity using Certified EHR Technology must continue to account for disclosures in accordance with 45 CFR 164.528, which may require the collection of additional information for disclosures that are not for treatment, payment, or health care operations.

We do not propose additional requirements at this time because we believe that several significant technical challenges will need to be addressed before it is possible to record additional information about disclosures in an efficient manner. For example, we are unaware of any particular technology solution that is capable of automatically recognizing the difference between a "use" and a "disclosure," as the HIPAA regulations define these terms. Additionally, we are concerned about the amount of electronic storage that will be necessary to record three years worth of information related to treatment, payment, and health care operations disclosures. We welcome public comment, particularly from the HIT developer community, as to these concerns as well as about the technical feasibility of recording other elements of information about a disclosure. We are specifically interested in comments as to the technical feasibility of recording the purpose or reason for the disclosure, to whom the disclosure was made (*i.e.,* recipient), and any other elements that may be beneficial for a patient to know about with respect to their health information.

It is important to note, as discussed above, that the Secretary has the discretion to modify the compliance date for the revised accounting-for-disclosure regulations to as late as 2013 for HIPAA covered entities that acquire electronic health records after January 1, 2009. The Secretary will address the compliance date for accounting for treatment, payment, and health care operations disclosures in a later rulemaking. In the interim, we again note that the standards and certification requirements adopted do not affect a HIPAA covered entity's compliance with the HIPAA Privacy or Security Rules.

As the use of Certified EHR Technology becomes more widespread and technology advances, we believe the ability to account for disclosures will continue to evolve. Accordingly, this first certification criterion and standard for accounting of disclosures is intended as an incremental step, which will be refined as the technology develops and regulatory requirements are issued. We plan to work with the HIT Policy Committee and HIT Standards Committee to receive recommendations regarding the policies that should be established to address these standards and certification criteria requirements and with the HHS Office for Civil Rights to appropriately coordinate the adoption of policies for the accounting of treatment, payment, and health care operations disclosures with the capabilities that Certified EHR Technology must include in the future.

d. Additional Requests for Public Comment

- We are interested in public comments to inform future deliberations on whether specific certification criteria could be adopted to further promote the capabilities Certified EHR Technology should provide with respect to meeting the accessibility needs of individuals with disabilities.
- We are also interested in public comments to inform future deliberations on whether specific certification criteria could be adopted to further promote the capabilities Certified EHR Technology should provide with respect to the prevention and detection of potential fraud, waste, and abuse.
- We are interested in public comment regarding the "candidate standards to support meaningful use Stage 2" listed in Table 2A. We are specifically interested in feedback regarding implementation feasibility, maturity, and prevalence in the industry.

IV. Collection of Information Requirements

This interim final rule contains no new information collection requirements subject to review by the OMB under the Paperwork Reduction Act (PRA). The HITECH Act establishes new information collection requirements, but those information collection requirements are addressed by other regulatory and programmatic activities (*e.g.*, the Medicare and Medicaid EHR Incentive Programs Proposed Rule).

The HITECH Act applies through Section 13111(b) to "federal information collection activities." The HITECH Act states that "with respect to a standard or implementation specification adopted under section 3004 of the Public Health Service Act, as added by section 13101, the President shall take measures to ensure that Federal activities involving the broad collection and submission of health information are consistent with such standard or implementation specification, respectively, within three years after the date of such adoption." Standards adopted in this interim final rule may affect how Federal agencies collect information in the future; however, the potential implications of this requirement will largely depend on actions taken by the Executive Office of the President, including how it interprets the terms "consistent," "broad," and "health information." We welcome comments on the potential for standards and implementation specifications adopted in this regulation to change the way information is collected by Federal agencies. We will share such comments with the OMB.

V. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) (UMRA), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). We have determined that this interim final rule is not an economically significant rule because

we estimate that the costs to prepare Complete EHRs and EHR Modules to be tested and certified will be less than $100 million per year. Nevertheless, because of the public interest in this interim final rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the interim final rule. We request comments on the economic analysis provided in this interim final rule with comment.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For more information on Small Business Administration's (SBA's) size standards, see the SBA's Web site.[20] Although the RFA only requires an initial regulatory flexibility analysis (IRFA) when an agency issues a proposed rule, HHS has a policy of voluntarily conducting an IRFA for interim final regulations. We examine the burden of the interim final regulation in Section V.D below.

Section 202 of the UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2009, that threshold is approximately $133 million. This rule will not impose an unfunded mandate on States, tribal government or the private sector of more than $133 million annually.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs of compliance on State and local governments, preempts State law, or otherwise has Federalism implications. We do not believe that our interim final rule imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications.

B. Why Is This Rule Needed?

Section 3004(b)(1) of the PHSA requires the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria by December 31, 2009. Certification criteria and associated standards and implementation specifications will be used to test and certify Complete EHRs and EHR Modules in order to make it possible for eligible professionals and eligible hospitals to adopt and implement Certified EHR Technology. The use of Certified EHR Technology is one of the requirements an eligible professional or eligible hospital needs to meet in order to qualify for an incentive payment under the Medicare and Medicaid EHR Incentive Programs.

C. Costs and Benefits

Throughout the following analysis we invite comments on specific portions of our analysis. The public, however, is invited to offer comments on any and all elements of the analysis and the assumption underlying the analysis.

1. Costs

This interim final rule is one of three coordinated rulemakings (the other two being the Medicare and Medicaid EHR Incentive Programs proposed rule and the HIT Certification Programs proposed rule) undertaken to implement the goals and objectives of the HITECH Act related to the adoption and meaningful use of Certified EHR Technology. Each rule's preamble contains a RIA section. While there is no bright line that divides the effects of this interim final rule and the other two noted above, we believe that each analysis properly focuses on the direct effects of the provisions it creates. This interim final rule estimates the costs commercial vendors, open source developers, and relevant Federal agencies [21] will incur to prepare Complete EHRs and EHR Modules to be tested and certified to adopted standards, implementation specifications, and certification criteria. The Medicare and Medicaid EHR Incentive Programs proposed rule estimates the impacts related to the actions taken by eligible professionals or eligible hospitals to become meaningful users, including purchasing or self-developing Complete EHRs or EHR Modules. The HIT Certification Programs proposed rule estimates the testing and certification costs for Complete EHRs and EHR Modules.

This interim final rule adopts standards, implementation specifications, and certification criteria and consequently establishes the capabilities that Complete EHRs or EHR Modules will need to demonstrate in order to be certified. Due to the fact that the Medicare and Medicaid EHR Incentive Programs require (among other things) that eligible professionals and eligible hospitals use Certified EHR Technology in order to receive incentive payments, we anticipate that commercial vendors and open source developers of Complete EHRs and EHR Modules will respond by preparing such technology to meet the certification criteria adopted in this interim final rule. We expect this to occur because commercial vendors and open source developers who do not prepare Complete EHRs or EHR Modules to be tested and certified risk losing market share (*i.e.*, eligible professionals and eligible hospitals seeking to achieve meaningful use will not buy Complete EHRs or EHR Modules that cannot outright or when combined with other EHR Modules meet the definition of Certified EHR Technology). It is important to note, however, as discussed in section 3001(c)(5)(A) of the PHSA, that Congress intended for the act of preparing for and subsequently seeking the certification of a Complete EHR or EHR Module to be voluntary.

As we discuss above, our analysis only focuses on the direct effects of the provisions created by this interim final rule. As a result, we only include estimates for the costs commercial vendors, open source developers, and relevant Federal agencies may incur to prepare Complete EHRs or EHR Modules to be tested and certified. We do not include in this analysis the costs to eligible professionals and eligible hospitals that choose to: (1) Purchase new Certified EHR Technology, or (2) self-develop or modify their current, HIT to become meaningful users. These costs are addressed in the Medicare and Medicaid EHR Incentive Programs proposed rule because they are directly related to the actions taken by eligible professionals or eligible hospitals to become meaningful users. Additionally, the cost for Complete EHRs and EHR Modules to be tested and certified is addressed in the HIT Certification Programs proposed rule and not in this interim final rule.

In conducting research to inform the estimates we make below we found several websites that listed, in an aggregate format, different types of Complete EHRs and EHR Modules designed for various types of health care providers as well as those that were designed primarily for specialists. Based on our research, we believe it is reasonable to assume that a few hundred unique Complete EHRs and EHR Modules make up the available universe of HIT for health care

[20] *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.*

[21] All Indian Health Service (IHS) facilities and the vast majority of Tribally-operated facilities funded by IHS utilize the Resource and Patient Management System (RPMS), the IHS health information and EHR system that is centrally developed and distributed by the IHS Office of Information Technology. It is our understanding that IHS provides information technology support to over 40 IHS and Tribal hospitals as well as health care providers at approximately 300 ambulatory facilities. The RPMS EHR is designed for both inpatient and ambulatory implementations and it is IHS's goal to remain consistent with the certification criteria adopted by the Secretary. As a result, we expect IHS will the RPMS EHR for testing and certification to applicable adopted certification criteria.

providers, including eligible professionals and eligible hospitals. This estimate includes within it specialty and other niche HIT that are not the intended focus of this interim final rule. While certain certification criteria may be applicable to these other types of HIT, the Secretary has not adopted a specific or complete set of certification criteria for them at this time. Therefore, our estimates for the impacts of this interim final rule solely focus on what we believe will be the likely amount of Complete EHRs and EHR Modules that are prepared to be tested and certified and how much that preparation will cost.

We have analyzed previously developed CCHIT ambulatory and inpatient certification criteria and believe that many, but not all, require the exact same capabilities required by the respective certification criteria adopted by the Secretary at 45 CFR 170.302, 45 CFR 170.304, and 45 CFR 170.306. Generally speaking, we believe this overlap includes most of the clinically oriented capabilities required by the certification criteria adopted by the Secretary. Accordingly, with respect to this impact analysis, we believe that a significant number of previously CCHIT-certified-EHRs will only incur moderate costs to prepare for certification. We assume, for the purposes of creating reasonable estimates, that previously CCHIT-certified-EHRs are similar to our definition of a Complete EHR. As a result, we have based our estimates in Table 3 with the expectation that these previously CCHIT-certified-EHRs will again be prepared for certification as Complete EHRs. To add further specificity to our estimates, we understand, according to CCHIT's Web site, there are 74 CCHIT-certified-EHRs that have been certified to its 2008 ambulatory certification criteria and 17 CCHIT-certified-EHRs, that have been certified to its 2007 or 2008 inpatient certification criteria.[22] [23] [24] Of these 74 and 17 previously CCHIT-certified-EHRs we expect that 90% will be prepared for certification to the certification criteria adopted by the Secretary. We do not believe that it is realistic to assume that 100% of previously CCHIT-certified-EHRs will be prepared for certification for a number of reasons. These reasons include: (1) A recognition that mergers and acquisitions within the marketplace have reduced the number of previously CCHIT-certified-EHRs; (2) that the subsequent resources needed to market and promote Certified EHR Technology may not be available at the present time; and (3) that some previously CCHIT-certified-EHRs will be tested and certified as EHR Modules rather than Complete EHRs. Given these assumptions we have estimated the number of previously CCHIT-certified-EHRs that will be prepared to be tested and certified will be 65 and 15, ambulatory and inpatient, respectively. We also believe it is reasonable to assume that of these 65 and 15, some will require more preparation than others (*i.e.*, we assume that some previously CCHIT-certified-EHRs include more capabilities than what CCHIT tested and certified and may be able to more easily meet the certification criteria adopted by the Secretary). Given this assumption we have created low and high ranges for the cost to prepare previously CCHIT-certified ambulatory and inpatient EHRs.

In creating our low and high ranges for the tables below we assumed based on our analysis of previously developed and required CCHIT certification criteria that certain capabilities (*e.g.*, the capability to maintain a medication list) have been implemented and deployed in HIT to such a large degree that there would be little or no modification required to prepare Complete EHRs or EHR Modules for testing and certification to certain certification criteria. We also assumed that the certification criteria adopted by the Secretary range from relatively simple capabilities (*e.g.*, recording a patient's smoking status) to more sophisticated capabilities (*e.g.*, clinical decision support). As a result, we have made a general assumption that the costs to prepare Complete EHRs and EHR Modules to be tested and certified will vary depending on a number of factors including, but not limited to, whether the Complete EHR or EHR Module: (1) Already includes the capability; (2) includes some aspect of the capability which would need to be updated; (3) does not currently include the capability at all. We believe it is reasonable to estimate that it will cost somewhere between $10,000 and $250,000 per certification criterion to prepare a Complete EHR or EHR Module for testing and certification taking into account the factors identified directly above. We have used this per certification criteria range as the basis for our low and high cost range estimates and for the ease of our calculations assume that the Secretary has adopted approximately 40 certification criteria.

For Table 3 we have made the following assumptions: (1) In general, previously CCHIT-certified-EHRs will need additional preparation to be tested and certified to 25% of the certification criteria adopted by the Secretary; (2) the average low and high per certification criterion cost for previously CCHIT-certified ambulatory EHRs to be prepared to be tested and certified will be $50,000 and $150,000, respectively; and (3) the average low and high per certification criterion cost for previously CCHIT-certified inpatient EHRs to be prepared to be tested and certified will be $75,000 and $200,000, respectively.

TABLE 3—ESTIMATED ONE-TIME COSTS FOR PREVIOUSLY CCHIT-CERTIFIED-EHRS TO BE PREPARED TO BE TESTED AND CERTIFIED AS COMPLETE EHRS (3-YEAR PERIOD)—TOTALS ROUNDED

Type	Number prepared for certification	One time cost per EHR ($M)			Total cost for all EHRs over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
2008 Ambulatory CCHIT-Certified-EHR	65	$0.50	$1.5	$1.0	$32.5	$97.5	$65.0
2007/2008 Inpatient CCHIT-Certified-EHR	15	0.75	2.0	1.38	11.25	30.0	20.63

[22] Some are marked with a conditional certification either "Pre-Market: These are conditionally certified EHRs which are new products that are fully certified once their operational use at a physician office site has been verified." or "eRx Conditional: These are conditionally certified pending advanced ePrescribing EHRs that are in the process of verifying their ability to conduct medication history, formulary and eligibility checking through a national network for electronic-prescribing transactions." We do not believe that these caveats have any effect on our estimates.

[23] *http://www.cchit.org/products/Ambulatory*—when certification years 2006 and 2007 are unchecked.

[24] *http://www.cchit.org/products/Inpatient.*

TABLE 3—ESTIMATED ONE-TIME COSTS FOR PREVIOUSLY CCHIT-CERTIFIED-EHRS TO BE PREPARED TO BE TESTED AND CERTIFIED AS COMPLETE EHRS (3-YEAR PERIOD)—TOTALS ROUNDED—Continued

Type	Number prepared for certification	One time cost per EHR ($M)			Total cost for all EHRs over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Total	80				43.75	127.50	85.63

The second type of cost we estimate includes the costs that we expect for CCHIT-certified ambulatory EHRs certified prior to 2008 ("out-of-date CCHIT–Certified-EHRs") and never previously CCHIT-certified-EHRs to be prepared to be tested and certified as Complete EHRs rather than being prepared to be tested and certified as an EHR Module.[25] We assume the EHR technology that falls into this category may require more extensive changes than previously CCHIT-certified-EHRs identified in Table 3. Again, we have estimated low and high preparation cost ranges. We assume that there will be very little growth in the Complete EHR market due to the market share[26] represented by the previously CCHIT-certified-EHRs included in Table 3 and the upfront costs required to bring a Complete EHR to market. As a result, we expect there to be 8 and 5 Complete EHRs (for use by eligible professionals and eligible hospitals, respectively) prepared to be tested and certified to all of the applicable certification criteria adopted by the Secretary.[27]

Again, using our general assumptions discussed above (40 certification criteria and a low and high range of $10,000 to $250,000 per certification criterion) we have made the following assumptions in our Table 4 calculations: (1) In general, out-of-date CCHIT–Certified-EHRs and never previously CCHIT-certified-EHRs will need additional preparation to be tested and certified to 60% of the certification criteria adopted by the Secretary; (2) the average low and high per certification criterion cost for Complete EHRs for eligible professionals to be prepared to be tested and certified will be $50,000 and $150,000, respectively; and (3) the average low and high per certification criterion cost for Complete EHRs for eligible hospitals to be prepared to be tested and certified will be $75,000 and $200,000, respectively.

TABLE 4—ESTIMATED ONE-TIME COSTS FOR NEVER CCHIT-CERTIFIED-EHRS AND OUT-OF-DATE CCHIT–CERTIFIED-EHRS TO BE PREPARED TO BE TESTED AND CERTIFIED AS COMPLETE EHRS (3-YEAR PERIOD)—TOTALS ROUNDED

Type	Number prepared for certification	One time cost per EHR ($M)			Total cost for all EHRs over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Complete EHRs for Eligible Professionals	8	$1.2	$3.6	$2.4	$9.6	$28.8	$19.2
Complete EHRs for Eligible Hospitals	5	1.8	4.8	3.3	9.0	24.0	16.5
Total	13				18.60	52.80	35.70

Finally, the third type of cost we estimate relates to the number of EHR Modules we expect to be prepared to be tested and certified and the costs associated with that preparation. As discussed above, we believe over time that EHR Modules will play an increasingly important role in improving the capabilities available to eligible professionals and eligible hospitals. It is also our belief that EHR Modules will lead to a more innovative and competitive marketplace. We believe that during meaningful use Stage 1, approximately seven types of EHR Modules will be practical given the current state of the HIT marketplace. We assume that EHR Modules will most likely be prepared to be tested and certified to provide the following types of capabilities: Electronic prescribing; administrative transactions; core clinical capabilities; computerized provider order entry; quality reporting; online patient portals; and interfacing with a health information organization to enable the electronic exchange of health information.

Generally speaking, of the available universe of HIT developers we assume that a small percentage will prepare the previously mentioned types of EHR Modules for certification prior to the beginning of meaningful use Stage 2 (*i.e.*, between 2010 and 2012). Furthermore, we assume during meaningful use Stage 1 there will be on average 7 EHR Modules prepared to be tested and certified for each type of EHR Module described above. As a result we estimate that there will be approximately 50 EHR Modules (number of modules X types of modules) prepared to be tested and certified. Again, we have provided low and high preparation cost estimates in Table 5 below. We assume that some of EHR Modules prepared for certification will be capable of meeting applicable certification criteria with little modification while other EHR Modules may not. Given the potential differences in preparation costs and combinations of certification criteria to create EHR Modules we believe it is reasonable to estimate a wide range for the costs to prepare these types of EHR modules for testing and certification.

[25] CCHIT began testing and certifying inpatient EHRs in 2007 and we assume that all of those EHRs are included in Table 3 which is why they are not included in this discussion.

[26] *http://www.cchit.org/about*—"* * * EHR products certified by mid-2009, representing over 75% of the marketplace."

[27] This estimate includes the fact that IHS's RPMS EHR was not included in Table 1 and that it will be preparing the RPMS EHR as a Complete EHR to meet the applicable certification criteria adopted by the Secretary for both ambulatory and inpatient settings.

TABLE 5—ESTIMATED ONE-TIME COSTS TO PREPARE EHR MODULES FOR CERTIFICATION TO APPLICABLE ADOPTED CERTIFICATION CRITERIA (3-YEAR PERIOD)—TOTALS ROUNDED

Type	Number prepared	One time cost per EHR module ($M)			Total cost all EHR modules over 3-year period		
		Low	High	Mid-point	Low	High	Mid-point
EHR Modules	50	$0.1	$0.5	$0.3	$5.0	$25.0	$15.0
Total	50				5.0	25.0	15.0

We invite comments on the number of commercial vendors and open source developers of Complete EHRs or EHR Modules that make up the marketplace and the number of Complete or EHR Modules that will be prepared for testing and certification. Because many of the adopted standards and implementation specifications are already in widespread use and because many of the adopted certification criteria require core capabilities that already exist in the marketplace today we believe that the costs incurred as a result of voluntary actions by the private sector to prepare for certification will be modest. We welcome comments on our estimates above.

In total, if we were to distribute the costs to prepare Complete EHRs and EHR Modules between 2010 and 2012 evenly per year we believe they would likely be in the range of $67.35 to $205.3 million or $22.45 to $68.43 million per year with an annual cost mid-point of approximately about $45.44 million. However, we do not believe that the costs will be spread evenly over these three years due to market pressures and the fact that higher upfront incentive payments are available under the Medicare and Medicaid EHR Incentive Programs. We assume this factor will motivate a greater ratio of commercial vendors and open source developers of Complete EHRs and EHR Modules to prepare such technology for testing and certification in 2010 and 2011 rather than 2012. We also assume that it will generally take 6 to 18 months for commercial vendors and open source developers of Complete EHRs and EHR Modules to prepare for testing and certification. As a result, we believe as represented in Table 6 that the costs attributable to this interim final rule will be distributed as follows: 45% for 2010, 40% for 2011 and 15% for 2012.

TABLE 6—DISTRIBUTED TOTAL PREPARATION COSTS (3-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (percent)	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2010	45	$30.31	$92.39	$61.35
2011	40	26.94	82.12	54.53
2012	15	10.10	30.80	20.45
3-Year Totals		67.35	205.3	136.33

Note that these cost estimates do not include additional costs to prepare for testing and certification that will likely be incurred when we adopt additional standards, implementation specifications, and certification criteria to support meaningful use Stages 2 and 3. We will account for costs associated with these additional standards, implementation specifications, and certification criteria in future rulemaking.

2. Benefits

We believe that there will be several benefits from this interim final rule. By adopting this initial set, the Secretary will set in motion what we believe will be an iterative process to further enhance the interoperability, functionality, utility, and security of health information technology and to support its meaningful use. The capabilities required by adopted certification criteria will help arm health care providers with tools to improve patient care, reduce medical errors and unnecessary tests. The standards adopted will aid in fostering greater interoperability. We also believe that this interim final rule will be a catalyst for a more competitive and innovative marketplace. Finally, adopted certification criteria can be used by commercial vendors and open source developers of Complete EHRs and EHR Modules as technical requirements to ensure that their HIT can be tested and certified and subsequently adopted and implemented as Certified EHR Technology by eligible professionals and eligible hospitals to help them qualify for incentive payments under Medicare and Medicaid EHR Incentive Programs.

D. Regulatory Flexibility Act Analysis

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. As noted above, although the RFA only requires an initial regulatory flexibility analysis when an agency issues a proposed rule, HHS has a policy of voluntarily conducting an initial regulatory flexibility analysis for interim final regulations.

We are implementing this interim final rule as required by section 3004(b)(1) of the PHSA. The objective of the interim final rule is for the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria for HIT.

While commercial vendors and open source developers of Complete EHRs and EHR Modules represent a small segment of the overall information technology industry, we believe that the entities impacted by this interim 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 size standard associated with this NAICS code is set at $25 million in annual

receipts[28] which "indicates the maximum allowed for a concern and its affiliates to be considered small entities."

Based on our analysis, we believe that a handful of multinational corporations and many national or regional businesses represent a significant majority of the potential Complete EHR and EHR Module developers and that many, if not all, exceed the specified SBA size standard. We make this assumption based on our understanding of the upfront investments necessary to develop and market HIT in a competitive marketplace as well as the upgrade and product modification costs that these businesses incur to stay competitive. However, we note, and request public comment on, the following constraint encountered during our analysis. 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 commercial vendors and open source developers of Complete EHRs and EHR Modules 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 at the present time to locate empirical data related to many of the commercial vendors and open source developers of Complete EHRs and EHR Modules to correlate to the SBA size standard. We therefore request public comment on any additional information regarding the business size of commercial vendors and open source developers of Complete EHRs and EHR Modules in the HIT marketplace to help inform our analysis.

Given the discussion above, we estimate that this interim final rule will have effects on commercial vendors and open source developers of Complete EHRs and EHR Modules, some of which may be small entities. However, we do not believe that the interim final rule will create a significant economic impact on a substantial number of these entities, regardless of size. The Secretary certifies that this interim final rule will not have a significant impact on a substantial number of small entities.

E. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

Nothing in this interim final rule imposes substantial direct requirement 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 have been adopted. This interim final rule with comment period affords all States an opportunity to identify any problems that our standards, implementation specifications, and certification criteria would create, and to propose constructive alternatives. We welcome comments from State and local governments.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires cost-benefit and other analyses before any rulemaking if the rule includes a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is approximately $130 million. The Department has determined that this rule would not constitute a significant rule under the Unfunded Mandates Reform Act, because it would impose no mandates.

The Office of Management and Budget reviewed this interim final rule with comment period.

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, the Department amends 45 CFR subtitle A to add subchapter D as follows:

SUBCHAPTER D—HEALTH INFORMATION TECHNOLOGY

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

Subpart A—General Provisions

Sec.
170.100 Statutory basis and purpose.
170.101 Applicability.
170.102 Definitions.

Subpart B—Standards and Implementation Specifications for Health Information Technology

170.200 Applicability.
170.202 Transport standards for exchanging electronic health information.
170.205 Content exchange and vocabulary standards for exchanging electronic health information.
170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.
170.299 Incorporation by reference.

Subpart C—Certification Criteria for Health Information Technology

170.300 Applicability.
170.302 General certification criteria for Complete EHRs or EHR Modules.
170.304 Specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting.
170.306 Specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting.

Authority: 42 U.S.C 300jj–14; 5 U.S.C. 552.

Subpart A—General Provisions

§ 170.100 Statutory basis and purpose.

The provisions of this subchapter implement section 3004 of the Public Health Service Act.

§ 170.101 Applicability.

The standards, implementation specifications, and certification criteria adopted in this part apply to Complete EHRs and EHR Modules and the testing and certification of such Complete EHRs and EHR Modules.

§ 170.102 Definitions.

For the purposes of this part:

Certification criteria means criteria:

(1) To establish that health information technology meets applicable standards and implementation specifications adopted by the Secretary; or

(2) That are used to test and certify that health information technology includes required capabilities.

[28] 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/idc/groups/public/documents/sba_homepage/guide_to_size_standards.pdf.*

Certified EHR Technology means a Complete EHR or a combination of EHR Modules, each of which:

(1) Meets the requirements included in the definition of a Qualified EHR; and

(2) 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.

Complete EHR means EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary.

Disclosure means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

EHR Module means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

Implementation specification means specific requirements or instructions for implementing a standard.

Qualified 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; and

(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; and

(iv) To exchange electronic health information with, and integrate such information from other sources.

Standard means a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, characteristics, or actions.

Subpart B—Standards and Implementation Specifications for Health Information Technology

§ 170.200 Applicability.

The standards and implementation specifications adopted in this part apply with respect to Complete EHRs and EHR Modules. When a section of this part includes adoption of both a standard and at least one alternative standard, use of the specified standard or alternatives will be considered compliant.

§ 170.202 Transport standards for exchanging electronic health information.

The Secretary adopts the following standards to define the common transport methods that must be used to electronically exchange health information formatted in accordance with the standards adopted under § 170.205.

(a) *Standard.* The Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.2 (incorporated by reference in § 170.299).

(b) *Alternative standard.* A stateless, client-server, cacheable communications protocol that adheres to the principles of Representational State Transfer (REST) must be used.

§ 170.205 Content exchange and vocabulary standards for exchanging electronic health information.

(a) *Patient summary record.*

(1) The Secretary adopts the following content exchange standards for the purposes of electronically exchanging a patient summary record or to use in creating an electronic copy of a patient summary record:

(i) *Standard.* Health Level Seven Clinical Document Architecture (CDA) Release 2, Level 2 Continuity of Care Document (CCD) (incorporated by reference in § 170.299).

(ii) *Alternative standard.* ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in § 170.299).

(2) The Secretary adopts the following vocabulary standards for the purposes of specifying the code set, terminology, or nomenclature to use to represent health information included in a patient summary record:

(i) Problem list.

(A) *Standard.* The code set specified for the conditions specified at 45 CFR 162.1002(a)(1).

(B) *Alternative standard.* International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) July 2009 version (incorporated by reference in § 170.299).

(ii) Procedures.

(A) *Standard.* The code set specified at 45 CFR 162.1002(a)(2).

(B) *Alternative standard.* The code set specified at 45 CFR 162.1002(a)(5).

(iii) Laboratory orders and results.

(A) *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).

(B) [Reserved]

(iv) Medication list.

(A) *Standard.* Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm.

(B) [Reserved]

(b) *Drug formulary check.* The Secretary adopts the following content exchange standard for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(1) *Standard.* Drug formulary and benefits information must be transmitted in accordance with 42 CFR 423.160(b)(5).

(2) [Reserved]

(c) *Electronically transmitting prescription information.*

(1) The Secretary adopts the following content exchange standard to provide for the transmission of a prescription or prescription-related information.

(i) *Standard.* An electronic prescription for a Medicare Part D covered drug that is prescribed for a Medicare Part D eligible individual must be transmitted in accordance with 42 CFR 423.160(b)(2)(ii), in all other circumstances, if consistent with applicable state and other Federal law, electronic prescriptions may be transmitted in accordance with 42 CFR 423.160(b)(2)(ii) or using the NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in § 170.299).

(ii) [Reserved]

(2) The Secretary adopts the following vocabulary standard for the purposes of specifying the code set to use to represent health information included in electronic prescriptions.

(i) *Standard.* Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm.

(ii) [Reserved]

(d) *Electronically exchange administrative transactions.* The Secretary adopts the following content exchange standards and associated implementation specifications for the following electronic transactions.

(1) *Standard and implementation specifications.* An eligibility for a health plan transaction as defined at 45 CFR 162.1201 must be conducted in accordance with:

(i) 45 CFR 162.1202(b) or for the period on and after January 1, 2012, in accordance with 45 CFR 162.1202(c); and

(ii) The operating rules specified in Phase 1 of the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) (incorporated by reference in § 170.299).

(2) *Standard and implementation specifications.* Eligibility inquiry and response transactions between dispensers and Part D sponsors for Part D prescription drugs must be conducted in accordance with 42 CFR 423.160(b)(3)(ii).

(3) *Standard and implementation specifications.* A health care claims or equivalent encounter information transaction as defined at 45 CFR 162.1101 must be conducted in accordance with 45 CFR 162.1102(b) or for the period on and after January 1, 2012, in accordance with 45 CFR 162.1102(c).

(e) *Electronically exchange quality reporting information.* The Secretary adopts the following content exchange standard and implementation specification for quality reporting.

(1) *Standard.* The CMS Physician Quality Reporting Initiative (PQRI) 2008 Registry XML Specification (incorporated by reference in § 170.299).

(2) *Implementation specification.* Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry (incorporated by reference in § 170.299).

(f) *Electronic submission of lab results to public health agencies.*

(1) The Secretary adopts the following content exchange standard for the electronic submission of lab results to public health agencies.

(i) *Standard.* HL7 2.5.1(incorporated by reference in § 170.299).

(ii) [Reserved]

(2) The Secretary adopts the following vocabulary standard for the purposes of representing lab results in an electronic submission to public health authorities.

(i) *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).

(ii) [Reserved]

(g) *Electronic submission to public health agencies for surveillance or reporting.* The Secretary adopts the following content exchange standards for electronic submission to public health agencies for surveillance or reporting:

(1) *Standard.* HL7 2.3.1 (incorporated by reference in § 170.299).

(2) *Alternative standard.* HL7 2.5.1 (incorporated by reference in § 170.299).

(h) *Electronic submission to immunization registries.*

(1) The Secretary adopts the following content exchange standards for electronic submission to immunization registries:

(i) *Standard.* HL7 2.3.1 (incorporated by reference in § 170.299).

(ii) *Alternative standard.* HL7 2.5.1 (incorporated by reference in § 170.299).

(2) The Secretary adopts the following vocabulary standard for electronic submissions to immunization registries.

(i) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009 version (incorporated by reference in § 170.299).

(ii) [Reserved]

§ 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:

(a) *Encryption and decryption of electronic health information.*

(1) *General.* A symmetric 128 bit fixed-block cipher algorithm capable of using a 128, 192, or 256 bit encryption key must be used.

(2) *Exchange.* An encrypted and integrity protected link must be implemented.

(b) *Record actions related to electronic health information.* The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, deleted, or printed; and an indication of which action(s) occurred must also be recorded.

(c) *Verification that electronic health information has not been altered in transit. Standard.* A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit. The secure hash algorithm (SHA) used must be SHA–1 or higher.

(d) *Cross-enterprise authentication.* A cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails must be used.

(e) *Record treatment, payment, and health care operations disclosures.* The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.

§ 170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave, SW., Washington, DC 20201, call ahead to arrange for inspection at 202–690–7151, and is available from the sources listed below.

(b) Organization for the Advancement of Structured Information Standards (OASIS), Post Office Box 455, Billerica, MA 01821, *http://www.oasis-open.org/home/index.php,* Telephone: 978–667–5115.

(1) Simple Object Access Protocol (SOAP), Version 1.2 (Second Edition), parts 0–2, W3C Recommendation April 27, 2007 (SOAP version 1.2), IBR approved for § 170.202.

(i) SOAP version 1.2 PART 0: Primer;

(ii) SOAP version 1.2 PART 1: Messaging Framework; and

(iii) SOAP version 1.2 PART 2: Adjuncts.

(2) [Reserved]

(c) 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—Level 2 Continuity of Care Document (CCD), April 01, 2007, IBR approved for § 170.205.

(d) 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 E2369–05: Standard Specification for Continuity of Care Record (CCR), year of adoption 2005, ASTM approved July 17, 2006, IBR approved for § 170.205.

(2) 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.

(e) 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) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008, (Approval date for ANSI: November 12, 2008), IBR approved for § 170.205.

(2) [Reserved]

(f) Council for Affordable Quality Healthcare (CAQH), 601 Pennsylvania Avenue, NW., South Building, Suite 500, Washington, DC 20004; Telephone (202) 861–1492 or *http://www.caqh.org/CORE_phase1.php.*

(1) Committee on Operating Rules for Information Exchange (CORE) Phase I Eligibility and Benefits Operating Rules Manual, April, 2006, IBR approved for § 170.205.

(2) [Reserved]

(g) Regenstrief Institute, Inc., LOINC® c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202–3012; Telephone (317) 423–5558 or *http://loinc.org/.*

(1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for § 170.205.

(2) [Reserved]

(h) 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 § 170.205.

(2) [Reserved]

(i) Centers for Disease Control and Prevention, National Centers for Immunization and Respiratory Diseases Immunization Information System Support Branch—Informatics 1600 Clifton Road Mailstop: E–62 Atlanta, GA 30333.

(1) HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009, IBR approved for § 170.205.

(2) [Reserved]

(j) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786–3000.

(1) CMS PQRI 2008 Registry XML Specification, December 10, 2008 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.

Subpart C—Certification Criteria for Health Information Technology

§ 170.300 Applicability.

The certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules.

§ 170.302 General certification criteria for Complete EHRs or EHR Modules.

The Secretary adopts the following general certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Drug-drug, drug-allergy, drug-formulary checks.*

(1) *Alerts.* Automatically and electronically generate and indicate in real-time, alerts at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, age, and computerized provider order entry (CPOE).

(2) *Formulary checks.* Enable a user to electronically check if drugs are in a formulary or preferred drug list in accordance with the standard specified in § 170.205(b).

(3) *Customization.* Provide certain users with administrator rights to deactivate, modify, and add rules for drug-drug and drug-allergy checking.

(4) *Alert statistics.* Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.

(b) *Maintain up-to-date problem list.* Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care in accordance with:

(1) The standard specified in § 170.205(a)(2)(i)(A); or

(2) At a minimum, the version of the standard specified in § 170.205(a)(2)(i)(B).

(c) *Maintain active medication list.* Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care in accordance with the standard specified in § 170.205(a)(2)(iv).

(d) *Maintain active medication allergy list.* Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care.

(e) *Record and chart vital signs.*

(1) *Vital signs.* Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, the height, weight, blood pressure, temperature, and pulse.

(2) *Calculate body mass index.* Automatically calculate and display body mass index (BMI) based on a patient's height and weight.

(3) *Plot and display growth charts.* Plot and electronically display, upon request, growth charts for patients 2–20 years old.

(f) *Smoking status.* Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current smoker, former smoker, or never smoked.

(g) *Incorporate laboratory test results.*

(1) *Receive results.* Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.

(2) *Display codes in readable format.* Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes.

(3) *Display test report information.* Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(4) *Update.* Enable a user to electronically update a patient's record based upon received laboratory test results.

(h) *Generate patient lists.* Enable a user to electronically select, sort, retrieve, and output a list of patients and patients' clinical information, based on user-defined demographic data, medication list, and specific conditions.

(i) *Report quality measures.*

(1) *Display.* Calculate and electronically display quality measures as specified by CMS or states.

(2) *Submission.* Enable a user to electronically submit calculated quality measures in accordance with the standard and implementation specifications specified in § 170.205(e).

(j) *Check insurance eligibility.* Enable a user to electronically record and display patients' insurance eligibility, and submit insurance eligibility queries to public or private payers and receive an eligibility response in accordance with the applicable standards and implementation specifications specified in § 170.205(d)(1) or (2).

(k) *Submit claims.* Enable a user to electronically submit claims to public or private payers in accordance with the standard and implementation

specifications specified in § 170.205(d)(3).

(l) *Medication reconciliation.* Electronically complete medication reconciliation of two or more medication lists by comparing and merging into a single medication list that can be electronically displayed in real-time.

(m) *Submission to immunization registries.* Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with:

(1) One of the standards specified in § 170.205(h)(1) and, at a minimum, the version of the standard specified in § 170.205(h)(2); or

(2) The applicable state-designated standard format.

(n) *Public health surveillance.* Electronically record, retrieve, and transmit syndrome-based public health surveillance information to public health agencies in accordance with one of the standards specified in § 170.205(g).

(o) *Access control.* Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information.

(p) *Emergency access.* Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency.

(q) *Automatic log-off.* Terminate an electronic session after a predetermined time of inactivity.

(r) *Audit log.*

(1) *Record actions.* Record actions related to electronic health information in accordance with the standard specified in § 170.210(b).

(2) *Alerts.* Provide alerts based on user-defined events.

(3) *Display and print.* Electronically display and print all or a specified set of recorded information upon request or at a set period of time.

(s) *Integrity.*

(1) *In transit.* Verify that electronic health information has not been altered in transit in accordance with the standard specified in § 170.210(c).

(2) *Detection.* Detect the alteration and deletion of electronic health information and audit logs, in accordance with the standard specified in § 170.210(c).

(t) *Authentication.*

(1) *Local.* Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.

(2) *Cross network.* Verify that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in § 170.210(d).

(u) *Encryption.*

(1) *General.* Encrypt and decrypt electronic health information according to user-defined preferences in accordance with the standard specified in § 170.210(a)(1).

(2) *Exchange.* Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in § 170.210(a)(2).

(v) *Accounting of disclosures.* Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(e).

§ 170.304 Specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an ambulatory setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Computerized provider order entry.* Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types:

(1) Medications;

(2) Laboratory;

(3) Radiology/imaging; and

(4) Provider referrals.

(b) *Electronically exchange prescription information.* Enable a user to electronically transmit medication orders (prescriptions) for patients in accordance with the standards specified in § 170.205(c).

(c) *Record demographics.* Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, and date of birth.

(d) *Generate patient reminder list.* Electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient preferences based on demographic data, specific conditions, and/or medication list.

(e) *Clinical decision support.*

(1) *Implement rules.* Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to specialty or clinical priorities that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list.

(2) *Alerts.* Automatically and electronically generate and indicate in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade.

(3) *Alert statistics.* Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.

(f) *Electronic copy of health information.* Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in:

(1) Human readable format; and

(2) On electronic media or through some other electronic means in accordance with:

(i) One of the standards specified in § 170.205(a)(1);

(ii) The standard specified in § 170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in § 170.205(a)(2)(i)(B);

(iii) One of the standards specified in § 170.205(a)(2)(ii);

(iv) At a minimum, the version of the standard specified in § 170.205(a)(2)(iii); and

(v) The standard specified in § 170.205(a)(2)(iv).

(g) *Timely access.* Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, medication allergy list, immunizations, and procedures.

(h) *Clinical summaries.*

(1) *Provision.* Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations and procedures.

(2) *Provided electronically.* If the clinical summary is provided electronically it must be:

(i) Provided in human readable format; and

(ii) On electronic media or through some other electronic means in accordance with:

(A) One of the standards specified in § 170.205(a)(1);

(B) The standard specified in § 170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in § 170.205(a)(2)(i)(B);

(C) One of the standards specified in § 170.205(a)(2)(ii);

(D) At a minimum, the version of the standard specified in § 170.205(a)(2)(iii); and

(E) The standard specified in § 170.205(a)(2)(iv).

(i) *Exchange clinical information and patient summary record.*

(1) *Electronically receive and display.* Electronically receive a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with § 170.205(a) and upon receipt of a patient summary record formatted in an alternate standard specified in § 170.205(a)(1), display it in human readable format.

(2) *Electronically transmit.* Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with:

(i) One of the standards specified in § 170.205(a)(1);

(ii) The standard specified in § 170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in § 170.205(a)(2)(i)(B);

(iii) One of the standards specified in § 170.205(a)(2)(ii);

(iv) At a minimum, the version of the standard specified in § 170.205(a)(2)(iii); and

(v) The standard specified in § 170.205(a)(2)(iv).

§ 170.306 Specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an inpatient setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Computerized provider order entry.* Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types:

(1) Medications;

(2) Laboratory;

(3) Radiology/imaging;

(4) Blood bank;

(5) Physical therapy;

(6) Occupational therapy;

(7) Respiratory therapy;

(8) Rehabilitation therapy;

(9) Dialysis;

(10) Provider consults; and

(11) Discharge and transfer.

(b) *Record demographics.* Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, date of birth, and date and cause of death in the event of mortality.

(c) *Clinical decision support.*

(1) *Implement rules.* Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to a high priority hospital condition that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list.

(2) *Alerts.* Automatically and electronically generate and indicate in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade.

(3) *Alert statistics.* Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.

(d) *Electronic copy of health information.* Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, procedures, and discharge summary in:

(1) Human readable format; and

(2) On electronic media or through some other electronic means in accordance with:

(i) One of the standards specified in § 170.205(a)(1);

(ii) The standard specified in § 170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in § 170.205(a)(2)(i)(B);

(iii) One of the standards specified in § 170.205(a)(2)(ii);

(iv) At a minimum, the version of the standard specified in § 170.205(a)(2)(iii); and

(v) The standard specified in § 170.205(a)(2)(iv).

(e) *Electronic copy of discharge information.* Enable a user to create an electronic copy of the discharge instructions and procedures for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.

(f) *Exchange clinical information and summary record.*

(1) *Electronically receive and display.* Electronically receive a patient's summary record from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, procedures, and discharge summary in accordance with § 170.205(a) and upon receipt of a patient summary record formatted in an alternate standard specified in § 170.205(a)(1), display it in human readable format.

(2) *Electronically transmit.* Enable a user to electronically transmit a patient's summary record to other providers and organizations including, at a minimum, diagnostic results, problem list, medication list, medication allergy list, immunizations, procedures, and discharge summary in accordance with:

(i) One of the standards specified in § 170.205(a)(1);

(ii) The standard specified in § 170.205(a)(2)(i)(A), or, at a minimum, the version of the standard specified in § 170.205(a)(2)(i)(B);

(iii) One of the standards specified in § 170.205(a)(2)(ii);

(iv) At a minimum, the version of the standard specified in § 170.205(a)(2)(iii); and

(v) The standard specified in § 170.205(a)(2)(iv).

(g) *Reportable lab results.* Electronically record, retrieve, and transmit reportable clinical lab results to public health agencies in accordance with the standard specified in § 170.205(f)(1) and, at a minimum, the version of the standard specified in § 170.205(f)(2).

Dated: December 28, 2009.

Kathleen Sebelius,

Secretary.

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Federal Register

Wednesday,
January 13, 2010

Part IV

The President

Proclamation 8472—National Influenza Vaccination Week, 2010

Federal Register
Vol. 75, No. 8
Wednesday, January 13, 2010

Presidential Documents

Title 3—

The President

Proclamation 8472 of January 8, 2010

National Influenza Vaccination Week, 2010

By the President of the United States of America

A Proclamation

Since the first United States cases were identified in April of last year, our Nation has witnessed the worldwide spread of the H1N1 influenza virus. To date, tens of millions of Americans have contracted this virus. While the vast majority of those affected have recovered without incident, an unusually high proportion of children and younger adults have developed serious complications, resulting in hospitalization or even death. We know that influenza vaccination is the best way to protect ourselves against the flu, and my Administration moved swiftly to respond to this threat by assisting in the development of a vaccine, which is now widely available and has shown to be both safe and effective.

Every American has a role to play in fighting the H1N1 flu. Expectant mothers, children, young adults, and all those under the age of 65 with chronic health conditions are at high risk for H1N1 flu-related complications and should get the vaccine as soon as possible. Those not at high risk can protect themselves and prevent the virus from spreading to more vulnerable members of their families and communities by getting vaccinated as well.

This week presents a window of opportunity for us to prevent a possible third wave of H1N1 flu in the United States. I strongly encourage those who have not yet received the H1N1 flu vaccine to do so. Visit flu.gov to find vaccination sites in communities across our country and to stay informed. Together, we can all fight the H1N1 flu and help protect our families, friends, and neighbors.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim the week of January 10–16, 2010, as National Influenza Vaccination Week. I encourage all Americans to observe this week by getting the H1N1 flu vaccine if they have not yet done so, and by asking their families, friends, and co-workers to do the same.

IN WITNESS WHEREOF, I have hereunto set my hand this eighth day of January, in the year of our Lord two thousand ten, and of the Independence of the United States of America the two hundred and thirty-fourth.

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Reader Aids

Federal Register

Vol. 75, No. 8

Wednesday, January 13, 2010

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Laws	**741–6000**
Presidential Documents	
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Other Services	
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Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

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FEDERAL REGISTER PAGES AND DATE, JANUARY

1–218 4
219–736 5
737–884 6
885–1012 7
1013–1268 8
1269–1524 11
1525–1696 12
1697–2052 13

CFR PARTS AFFECTED DURING JANUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
8469 885
8470 1265
8471 1267
8472 2051

Executive Orders:
12958 (Revoked by 13526) 707
13292 (Revoked by 13526) 707
13526 ..... 707, 1013
13527 737

Administrative Orders:
Memorandums:
Memorandum of December 15, 2009 1015
Memorandum of December 29, 2009 733
Orders:
Order of December 29, 2009 735

6 CFR

Proposed Rules:
27 1552

7 CFR

305 1
319 1
980 1269
984 1525
993 1269
1400 887

Proposed Rules:
205 1555
930 1724

9 CFR

94 1697

10 CFR

50 13
430 652
431 ..... 652, 1122

Proposed Rules:
32 1559
431 186

11 CFR

1 29
2 29
4 29
5 29
100 29
101 29
102 29
104 29
110 29
113 29
114 29
201 29
300 29

12 CFR

229 219
925 678
944 678
1263 678
1290 678

Proposed Rules:
360 934
906 1289
1207 1289

13 CFR

Proposed Rules:
121 1296
124 1296

14 CFR

25 ..... 32, 35, 37, 39, 1527
39 ..... 221, 224, 901, 904, 906, 910, 1017, 1527, 1529, 1533, 1536, 1538, 1697
71 ..... 42, 43, 226
97 ..... 915, 916
121 739

Proposed Rules:
25 ..... 75, 81
27 ..... 793, 942
29 ..... 793, 942
39 ..... 89, 91, 258, 260, 262, 264, 801, 950, 1297, 1560, 1563, 1731
91 942
121 942
125 942
135 942

15 CFR

90 44
738 1028
744 1699
902 554

Proposed Rules:
922 952

16 CFR

Proposed Rules:
312 1734

17 CFR

275 ..... 742, 1456
276 1492
279 1456

19 CFR

Proposed Rules:
101 266
113 266
133 266

20 CFR
416....1271

21 CFR
522....1274
529....1021
558....1275

23 CFR
635....46

24 CFR
257....1686

26 CFR
1....1704
301....48
Proposed Rules:
1....1301
31....1735
301....94

30 CFR
250....1276

31 CFR
1....743
285....745
Proposed Rules:
240....95

32 CFR
724....746
Proposed Rules:
2004....1566

33 CFR
27....1704
100....748
117....227, 1705, 1706
138....750
165....754, 1706, 1709
Proposed Rules:
117....1738
147....803

39 CFR
111....1540
601....1541
3020....1280
Proposed Rules:
111....282
3050....1301

40 CFR
52....54, 56, 230, 232, 1284, 1543, 1712, 1715, 1716
63....522
81....56, 1543
180....760, 763, 767, 770
262....1236
263....1236
264....1236
265....1236
266....1236
271....918, 1236
700....773
721....773
723....773
725....773
Proposed Rules:
50....1566
52....97, 283, 953, 958
58....1566
180....807
320....816
721....1180

41 CFR
301–10....790

42 CFR
Proposed Rules:
412....1844
413....1844
422....1844
495....1844

44 CFR
64....60

45 CFR
170....2014

47 CFR
25....1285
73....1546

48 CFR
Proposed Rules:
225....832, 1567
252....832, 1567
928....964
931....964
932....964
933....964
935....964
936....964
937....964
941....964
942....964
949....964
950....964
951....964
952....964

49 CFR
171....63
172....63
173....63
175....63
178....63
219....1547
238....1180
544....1548
830....922
Proposed Rules:
172....1302
173....1302
175....1302
395....285

50 CFR
17....235
21....927
22....927
300....554
635....250
648....1021
660....932
665....1023
679....554, 792, 1723
Proposed Rules:
17....1567, 1568, 1574, 1741, 1744
226....1582
300....1324
17....286, 310, 606
223....316, 838
224....316, 838
226....319
648....1024
660....1745

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

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H.R. 4314/P.L. 111–123
To permit continued financing of Government operations. (Dec. 28, 2009; 123 Stat. 3483)

H.R. 4284/P.L. 111–124
To extend the Generalized System of Preferences and the Andean Trade Preference Act, and for other purposes. (Dec. 28, 2009; 123 Stat. 3484)

H.R. 3819/P.L. 111–125
To extend the commercial space transportation liability regime. (Dec. 28, 2009; 123 Stat. 3486)

Last List December 31, 2009

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